CHINA'S HEALTHCARE SECTOR, DRUG SAFETY, AND THE U.S.-CHINA TRADE INMEDICAL PRODUCTS

HEARING

BEFORE THE

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

ONE HUNDRED THIRTEENTH CONGRESS
SECOND SESSION

THURSDAY, APRIL 3, 2014

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UNITED STATES-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

WASHINGTON: 2014

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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).

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

June 10, 2014

The Honorable Patrick J. Leahy
President Pro Tempore of the Senate, Washington, D.C. 20510
The Honorable John A. Boehner
Speaker of the House of Representatives, Washington, D.C. 20515

DEAR SENATOR LEAHY AND SPEAKER BOEHNER:

We are pleased to notify you of the Commission's April 03, 2014 public hearing on "China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products." The Floyd D. Spence National Defense Authorization Act (amended by Pub. L. No. 109-108, section 635(a)) provides the basis for this hearing.

At the hearing, the Commissioners received testimony from the following witnesses: Dr. Christopher J. Hickey, Country Director, U.S. Food and Drug Administration, People's Republic of China; Dr. Karen Eggleston, Faculty Director, Asia Health Policy Program, Stanford University; Dr. Yanzhong Huang, Senior Fellow for Global Health Policy, Council on Foreign Relations; Xiaoqing Lu Boynton, Director, Albright Stonebridge Group; Benjamin Shobert, Managing Director, Rubicon Strategy Group, and Senior Associate, National Bureau of Asian Research; Rod Hunter, Senior Vice President, International Affairs, PhRMA; Ralph Ives, Executive Vice President, Global Strategy and Analysis, AdvaMed; Allan Coukell, Senior Director, Drugs and Medical Devices, The Pew Charitable Trusts; Charles Bell, Programs Director, Consumers Union; Dr. Ginger Zhe Jin, Professor of Economics, University of Maryland; and Dr. Roger Bate, Visiting Fellow, American Enterprise Institute. This hearing address China's recent healthcare reforms, market access for U.S. medical goods and services in China, and the safety of medical products imported from China into the United States. This hearing also consider whether U.S. drug and medical device makers are able to compete in China's market. It will also assess the U.S. Food and Drug Administration's ongoing efforts to regulate drugs and drug ingredients imported from China into the United States.

We note that prepared statements for the hearing, the hearing transcript, and supporting documents submitted by the witnesses are available on the Commission's website at 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 other issues enumerated in its statutory mandate, in its 2014 Annual Report that will be submitted to Congress in November 2014. Should you have any questions regarding this hearing or any other issue related to China, please do not hesitate to have your staff contact our Congressional Liaison, Reed Eckhold, at (202) 624-1496 or via email at reckhold@uscc.gov.

Sincerely yours,

Hon. Dennis C. Shea
Chairman

Hon. William A. Reinsch
Vice Chairman

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CHINA'S HEALTHCARE SECTOR, DRUG SAFETY, AND THE U.S.-CHINA TRADE INMEDICAL PRODUCTS

THURSDAY, APRIL 03, 2014

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Washington, D.C.

The Commission met in Room 328A of Russell Senate Office Building, Washington, DC at 8:30 a.m., Chairman Dennis Shea and Vice Chairman William Reinsch (Hearing Co-Chairs), presiding.

OPENING STATEMENT OF CHAIRMAN DENNIS SHEA HEARING CO-CHAIR

CHAIRMAN SHEA: Good morning, everyone, and welcome to the fourth hearing of the U.S-China Economic and Security Review Commission's 2014 Annual Report cycle.

I want to thank our witnesses for being here today and for the time they have put into their excellent written testimony. We owe special thanks to Dr. Christopher J. Hickey from the Food and Drug Administration who has made the long trip from Beijing.

Before we begin, let me take a moment to thank the Senate Agriculture Committee, Chairman Stabenow, and her staff for securing this room for us today.

Today's hearing addresses three important topics: how is China's healthcare sector impacting China's economy and stability and U.S.-China economic relations; are U.S. companies able to compete fairly in China's expanding market for drugs, medical services and healthcare services--medical devices; and finally what is being done to mitigate the safety risks associated with medical product shipments from China to the United States?

We will begin today's proceedings with an administration panel. Dr. Hickey will inform us about the FDA's latest efforts to improve the regulation of medical products manufactured in China. We will explore this issue in more detail this afternoon in our third panel.

Product safety is a pressing issue for the United States. While our country believes in maintaining open borders, our reliance on imports has exposed consumers to considerable risks. In a globalized economy, U.S. companies are continually outsourcing production, frequently to places that have inadequate safety practices.

Medical products are a case in point. Foreign imports now account for 40 percent of our finished drugs and 50 percent of our medical devices. Approximately 80 percent of manufacturers of active pharmaceutical ingredients are located outside the United States. Scores of U.S. patients fell ill in 2007 to 2008 from tainted heparin sourced from China. Since then, FDA-regulated shipments from China have grown more

than threefold to 4.5 million in 2012. About two-thirds of those shipments are drugs and medical devices.

Today's hearing will also take a broader look at China's healthcare sector. China's population is aging. Chronic and non-communicable diseases are proliferating. An emerging middle class is demanding better quality care. Keeping China's population healthy has important implications not only for China's internal stability but also for its transition from the world's factory to a consumer-driven, service-oriented economy.

The Chinese government is investing to expand insurance coverage and improve care, but the country's healthcare provision remains inadequate.

For major U.S. companies that market drugs, medical devices and healthcare services, China represents an important opportunity. Market access barriers, though, may be tilting the playing field against U.S. companies, a losing proposition for both the U.S. economy and Chinese patients.

I will now cede the floor to my co-chair, Vice Chairman Bill Reinsch, for his opening remarks.

PREPARED STATEMENT OF CHAIRMAN DENNIS SHEA HEARING CO-CHAIR

Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products

April 3, 2014

Opening Statement of Chairman Dennis C. Shea

Good morning everyone, and welcome to the fourth hearing of the U.S.-China Economic and Security Review Commission's 2014 Annual Report cycle. I want to thank our witnesses for being here today, and for the time they have put into their excellent written testimony. We owe special thanks to Dr. Christopher J. Hickey from the Food and Drug Administration, who has made the long trip from Beijing. Before we begin, let me take a moment to thank the Senate Agriculture Committee, Chairman Debbie Stabenow, and her staff for securing this room for us today.

Today's hearing addresses three important topics: How is China's healthcare sector impacting China's economy and stability, and U.S.-China economic relations? Are U.S. companies able to compete fairly in China's expanding market for drugs, medical devices, and healthcare services? And finally, what is being done to mitigate the safety risks associated with medical product shipments from China to the United States?

We will begin today's proceedings with an administration panel. Dr. Hickey will inform us about the FDA's latest efforts to improve the regulation of medical products manufactured in China. We will explore this issue in more detail this afternoon in Panel III. Product safety is a pressing issue for the United States. While our country believes in maintaining open borders, our reliance on imports has exposed consumers to considerable risks. In a globalized economy, U.S. companies are continually outsourcing production, frequently to places that have inadequate safety practices. Medical products are a case in point. Foreign imports now account for 40 percent of our finished drugs and 50 percent of our medical devices. Approximately 80 percent of manufacturers of active pharmaceutical ingredients are located outside the United States. Scores of U.S. patients fell ill in 2007-2008 from tainted Heparin sourced from China. Since then, FDA-regulated shipments from China have grown more than threefold, to 4.5 million in 2012 – about two-thirds of those shipments are drugs and medical devices.

Today's hearing will also take a broader look at China's healthcare sector. China's population is aging. Chronic and non-communicable diseases are proliferating. An emerging middle class is demanding better-quality care. Keeping China's population healthy has important implications not only for China's internal stability, but also for its transition from the "world's factory" to a consumer-driven, service-oriented economy. The Chinese government is investing to expand insurance coverage and improve care, but the country's healthcare provision remains inadequate. For major U.S. companies that market drugs, medical devices, and healthcare services, China represents an important opportunity. Market access barriers, though, are tilting the playing field against U.S. companies – a losing proposition for both the U.S. economy and Chinese patients.

I will now cede the floor to my co-chair, Vice-Chairman Bill Reinsch, for his opening remarks.

OPENING STATEMENT OF VICE CHAIRMAN WILLIAM REINSCH HEARING CO-CHAIR

VICE CHAIRMAN REINSCH: Thank you, Mr. Chairman.

This is our Commission's first hearing devoted to healthcare and pharmaceuticals in China. Historically, this issue has played a less prominent role in U.S.-China economic relations. That's changing.

China's citizens are contracting illnesses like Alzheimer's, diabetes and lung cancer at an increasing rate. Given that China's ratio of retirees to workers is increasing, and its per capita income is still low, there will be increased pressure to improve healthcare without escalating costs.

The Chinese government has responded by allocating more of its budget to healthcare. Some $371 billion was spent between 2009 and 2013, and the latest annual budget proposal revealed last month shows spending on healthcare exceeding that on science and technology.

Spending alone, though, won't do the job. China needs to reform its public hospitals, remove distorted incentives, and allot a bigger role to foreign companies in the private sector. Our witnesses on panel one are going to tell us more about these trends.

Panel two today will look at market access for U.S. medical goods and services in China. For U.S. drug and device companies, establishing a presence in the world's most populous and fastest-growing economy is becoming a necessity. Healthcare spending in China amounted to about $500 billion last year, large compared to other emerging markets, but small compared to U.S. spending of nearly three trillion.

The growth potential is enormous, but for U.S. companies, entering China entails significant risks because the state intervenes in a heavy-handed way in the healthcare market. Local authorities often determine which drugs are eligible for reimbursement from government-run insurers. Government efforts to control the price of drugs and devices have hurt company margins and exacerbated corruption in China's hospitals, which rely heavily on drug sales.

Companies also face delays in marketing patented drugs and the threat of IP theft by drug regulators and generic drug makers. The crackdown on GlaxoSmithKline last year due to bribery allegations added to regulatory uncertainty for foreign companies attempting to do business in China.

We're going to begin. I'd like to remind witnesses to keep their remarks to seven minutes except in Dr. Hickey's case, apparently you have nine minutes.

CHAIRMAN SHEA: That's fine.

VICE CHAIRMAN REINSCH: So that we have time for our question and answer session.

Each of your written statements will be submitted for the record and will be available online at the Commission's Web site. Note also that we will break for lunch after panel two at one o'clock and return for panel three at 2:00 p.m.

We'll begin with Dr. Hickey who gets today's prize for coming the longest distance, not the all-time prize because we once, I recall, had a witness from New Zealand, which I think at least has a longer flight time.

Since 2008, Dr. Hickey has served as the Country Director for the U.S. Food and Drug Administration for the People's Republic of China. He serves as overall lead for FDA's efforts in China and leads a staff team that includes personnel in Beijing, Shanghai, and Guangzhou.

From 2004 to 2008, Dr. Hickey served in the Office of Global Health Affairs at the U.S. Department of Health and Human Services. At HHS, Dr. Hickey played a key role in the negotiation of the International Health Regulations, the U.N. Convention on the Rights of Persons with Disabilities, which unfortunately the Senate has yet to ratify, and product-safety agreements with China's State Food and Drug Administration and General Administration of Quality Supervision, Inspection and Quarantine.

Dr. Hickey earned his Ph.D. in sociology from the University of Virginia in 2002.

Dr. Hickey, go ahead.

PREPARED STATEMENT OF VICE CHAIRMAN WILLIAM REINSCH HEARING CO-CHAIR

Thank you, Chairman Shea. This is our Commission's first hearing devoted to healthcare and pharmaceuticals in China. Historically, this issue has played a less prominent role in U.S.-China economic relations, but that is changing. China's citizens are contracting illnesses like Alzheimer's, diabetes, and lung cancer at an alarming rate. Given that China's ratio of retirees to workers is increasing, and its per capita income is still low, healthcare needs to improve without escalating costs.

The Chinese government has responded by allocating more of its fiscal budget to healthcare – some $371 billion was spent between 2009 and 2013, and the latest annual budget proposal, unveiled in March, shows spending on healthcare (roughly $50 billion) exceeding that on science and technology. Spending alone, though, won't do the job. China needs to reform its public hospitals, remove distorted incentives, and allot a bigger role to foreign companies and the private sector. Our excellent witnesses on Panel I will tell us more about these trends.

Panel II today will look at market access for U.S. medical goods and services. For U.S. drug and device companies, establishing a presence in the world's most populous and fastest-growing economy is becoming a necessity. Healthcare spending in China amounted to about $500 billion last year; large compared to other emerging markets, but small compared to U.S. spending of nearly $3 trillion. The growth potential is enormous, but for U.S. companies, entering China entails significant risks, because the state intervenes in a heavy-handed way in the healthcare market. Local authorities often determine which drugs are eligible for reimbursement from government-run insurers. Government efforts to control the price of drugs and devices have hurt company margins and exacerbated corruption in China's hospitals, which rely heavily on drug sales. Companies also face delays in marketing patented drugs and the threat of IP theft by drug regulators and generic drug makers. A crackdown on British drug-maker GlaxoSmithKline last year, on bribery allegations, added to regulatory uncertainty.

So, let's begin. I'd like to remind our witnesses to keep remarks to 7 minutes so that we have time for our question-and-answer session. Each of their written statements will be submitted for the record and will be available online at the Commission's website. Note also that we will break for lunch after Panel II at 1 pm and return for Panel III at 2 pm.

ADMINISTRATIVE PANEL INTRODUCTION OF VICE CHAIRMAN WILLIAM REINSCH HEARING CO-CHAIR

Dr. Hickey, let's start with you. Since 2008, Dr. Hickey has served as the Country Director for the U.S. Food and Drug Administration (FDA) for the People's Republic of China. He serves as overall lead for FDA's efforts in China, and leads a staff team that includes personnel in Beijing, Shanghai, and Guangzhou. From 2004 to 2008, Dr. Hickey served in the Office of Global Health Affairs at the U.S. Department of Health and Human Services (HHS). At HHS, Dr. Hickey played a key role in the negotiation of the International Health Regulations, the UN Convention on the Rights of Persons with Disabilities, and product-safety agreements with China's State Food and Drug Administration and General Administration of Quality Supervision, Inspection and Quarantine. Dr. Hickey earned his Ph.D. in sociology from the University of Virginia in 2002.

OPENING STATEMENT OF DR. CHRISTOPHER J. HICKEY
COUNTRY DIRECTOR, U.S. FOOD AND DRUG ADMINISTRATION, PEOPLE'S REPUBLIC OF CHINA

DR. HICKEY: Chairman Shea, Vice Chairman Reinsch, and Commissioners gathered here this morning, I am Christopher Hickey, FDA's Country Director for the People's Republic of China. Today I'll discuss the challenges of an increasingly globalized marketplace, describe FDA's actions to safeguard the global supply chain, and discuss our activities related to China, particularly in connection with medical products.

FDA-regulated products originate from more than 200 countries and enter our market through more than 300 U.S. ports. Americans benefit greatly from global sourcing of medical products. Approximately 40 percent of finished drugs in the United States come from overseas as well as more than 50 percent of all medical devices, and about 80 percent of the manufacturers of active pharmaceutical ingredients are located outside the United States.

This rapid globalization of commerce poses challenges. Some countries lack strong regulatory systems. They don't have the resources or tools to make sure that firms follow appropriate processes to ensure the safety and quality of medical products.

In this context, risks to product safety and quality come from multiple sources: increased numbers of suppliers; more complex products; and intricate multinational supply chains, to name but a few.

Many of the challenges associated with globalization manifest themselves in China. These issues include problems with data integrity, inadequate implementation of quality systems and manufacturing, adulteration or contamination of products, and inadequate validation of manufacturing processes.

It's important to note, though, that these challenges we see in China mirror problems we see in other countries with developing regulatory systems.

In this sense, we can only understand challenges from medical products in China within the broader global context. In today's world, FDA works with numerous partners, domestic and international, to enhance responsibility and oversight for safety and quality throughout the supply chain.

We work with key regulatory agencies around the globe to provide information, tools, training, and exchange programs, which, in turn, help to strengthen overall regulatory capacity and ultimately safety.

In the last several years, Congress has passed two new laws that grant FDA enhanced authority to oversee the safety of imported medical products. The Food and Drug Administration Safety and Innovation Act, which became law in 2012, grants FDA important new authorities to improve the safety and integrity of the drug supply chain, including drugs imported into the United States.

The Drug Quality and Security Act, passed last year, outlines critical steps to build an electronic interoperable system to identify and trace certain prescription drugs distributed in the United States.

These new authorities move FDA firmly into the 21st century and give us enhanced ability to address the issues that globalization presents. These types of challenges are nowhere more evident than in U.S. trade with China. China is the source of a large and growing volume of imported foods, medical products and ingredients.

In the years spanning Fiscal Year 2007 and Fiscal Year 2013, the total number of shipments of FDA-regulated products from China increased from approximately 1.3 million entry lines to almost 5.2 million entry lines. Of the almost 5.2 million lines arriving from China in Fiscal Year 2013, about 25,000 were drugs and biologics, and 3.4 million were medical devices.

In this context, a "line" is an FDA entry line, which represents each portion of a shipment that an importer lists as a separate item on an entry document.

As the number of medical products coming from China has increased so have the challenges. There are currently a number of FDA Import Alerts that include medical products from firms located in China. These alerts signal FDA inspectors at the U.S. border to pay special attention to products from a particular country, manufacturer, shipper or importer.

Under these Import Alerts, products may be detained at the border and may be refused admission into U.S. commerce unless the importer is able to demonstrate that their products are in compliance with relevant laws and regulations.

FDA inspections have also increased significantly over the last several years in China. As recently as Fiscal Year 2007, FDA performed only 19 drug inspections in China. Over the last three Fiscal Years, we've averaged 79 inspections each year in China.

Similarly, medical device inspections in 2007 numbered only 22 while our average over the last two years for device inspections has jumped to 87.

But we know that we need to continue to strengthen our efforts in this area. The agency's Fiscal Year 2015 budget has requested $10 million in funding to continue support for the China Initiative, which will strengthen the protection of American patients by adding nine drug inspectors to FDA's China Office.

We recognize, though, that strategic engagement in China starts first and foremost with engagement with Chinese regulators. China's Food and Drug Administration, or CFDA, is responsible for the regulation of food, drugs and devices for domestic distribution in China and for regulation of certain exported drugs and medical devices.

In March 2013, Chinese central authorities created CFDA as the inheritor of the role formerly played by the State Food and Drug Administration, or SFDA. (In the remainder of my testimony, I'll alternate

between references to CFDA and SFDA, depending on the name under which this agency operated at the time that I'm referencing in my testimony.) The reform of CFDA is still in process. It remains an agency with numerous challenges, including implementation of standards for good manufacturing practices, deepening its technical and scientific capacity, and balancing the role of central and provincial authorities throughout China.

FDA coordinates its engagement with CFDA through the work of the China Office, which I head. Our office's mission is to strengthen the safety, quality and effectiveness of FDA-regulated products produced in China for export to the United States.

We work to fulfill this mission through several means--through collaboration with Chinese regulatory counterparts, through outreach to regulated Chinese firms, through monitoring trends and events that could affect the safety of FDA-regulated products, through inspections, and through collaboration with key stakeholders.

FDA currently has 13 staff in China posted in Beijing, Shanghai, and Guangzhou. This includes eight U.S. civil servants and five Chinese staff. Using funding that Congress provided in 2013, FDA is currently working to increase to 27 the number of U.S. staff that it posts in China.

We've established a strong working relationship with CFDA. Since 2008, we've conducted formal monthly meetings to discuss strategy and regulatory issues, collaboration and joint capacity building, and emerging issues of bilateral concern. Collaborative discussions on the staff level occur on a weekly or even daily basis.

I'd like to give a few brief examples of how our collaborations brought about concrete results. In 2009 and 2010, then-SFDA sought out FDA's input as it worked to reform its GMP (Good Manufacturing Practices) regulations for drugs. We saw significant elements of FDA's suggestions incorporated into then-SFDA's new standards, which were published in 2011, and when now-CFDA went to implement these standards, an expert from FDA's China Office trained over 1,000 Chinese inspectors on how to conduct inspections against these standards.

Regarding clinical trials, over the course of three years, from 2010 to 2012, FDA experts conducted multiple workshops with then-SFDA to create a self-sustaining system to train Chinese inspectors on how to assess the quality and reliability of data from sites that conduct clinical trials.

In the area of medical devices, experts from FDA's Center for Devices and Radiological Health now meet regularly with their counterparts from CFDA under the auspices of the International Medical Devices Regulatory Forum, as China has recently joined this key initiative. Our China Office has helped to encourage CFDA's participation in this important multilateral venue.

And finally, in the area of inspections and enforcement, CFDA inspectors now regularly observe FDA inspections in China, and since 2012, FDA's Office of Criminal Investigations has worked closely with CFDA to strengthen U.S.-China collaboration in the fight against Internet-based

illegal distribution of falsified, counterfeit and adulterated goods.

In conclusion, FDA's priorities in China match its priorities worldwide. We work to ensure the safety and efficacy of FDA-regulated products. Manufacturers are best situated to make certain that appropriate processes are in place to ensure safety and quality in production.

Regulatory bodies should hold companies accountable for lapses in the production process. Inspections and testing play an important role in that process but need to be used as part of a larger system that emphasizes a preventive control to the production of safe, effective, high quality medical products.

And in our globalized world, it's increasingly important that regulatory partners work together to ensure the safety of products as they move across borders. Patients and consumers, whether in Beijing or in Boston, deserve no less.

I'm happy to answer any questions.

PREPARED STATEMENT OF Dr. Christopher J. Hickey, Country Director, U.S. Food and Drug Administration, People's Republic of China

TESTIMONY OF CHRISTOPHER HICKEY, PH.D. COUNTRY DIRECTOR PEOPLE'S REPUBLIC OF CHINA

U.S. FOOD AND DRUG ADMINISTRATION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

"CHINA'S HEALTHCARE SECTOR, DRUG SAFETY, AND THE U.S.- CHINA TRADE IN MEDICAL PRODUCTS"

BEFORE THE

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

APRIL 3, 2014

INTRODUCTION

Chairman Shea, Vice Chairman Reinsch, and Members of the Commission, I am Christopher Hickey, Country Director for the People's Republic of China, in the Office of International Programs within the Office of Global Regulatory Operations and Policy at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's efforts to ensure global product safety and quality and our work related to China.

FDA is responsible for protecting public health by helping to ensure 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.

In my testimony today, I will discuss the challenges of an increasingly globalized marketplace, describe FDA's actions to safeguard the global supply chain, and discuss FDA's activities related to China, particularly in connection with medical products.

Challenges of Globalization

Sweeping economic and technological changes have revolutionized international trade over the last several decades and have created a truly global marketplace for goods and services. Products that FDA regulates represent a substantial component of this global economy, and account for about 20 percent of all U.S. consumer spending. Food and medical products, and their ingredients and components—products that directly and profoundly affect the health and welfare of the U.S. public—are increasingly sourced from abroad. Today, FDA-regulated products originate from more than 200 countries and territories and enter our market through more than 300 U.S. ports. The number of FDA-regulated shipments from abroad has more than tripled from 8 million import entry lines per year a decade ago to over 29 million entry lines in Fiscal Year (FY) 2013. In FY 2014, FDA anticipates that entry lines from abroad will reach 31 million.

Please note that FDA tracks import shipments using entry lines. For the Agency, an entry line represents each portion of a shipment that an importer lists as a separate item on an entry document. It is important to highlight the fact that entry lines do not have a direct relationship with the actual number of imported items. Some entry lines may represent one item, while others may represent thousands. This is a known limitation of the data in FDA import systems, because import filers are not required to declare volume per line and there is no standard format for declaring volume. As trade increases and U.S. consumers continue to demand global products, FDA's ability to ensure the safety and quality of these imported products will depend on its execution of a number of key strategies for global engagement

Americans benefit greatly from global sourcing of medical products. For example, to support the care of patients, health professionals can draw from drugs and medical devices developed anywhere in the world, if they have been approved or cleared by FDA. Approximately 40 percent of finished drugs in the United States come from overseas, as well as more than 50 percent of all medical devices. Approximately 80 percent of the manufacturers of active pharmaceutical ingredients are located outside the United States.

This rapid globalization of commerce poses challenges. For example, drugs and medical device manufacturers have the responsibility for the safety and quality of the drugs and devices they produce. Some countries do not have strong regulatory system oversight to ensure industry is meeting the standards required for safety and quality of these products.

Increased numbers of suppliers, more complex products, and intricate multinational supply chains can introduce risks to product safety and quality. Unfortunately, these factors also mean that consumers can more easily be exposed to risks, including those from intentional or unintentional adulteration, as well as those that come from exposure to contaminated products. Below, I will discuss FDA's implementation of its comprehensive strategy to use strong global partnerships to enhance the safety of imported products.

Many of the challenges associated with globalization manifest themselves in China; however, challenges we see in China mirror challenges we see in other countries with developing regulatory systems. In recent years, FDA has faced several public health threats related to imports from China. The members of this Commission will recall the threats to the safety of the country's heparin supply in 2007 and 2008, which emerged when Chinese suppliers of heparin (a critical drug that helps to prevent blood clots) substituted a lower-cost, adulterated raw ingredient in their shipments to U.S. drug makers. This substitution caused numerous deaths, as well as severe allergic reactions. In 2007, FDA found shipments of toothpaste from China that contained poisonous levels of diethylene glycol, a product used in antifreeze. And in China's domestic supply chain in 2012, numerous companies used industrial-grade gelatin to make pharmaceutical-grade gelatin capsules for drugs and dietary foods. This industrial-grade gelatin contained more chromium than the edible gelatin that firms should have used.

FDA's success in protecting the American public depends increasingly on the Agency's ability to reach beyond U.S. borders and engage with its regulatory counterparts in other countries. This collaboration encourages the implementation of science-based standards to ensure the quality and safety of FDA-regulated products manufactured overseas and imported into the United States. It is equally important for FDA to partner with industry, and with regional and international organizations to accomplish this goal. FDA works with numerous partners to enhance responsibility and oversight for safety and quality throughout the supply chain.

Safeguarding the Global Supply Chain

To address the challenges described above and strengthen protections for American consumers, FDA engages in several different ways and collaborates with numerous stakeholders. Our efforts are in line with the 2012 U.S. *National Strategy for Global Supply Chain Security*,[1] which emphasizes the importance of taking a layered, risk-based approach to building global supply chain systems that are secure, efficient, and resilient. In 2011, FDA released its report, *Pathway to Global Product Safety and Quality* (the *Pathway* report),[2] which outlined the Agency's strategy to transform itself from a predominantly domestically focused Agency to one that is equipped to engage in today's complex, globalized regulatory environment. I would like to discuss just a few of the activities we are pursuing as part of this strategy.

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[1] *http://www.whitehouse.gov/sites/default/files/national_strategy_for_global_supply_chain_security.pdf*

[2] *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf*

International Offices and Foreign Posts

FDA's international offices and foreign posts help to build strong partnerships with our foreign counterparts by providing enhanced opportunities for cooperation and capacity building. They also expand our knowledge base, and provide a local platform for inspection of foreign facilities, particularly in emergency situations, when the ability to deploy in-country investigators is most vital. We now have a permanent FDA presence overseas in 11 foreign posts in eight countries. Our overseas officials are posted in China, India, Latin America, Europe, and South Africa.

Risk-based Monitoring of Imported Products

The Agency electronically screens all 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. PREDICT utilizes information sources that include data from FDA and the U.S. Customs and Border Protection (CBP), as well as data collected from our foreign office, foreign regulatory counterparts, other Federal agencies, and our state counterparts. It also utilizes risk analyses we receive from academic institutions and international organizations. As we continue to increase data sharing with state, Federal, and foreign government partners, as well as private partners, we will continue to incorporate more information into PREDICT. This application allows FDA to focus its resources on imports that are most likely to pose a danger, while simultaneously facilitating entry of low-risk products. FDA, the U.S. Department of Agriculture (USDA), and the U.S. Department of Homeland Security have also developed improved systems for monitoring for the potential of economically motivated adulteration, which uses CBP and trade data.

Technical Cooperation and Capacity Building

FDA recognizes the need to engage in effective regulatory cooperation with our global partners. It is important, where possible, for FDA to provide strategic support for counterpart regulators: governments are uniquely positioned to provide regulatory oversight of products, which today move fluidly through complex global supply chains. FDA is working strategically with key regulatory agencies to provide information, tools, training, and exchange programs that contribute to strengthening overall capacity, which can help to undergird our global safety net. Later in my testimony, I will describe some of our collaborative efforts with the Chinese Government.

This Commission asked FDA to articulate its views on Rx360. Rx360 is a nonprofit organization led by volunteers from the pharmaceutical and biotech industries. Both

manufacturers and suppliers participate in Rx360's efforts to enhance the security of drugs by ensuring the quality and authenticity of products as they move through the supply chain. FDA

has been invited to participate in some Rx360 meetings, including Rx360's Supply Chain Steering Committee, as an observer. Rx360—especially its Supply Chain Steering Committee— has been a valuable resource for FDA. This Steering Committee has frequently solicited FDA's input so that Rx360 can, where appropriate, more closely align with FDA goals. In this context, Rx360 has often provided useful information to FDA in connection with supply chain security issues. Rx360's valuable work is exemplified by a recent campaign entitled "Protect Your Patients -- Know Your Supplier," which aims to educate the public about the following:

- The current global context in which counterfeiting and diversion occur.
- The challenges of unapproved drugs sourced from outside of the United States, especially when these products are pitched to health care providers as cost-saving measures.
- Risks associated with purchasing unapproved medication, such as threatened patient safety and criminal and civil liability for purchasers.
- How to determine if a product is legitimate.
- Tips for purchasing medication and verifying legitimacy.

We have found this campaign as well as other Rx360 collaborative efforts with FDA to be productive, and we look forward to continued partnership in the years to come.

Implementing Major New Laws

In addition to these activities, FDA is helping ensure the safety of imported medical products with

with the significant new authorities provided to it by Congress.

- The Food and Drug Administration Safety and Innovation Act (FDASIA)

  With the passage of FDASIA in 2012, Congress granted FDA important new authorities, reauthorized FDA's ability to collect user fees for its reviews of applications to market human drugs and medical devices, and similarly, authorized FDA, for the first time, to collect user fees for reviews of generic human drugs and biosimilar biologics. These

authorities and fees will help to promote and protect public health in a number of key areas. They will help the Agency to continue to strengthen a predictable and efficient review process for medical products. These authorities and fees will also help FDA to combat drug shortages and enhance our efforts to ensure that American consumers have more timely access to safe,
high-quality, affordable medicines. Finally, FDASIA will help to create incentives for industry to develop new antibacterial and antifungal drugs.

Title VII of FDASIA focuses on improving the safety and integrity of the drug supply chain and drugs imported into the United States. Title VII's new authorities increase FDA's ability to act in several key areas. First, Title VII enhances FDA's ability to collect and analyze data to support risk-informed decision-making. Second, it gives FDA more tools to make accurate evaluations of facilities on the basis of risk. Third, it gives FDA greater authority to partner with foreign regulatory authorities to leverage resources through information-sharing and recognition of regulatory counterparts' inspections, when FDA deems such recognition appropriate. Finally, at the broadest level, it gives the Agency greater authority to mandate that firms meet more stringent requirements for safety and quality throughout the supply chain. For example, the law requires foreign and domestic companies to provide complete information on threats to the security of the drug supply chain and improves current registration and listing information, which will help to ensure that FDA has accurate and up- to-date information about foreign and domestic manufacturers.

The new authorities that FDASIA provides align with the strategies outlined in the *Pathway* report. FDASIA promotes collaboration with global regulatory partners, use of data systems to facilitate information-sharing, and the key role of risk analytics. FDA is making significant strides in its implementation of this important new law.

- Drug Quality and Security Act (DQSA)

The recently enacted DQSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.[3] Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA to develop this new system over the next decade. Within 10 years of enactment of this law, this new system will facilitate the exchange of information about where a drug has been in the supply chain, even down to the level of individual packages. The new system will enable FDA to verify the legitimacy of drug product identifiers down to the package level; enhance detection and
notification of illegitimate products in the drug supply chain; and facilitate more efficient

[3] In the *Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations*, March 2011, at p. 2 ("White Paper"), the Administration recommended legislation to adopt a track-and-trace system for pharmaceuticals and related products. See *http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf*.

recalls of drug products.[4] Manufacturers, wholesale distributors, repackagers, and pharmacies must immediately quarantine and promptly investigate drug products deemed suspect or illegitimate. This could include suspected counterfeits, unapproved drugs, or dangerous goods, such as a recalled drug product. The relevant stakeholders noted above will be responsible for alerting FDA about such findings. This new system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

FDA Activities Related to China

Nowhere is the shift toward a global marketplace more evident than in U.S. trade with China. China is the source of a large and growing volume of imported foods, medical products, and ingredients. Establishments that are involved in the production and distribution of medical products intended for use in the United States generally are required to register annually with FDA. Most of these establishments are also required to list the products that are made there. For example, in FY 2008 (the first year that data was collected in accordance with current standards), there were about 2,700 registered Chinese establishments; in FY 2013, there were almost 4,000. In FY 2008, there were about 10,500 device listings associated with Chinese establishments, while in FY 2013, there were more than 17,000 device listings, the vast majority of which were for Class I (low-to-moderate risk) and Class II (moderate-to-high risk) medical devices. As I mentioned earlier, FDA tracks import shipments by entry lines—the portion of a shipment listed as a separate item on an import entry document. In the years spanning FY 2007 and FY 2013, the total number of shipments of FDA-regulated products from China increased from approximately 1.3 million entry lines to 5.16 million lines. Of the 5.16 million lines arriving from China in FY 2013, almost 25,000 lines were drugs and biologics and 3.4 million lines were medical devices—again, the majority of these (96 percent) were Class I or Class II medical devices, including surgical drapes and gowns, syringes and tubing, graduated medication containers, and gloves.

As the number of medical products coming from China has increased, so have the challenges. There are currently a number of active FDA Import Alerts that include medical products from firms located in China. These alerts signal FDA investigators at the U.S. border to pay special attention to a particular product, or a range of products from a particular country, manufacturer, shipper, or importer. Under these Import Alerts, products may be detained at the border and may be refused admission into U.S. commerce, unless the importer is able to demonstrate that the products are in compliance with relevant laws and regulations. The Import Alert process is a dynamic one, with firms and countries being added and removed on a regular basis. Product recalls are another challenge. Recalls of Chinese medical devices have been on the rise since

[4] Under current law, recalls for drug products are voluntary, as FDA does not have the authority to issue mandatory recalls of drug products.

2011, from 11 in 2011 to 32 in 2013. FDA has issued most of these recalls because of design-related issues.

Drug inspections in China also have been increasing. In 2010, FDA conducted 46 drug inspections in China; in 2011, that number increased to 88; in 2012, FDA conducted 58 drug inspections; and in 2013, the Agency conducted 84 such inspections. The majority of the drug inspections FDA conducts in China focus on manufacturers of active pharmaceutical ingredients intended for use in generic drugs and on sites that produce over-the-counter drugs.

FDA is addressing the challenges outlined above in several different ways. We currently have 13 staff in China, posted in Beijing, Shanghai, and Guangzhou. This includes eight U.S. civil servants and five Chinese staff. Using funding Congress provided in 2013, FDA is currently working to increase to 27 the number of U.S. officers it posts in China. The mission of FDA's China Office is to strengthen the safety, quality, and effectiveness of FDA-regulated products produced in China for export to the United States. FDA's China Office works to fulfill this mission through:

- Collaborating, capacity-building, and confidence-building with Chinese regulatory counterparts at central, provincial, and municipal levels;
- Conducting outreach to regulated Chinese firms that wish to export their products to the United States to enhance understanding of—and compliance with— FDA requirements;
- Monitoring and reporting on conditions, trends, and events that could affect the safety and effectiveness of FDA-regulated products exported to the United States;
- Conducting inspections at facilities that manufacture FDA-regulated goods; and
- Working closely with other key government and non-government stakeholders who work to strengthen the safety of FDA-regulated products manufactured in China.

In addition to other budget requests that focus on imports from China, the Agency's FY 2015 budget has requested $10 million in funding specifically for continuing the China Initiative. These new resources will strengthen the protection of American patients in the following ways:

- Strengthening FDA's inspectional and analytical capabilities by adding nine drug inspectors to FDA's China Office. The United States and China were able to address problems associated with visas for these staff during the visit of Vice President Biden to
- Beijing in December 2013, and FDA anticipates posting these new staff in country in

Fiscal Years 2014 and 2015. This will allow more rapid access to Chinese facilities and will help to increase the number of FDA inspectors who have in-depth knowledge and expertise about current challenges that Chinese industry faces.

- Broadening the range of inspections FDA performs in China. In addition to inspecting Chinese facilities that manufacture food and medical products for export to the United States, FDA will increase the number of sites it inspects that conduct clinical trials pursuant to investigational new drug (IND) applications, and will also perform follow-up inspections to ensure that firms continue to produce and manufacture food and medical products under safe conditions.
- Increasing opportunities for engagement with Chinese regulatory counterparts. Direct observation of FDA inspections can bolster Chinese regulators' understanding of FDA's requirements and processes and strengthen China's inspectional capacity.
- Enhancing Chinese regulators' knowledge of U.S. safety standards through participation in workshops and seminars, such as the International Conference on Harmonisation and the International Pharmaceutical Regulators Forum. These opportunities help facilitate dialogue and encourage scientific exchange on the critical role inspections play in improving the safety and quality of food and medical products.
- Strengthening FDA's ability to use informatics tools, such as trend analysis, predictive modeling, and geospatial mapping. These tools will help to sharpen FDA's understanding of potential public-health risks. Increased use of data will help FDA strengthen its systems in several key areas, including the implementation of science-based, harmonized standards. The ultimate goal is to detect and address risks through preventive, risk-based approaches before those risks result in harm to U.S. consumers.

China's Food and Drug Administration

China's Food and Drug Administration (CFDA) is responsible for regulation of food, drugs, and devices for domestic distribution in China, and for regulation of certain exported food, drugs, and devices. In March 2013, as part of attempts to reform China's food safety system, Chinese central authorities created CFDA as the inheritor of the role formerly played by the State Food and Drug Administration (SFDA). Even with this reform, which is still in process, CFDA remains an agency with several key remaining challenges. In 2011, SFDA published new requirements for good manufacturing practices for drug manufacturing—standards that were widely viewed as a significant step forward. By the end of 2013, CFDA had made numerous strides in implementing these requirements, but significant work remains. Like many Chinese Government ministries, CFDA also faces significant challenges as it works to balance the role of central and provincial authorities. CFDA will continue to work for some time to develop sufficient technical and scientific depth to address China's current challenges.

FDA, through efforts led by its China Office, has established a strong working relationship with CFDA. Since 2008, we have conducted formal monthly meetings with CFDA to discuss strategic regulatory issues, collaboration and joint capacity building, and emerging issues of bilateral concern. Collaborative discussions on the staff level occur on a weekly, or even daily, basis. And each year since the signing of our 2007 Agreement with SFDA on the safety of

medical products, we have convened a high-level bilateral meeting between senior U.S. and Chinese regulatory authorities. We have made key strides with CFDA. In 2009 and 2010, as SFDA worked to reform its GMP regulations for drugs, it sought out FDA's input into its draft regulations. The FDA China Office, working with experts in FDA's Center for Drug Evaluation and Research, provided feedback on these draft provisions and saw significant elements of FDA's suggestions incorporated into SFDA's new standards, which were published in 2011. When CFDA went to implement these standards, an expert from FDA's China Office conducted training for over one thousand Chinese inspectors on how to conduct inspections against such standards.

In the area of clinical trials, we have made substantive efforts, as well. Over the course of three years, from 2010 through 2012, an FDA expert conducted multiple workshops with SFDA to create a self-sustaining system to train Chinese inspectors on how to assess the quality and reliability of data from sites that conduct clinical trials.

In the area of medical devices, experts from FDA's Center for Devices and Radiological Health now meet regularly with their counterparts from CFDA under the auspices of the International Medical Devices Regulatory Forum, as China has recently joined this key Forum. FDA's China Office helped to encourage CFDA's participation in this important multilateral venue.

In the area of inspections and enforcement, FDA has made significant progress with CFDA, as well. CFDA inspectors now regularly observe FDA inspections in China. And since 2012, FDA's Office of Criminal Investigations has worked closely with CFDA to enhance U.S.-China collaboration in the fight against Internet-based, illegal distribution of adulterated drugs. In recent years, CFDA has taken initial steps to learn about the requirements to join the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), an international organization consisting of 44 member regulatory agencies (including FDA) and partner organizations, such as the World Health Organization and the United Nations Children's Fund, which oversee the manufacture of pharmaceutical drugs imported into their regions. FDA has met with CFDA on several occasions to explain the PIC/S accession process and what is needed to apply and become a member. PIC/S' Secretariat has also encouraged CFDA to participate in PIC/S' international training programs.

Finally, FDA has seen significant strides in cross-cutting areas as well. Following a high-level agreement during the visit of FDA Commissioner Margaret Hamburg to China in August 2012, FDA and SFDA created a working group on economically motivated adulteration (EMA).
EMA—the fraudulent substitution of a substance in a product to increase value or reduce production costs for the purposes of economic gain—has played a key role in a number of recent product safety crises in China, including the series of adverse events associated with adulterated heparin in 2008, and the 2012 use of so-called "gutter oil" in antibiotics manufactured in China.[5] EMA continues to be a key factor in understanding product safety

[5] "Gutter oil" can be defined as spent cooking oil that is normally discarded (into the street) and that might contain toxic products from thermal degradation.

issues in China today. The U.S.-China working group on EMA in medical products now meets on a regular basis, linking Washington-based experts with CFDA's key decision-makers. Through its engagement in this working group, FDA aims to expand the thinking of Chinese regulators about EMA and to create a common platform to work to address the underlying incentives that prompt some perpetrators to adulterate products to make a quick profit.

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 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 the production of safe, effective, high-quality medical products. 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 we have seen in recent years.

I am happy to answer any questions you may have.

ADMINISTRATIVE PANEL QUESTION AND ANSWER

CHAIRMAN SHEA: Well, Dr. Hickey, thank you very much for that testimony, and again thank you for traveling here, and most importantly, thank you for the important work that you do on behalf of the American people in Beijing and in China.

I want to ask a few questions. I'll start off by asking some questions about facts. Maybe you could help me out. I asked our staff what the main imports from China of drugs and active ingredients are, and they said that China accounts for about 71 percent of ibuprofen imports; 45 percent of acetaminophen imports; 32 percent of aspirin imports; said about 49 percent of glands and organs used to manufacture heparin; 49 percent of vitamin imports and pro-vitamin imports.

Do these numbers sound accurate? You said it was difficult to get a handle on what those numbers were.

DR. HICKEY: Yeah, it is a challenge to have exact numbers, but certainly China is, yes, known to be a leading supplier of active pharmaceutical ingredients for products like ibuprofen and acetaminophen. Aspirin and heparin are also a key areas. And then also a manufacturer of ingredients for dietary supplements.

CHAIRMAN SHEA: Okay. So they're a significant manufacturer of drug and drug ingredients that get imported into the United States. That's pretty clear.

DR. HICKEY: That's right.

CHAIRMAN SHEA: Now, you said you had 13 staff in China, eight U.S. civil servants and five Chinese nationals who are employees.

DR. HICKEY: Right.

CHAIRMAN SHEA: You're the Food and Drug Administration. How many of those 13 are on the drug side of the business?

DR. HICKEY: So we have in Beijing, we have a drug GMP, or an expert on Good Manufacturing Practices, who does consultations with the Chinese government and the training that I referenced, as well as inspections, and then we have an inspector based in Shanghai who does inspections as well, but dedicates his full time to inspections. As I mentioned, we're looking forward to the expansion of our office.

CHAIRMAN SHEA: Right. So you have one inspector in Beijing and one inspector in Shanghai. Is that basically it?

DR. HICKEY: That's right. And the other thing I should mention is that we have about half the time of another one of our policy experts in Beijing focuses on drug-related issues.

CHAIRMAN SHEA: Okay. So about two-and-a-half FTEs on drug inspection.

Now, in your written testimony, you said that the number of establishments in China if they want to manufacture drug imports to the U.S., they have to register with the FDA.

DR. HICKEY: Right.

CHAIRMAN SHEA: And you said in 2008, there were 2,700 such registered Chinese establishments. In 2013 there were about 4,000. And so two-and-a-half FTEs for that many establishments seems almost a hopeless task. That's the impression I get, even with the bump-up in numbers. If you get four or five, it's still like a hopeless task.

I'm going to give you the opportunity to set me straight, but it seems to me you're woefully inadequately staffed for this particular job, and you rely, by necessity, on Chinese FDA for their own inspection regime, and the supply chain security operations of the Western manufacturers who have their operations in China.

Is that correct?

DR. HICKEY: Well, I would say, yeah, we're looking forward to increasing the numbers. I think any U.S. government agency that works in China is always challenged in terms of the sheer size of China in any given area.

In this particular area, I would say we do place primary responsibility on manufacturers. They have to take the responsibility for making sure that the systems are in place to make sure that they're manufacturing products in a safe manner.

We then have a number of systems in place and a number of tools that we can use to monitor the safety of drugs entering the United States. So we are looking to use more information from the Chinese system. We signed an agreement in 2007 through which we can get information from the Chinese about firms that might represent higher or lower risks. So that helps to increase our tools.

But primarily we're looking for us at placing responsibility on industry, inspections that we're doing, not only inspections associated with drug applications at FDA, but also surveillance, and then sampling at the border as well, and then post-market surveillance.

So we have a number of tools in place. You can do more with more resources, but it is a challenge.

CHAIRMAN SHEA: This is a tough question, I'm putting you on the spot a little bit, Dr. Hickey. Could you give the American people assurance that the drug imports and drug ingredients imported from China coming into the United States today in increasingly larger numbers are safe?

DR. HICKEY: Well, I would say clearly there have been a number of high profile cases that have highlighted some of the challenges with safety in China, not only with their exported products but domestically as well. So there are challenges there, and there is a wide spectrum of level of proficiency among drug manufacturers in China. So there clearly are challenges.

Just to underscore the points I made a minute ago: we place primary responsibility on industry. We're seeking to get more information from Chinese authorities. We have tools in place to safeguard products coming into the United States, and, you know, it is a process that we're undertaking with Chinese regulators to assure the safety of products entering

the United States.

CHAIRMAN SHEA: Okay. Well, thank you very much.

Commissioner Fiedler.

COMMISSIONER FIEDLER: Thank you.

The word "inspection" in the Chinese context has different meaning when it involves people from the United States. I'll give you the example. The Chinese will not say that the U.S. government can inspect forced labor camps, but they can visit them because inspection has implications on sovereignty that visit doesn't.

So the question I really have is what is the difference between an inspection in China and an inspection in the United States? Advanced notice; how long are you there; what inhibitions do you have when you're inside; what access to information? What are the differences between an inspection in China and in the United States?

DR. HICKEY: Right. Well, I would say substantially they're the same. There are a few slight differences that I'll highlight. So when we're operating overseas, whether it's in China or India or anywhere else, we don't have the same authorities to enter a premise that we do in the United States, and that's just a reality that we deal with.

And so as a result, in the vast majority of cases when we're doing inspections in China or in India or elsewhere, we are notifying firms in advance and working to schedule those inspections in advance.

We do reserve the right, and we have, in a handful of cases, done inspections unannounced as we would in the United States in a number of cases. So we have the ability to do that, we have done that, and we have had a variety of responses from firms in those cases.

We, fortunately, now have the ability, under new laws that were passed that I referenced in my testimony, if a firm denies, delays, refuses our inspection, we can refuse the ability of them to export products to the United States. So the one thing that I would just say in terms of a little bit of a difference between your labor camp example and what we've got is that if firms want to continue exporting to the United States, they have to agree to be inspected.

COMMISSIONER FIEDLER: That, I agree with you, is a significant difference.

U.S. manufacturers presumably go to China to produce their product cheaper than they would somewhere else, whether it's the United States or Puerto Rico or Europe. So they get some saving.

Has FDA considered increasing a company's internal inspection and surveillance capacity to offset the risks that exist, at their own costs, as opposed to yours and mine as taxpayers? So, in other words, you want to manufacture in China, you have to have additional safeguards and report to us as a U.S. manufacturer and/or require your subcontractors to do so, so that you're getting them to pay for the inspection process.

DR. HICKEY: Well, through--

COMMISSIONER FIEDLER: To scale it, yeah.

DR. HICKEY: Just briefly, so through our series of user fee acts, there are industries paying to help fund our review of drugs. I would say with the new authorities that we've been given, especially under the Food and Drug Administration Safety and Innovation Act, we are able much more now in 2014 than we were even in say 2010 or 2011 to apportion our resources in terms of inspections based on risk.

Under the old model, for instance, we had to inspect firms in the United States with a certain frequency. That requirement has changed now, and the direction from Congress to FDA is to do inspections on the basis of risk.

The only other thing I would say is that we don't look at a site one way or another with respect to where it's located, whether it's in China or India, but with respect to whether it represents higher risk.

COMMISSIONER FIEDLER: Well, countries--I would imagine that you class some countries as riskier than others?

DR. HICKEY: Not, per se, that in general. We do have countrywide Import Alerts, and in a few cases we have said that product from China, for instance--more on the food side of things--aquaculture coming from China represents a higher level of risk.

COMMISSIONER FIEDLER: Right.

DR. HICKEY: But most of our import regulatory actions that we take are more specifically targeted.

COMMISSIONER FIEDLER: Thank you.

CHAIRMAN SHEA: Vice Chairman Reinsch.

VICE CHAIRMAN REINSCH: Let me first pursue one of Commissioner Fiedler's lines. I understand the sovereignty issue, the difference between being in the United States and being elsewhere. First, where else does FDA have offshore inspection capability besides China?

DR. HICKEY: So we have capability in India and in Latin America.

VICE CHAIRMAN REINSCH: Do you notice differences between the way the Chinese treat you and the way the other countries treat you?

DR. HICKEY: Well, there is certainly since we're focusing today on medical products, just let me--

VICE CHAIRMAN REINSCH: Right.

DR. HICKEY: --talk mainly about drugs. So there is a difference in terms of where India focuses and where China focuses. India's focus primarily is on finished generic products. China's focus is on active pharmaceutical ingredients.

And historically, FDA has done many more inspections of finished producers, and it's only been in the last two years with the passage of these new laws that we've begun to increase our inspections at sites that manufacture active pharmaceutical ingredients.

So the only thing I would say is that sites in China, whether they're manufacturers of active pharmaceutical ingredients or, for instance,

workshops that do the rendering that creates crude heparin that goes into heparin, those kinds of sites are not accustomed to being inspected as much as let's say a Ranbaxy in India. So there's less familiarity perhaps with how our inspections work and what our inspection regime is.

VICE CHAIRMAN REINSCH: How do your inspections work? You show up and what do you do once you get there?

DR. HICKEY: That's a good question. So, as I said, in the vast majority of cases, we provide advance notice. For our drug and medical device inspections, our focus in China and elsewhere, everywhere else in the world, is on systems. So our inspections are not a checklist. Our inspections rely on FDA investigators who go into facilities and look at the big picture of the manufacturing process and analytically say—"Where are the largest risk points?"

It can be anywhere from a one-day or two-day to a four or five-day or more inspection that looks at records. It may do sampling and testing, but much of what we focus on in the area of medical products is looking at how well firms have identified the risks that are there in the production of their process, what they've done to address those risks, and how they've documented the way that they address those risks.

So, and then there may be some sampling if it's warranted. There have been cases that, a handful of cases where firms have been less cooperative, and we now have the authority to place them on what we call "import alert," and that's what I referenced in my verbal testimony.

VICE CHAIRMAN REINSCH: You mentioned earlier that you have a criminal investigation unit. Can you give us a rough division in the case of China with respect to drugs and medical devices, when you identify difficulties or identify problems, do you find that most often it's a case of simply lax procedures and errors as opposed to, you know, a deliberate criminal conspiracy to produce phony materials?

DR. HICKEY: Right. Well, certainly some of the cases that have grabbed headlines have been those cases where it was intentional, heparin as one example. That doesn't represent the normal case. The normal case is more what you described as lax production or just a lack of awareness of FDA requirements and just a lack of knowledge of how certain things should be done.

So those are the kinds of things that we typically see. Our Office of Criminal Investigations focuses a good deal of its energy on falsified, counterfeit medicines, and looking from the U.S. side of things to trace back to see where these criminal rings often begin and where the process begins and seeks to find those who are behind the production of counterfeit or falsified medicines, and we have had success in a case or two where we've found individuals in China who were responsible. Through undercover officers, we were able to bring them to the United States and make an arrest and put them on trial, and there's an instance or two where they're serving time currently.

VICE CHAIRMAN REINSCH: Do you have cooperation from

Chinese law enforcement authorities, too? Can you turn this information over to them and they'll prosecute them in China, as well, or do they not care about that?

DR. HICKEY: Some of that collaboration is really in its early stages so our Office of Criminal Investigations works with representatives at the Chinese Embassy here in Washington from the Ministry of Public Security on those issues.

Because we don't--there is a bit of separation between the operations of--on the criminal side at FDA and the operations on the civil side, that work goes on largely from the U.S. side.

VICE CHAIRMAN REINSCH: Thank you.

CHAIRMAN SHEA: Commissioner Slane.

COMMISSIONER SLANE: Thank you.

We were in China last year. There was a lot of pushback to your agency and delays in getting you visas, and basically they weren't very cooperative. I mean has that situation changed or is that the current status?

DR. HICKEY: So maybe let me just briefly kind of give the big picture. In February 2012, the administration included in its proposal for budget Fiscal Year 2013 a bump-up for our office of $10 million to increase staff, and it was at that point that we began engaging with our Chinese counterparts about our desire to increase FDA staffing in China.

We did that at a number of different levels--my level, the level of the Commissioner and others. We began in October 2012 to see delays in the issuance of visas for those increased staff. We were able during the visit of the Vice President in 2013 to come to agreement with the Chinese on this issue and on them beginning to issue visas for our staff.

I should say that we were looking to more than triple our staff through this bump-up in funding, and that's a big request, I think, for any government, whether the Chinese government or any other. This is a relatively new thing to place regulatory staff and inspectors overseas in one another's country. There have been inspections going on overseas and crossing borders for many years, but to place staff in-country was a big request, and clearly we were concerned with the delays.

We did in that interim period work to make sure that we got the job done for the American people. So we got the inspections done that we needed to get done by bringing over FDA investigators who were detailed for 60, 90 or 120 days and were able to do inspections.

So we, as I say, believe that we were able to continue to do our job for the American people, but we were glad to see final agreement in December.

The last thing I should say because I know there has been some attention to this issue in recent weeks is that placement of U.S. staff overseas is complex, even in situations where you're not facing visa difficulties. There are, especially when you're talking about significant increases in staffing, there are needs to make sure that there's appropriate space for staff that's secure. There's need to make sure in the case of FDA

investigators that they have the access to the right databases, which means FDA databases which are not available through normal State Department means.

And so we have gone through that process in recent months, and we are just now in process of submitting applications for visas for our increased staffing. So that's the status where we stand today.

COMMISSIONER SLANE: So is the attitude of the Chinese changing, in your opinion. They didn't seem very welcoming, and they're great at agreeing to things, and the issue becomes have they implemented the agreement? What is your feeling on their--I mean they didn't seem like they were very welcoming.

DR. HICKEY: I would say that we were very pleased to be able to work with the White House and the Vice President's Office in December to address the issue because it raised to leadership in the Chinese government the broader issue for the American people of the need for FDA to be able to do the inspections that it needs to do, and I think that really helped to move things. So we faced delays for many months, but I think when the senior levels of the Chinese government were engaged, we saw some movement on the issue.

COMMISSIONER SLANE: Thank you.

CHAIRMAN SHEA: Dr. Tobin.

COMMISSIONER: Thank you, Mr. Chairman.

I have a series of questions. First, one further follow-up on Commissioner Slane's question; the five Chinese nationals that you are hiring, are you hiring or is somebody else making the choice of who comes aboard and vetting them?

DR. HICKEY: No, sir, those five staff are selected by us. This is how U.S. Government agencies, whether State, Defense, USDA, FDA, do their work, especially in countries like China where you're facing significant cultural and language challenges.

And they range from staff who provide administrative support to those who are really integral to our efforts to liaise with the Chinese government and staff who support inspections and go out and do translation for our inspectors.

COMMISSIONER TOBIN: Okay. Thank you on that. From a business point of view, foreign businesses usually cannot do the hiring in China. They have to have it vetted through the Party,--

DR. HICKEY: Right.

COMMISSIONER TOBIN: And this may be still happening there.

Back to the inspections where I'm glad Commissioner Fiedler was digging in,and I want to ask you still further.

DR. HICKEY: Yeah.

COMMISSIONER TOBIN: Anybody who has been to China knows the problems they have with the air, the problems they have with the water, and the fact that there are all kinds of not poisonous minerals in the

earth itself, chromium and the like. It seems to me knowing that we're going to be, Americans or Chinese, ingesting such drugs, I would want to inspect or make certain that there's rigorous inspection at the input level, at the front end.

DR. HICKEY: Right.

COMMISSIONER TOBIN: How does your team make certain that what goes in is intact, safe and clear.

DR. HICKEY: Right, right. So this is part of the inspection regime that I was mentioning earlier. So when an FDA investigator goes into a facility, their role is to look at the broader system and see how the broader system of production works in that particular facility, but then through the process, it often is four or five days for a more complex facility, what do their records say about where, for instance, water comes from? Or in the case of drugs, it's where the suppliers come from.

Do the records that they've kept seem to indicate that those products are safe? Do the records look falsified? And we've had a few cases where they have. So there are a variety of ways that we can, you know, look at shipping records. We can look at when products come in versus when products go out. Feasibility of the ability to store a certain amount of product in a particular period of time.

Those kinds of things are all investigative tools that we use to look at these types of issues.

COMMISSIONER TOBIN: So there needs to be a basis of trust?

DR. HICKEY: Trust meaning just trust?

COMMISSIONER TOBIN: I mean hoping that that which is recorded to be the ingredients is what the actual end-state ingredients are.

DR. HICKEY: Well, I would say more what we're looking at is we want to verify that what they've represented is actually the case. I mean just to give an example--this is from a food inspection, but you could have a similar case with a medical product. One of our investigators at one point looked at the recordkeeping in a particular Chinese firm and saw that the handwriting of this record was done all in the same color ink, all in the same handwriting, which put off a signal to them that perhaps it was falsified because people don't tend to always pick up the same color of pen, and it's not always the same person.

So this investigator did background work to say, all right, let's look at your purchasing records, let's look to see what went out, and in some cases, if firms are shipping on behalf of other firms, let's see whether it's feasible to produce that amount of product as it's headed out the door. Well, it's not. So where are you getting this stuff?

So I would say more that what we want to do is verify what the records indicate.

COMMISSIONER TOBIN: May I?--

CHAIRMAN SHEA: Sure. Go ahead.

COMMISSIONER TOBIN: Okay. Thank you.

A further question. What communication loop do you have--let's

say I'm at Johns Hopkins University, and I'm in, you know, way up there in the ing department,. I've got a team of people working for me, and I'm buying medical equipment critical drugs. Do you have any, any feedback loop that comes back from the knowledgeable buyers of these products in bulk which gives you information on problems?

What's the communication loop from knowledgeable buyers into FDA and does it link to what you're doing in China?

DR. HICKEY: Yeah. This is not my particular area of expertise. I'll just maybe give a brief response and then get back to you with more later. What I can say is that we do have significant efforts in the area of post-market surveillance so looking at products that are on the market and seeing whether those products remain safe.

Many of our resources at FDA are focused on the preapproval process, but then we also understand that it's important after products get on the market to continue to surveil those products and see if they remain safe.

So, just in brief, as a non-expert I can give you that response, but I'm glad to give you more information later on.

COMMISSIONER TOBIN: We would like that. That would be great. Thank you.

CHAIRMAN SHEA: Thank you.

Commissioner Goodwin.

COMMISSIONER GOODWIN: Thank you, Mr. Chairman. Thank you, Doctor, for your time today.

At the risk of belaboring the point, I'd like to return to some of your testimony earlier this morning about placing this primary responsibility, in your own words, on manufacturers for ensuring certain safety requirements are met.

You had mentioned earlier that that includes identifying risks, documenting how those risks are addressed--

DR. HICKEY: Uh-huh.

COMMISSIONER GOODWIN: --and so forth. My question is how formalized is your process for evaluating what they do? Are the firms, including Western manufacturers, required to submit risk management plans to you? Are they subject to approval? And are they subject to any sort of periodic and formal compliance checks?

DR. HICKEY: Yeah. So let me just, a couple points that I want to make related to the Food and Drug Administration Safety and Innovation Act.

So that act, which became law in 2012, has given us a number of enhanced tools to be able to require industry to provide those types of things. So one thing is that it's very important to emphasize that through the Food and Drug Administration Safety and Innovation Act, or FDASIA, and then also through the Drug Quality and Safety Act, which was passed last year, we will, as this is implemented over the next number of years, firms will have increased requirements to provide to FDA information about where the risks are in the supply chain, where known falsified products are, where

their suppliers are coming from.

So I would say, again, that we're in a better place now than we were three years ago in terms of the tools that we require of industry for the safe manufacture of drugs.

COMMISSIONER GOODWIN: Let me shift gears a little bit. Talk a little bit about the risks posed to American consumers by the importation of nutritional supplements from China, products that are largely unregulated by the FDA, even here domestically?

DR. HICKEY: So dietary supplements, and I was talking with Commissioner Tobin about this before the hearing, this represents an area of significant focus for us in China. Again, when I opened the office in 2008, we really had not done much work in this area at all, and we had a number of different people coming to us, talking about the concerns that you raise.

In recent years, we've significantly increased our inspections in this area, and much of our focus has been on the suppliers of ingredients, and we have had recent inspections--some of them, I believe, are still in process in terms of cases being opened--but where we have found significant concerns in terms of falsification of records, where we've found lax GMP practices or no GMP practices.

We had one case in 2012 where we found problems at a firm in China. We shared with then- SFDA our concerns and our reports, and they went out and did a follow-up inspection and shut down the facility. So it's a concern, and I think you raise some legitimate issues, but we have taken action on those issues in recent years in a way that we did not in the early years of our engagement in China.

COMMISSIONER GOODWIN: Just to use the example that you alluded to, in an instance such as that, if you had reported it to your counterparts in the Chinese government, and their response was inadequate, in your estimation, what options would you have to address the concerns that you had previously expressed?

DR. HICKEY: Yeah, good question. I mean regardless of what the response of a foreign regulator is, we still have the full authority to take action based on what we find in our inspection.

So I would actually have to get back to you. My recollection is failing me on what we did in that particular case, but I believe we put in place an Import Alert on this particular firm, which meant that their products when they arrived in the United States couldn't proceed without affirmative proof that these products complied with U.S. law.

So we've got those tools regardless, but we reach out to our regulatory counterparts because often they can take that action that we can't--shutting down the firm. If they had not taken that action, we would still have been able to protect American consumers, but we'd like to take the next step in this globalized world that I described in my testimony.

COMMISSIONER GOODWIN: Let me, with the chair's indulgence, if I could just very quickly, and revealing my own ignorance--

CHAIRMAN SHEA: You have my indulgence.

[Laughter.]

COMMISSIONER GOODWIN: --regarding the complexities of this area of the law. So if they're placed on import alert list--

DR. HICKEY: Right.

COMMISSIONER GOODWIN: --they can't get in the country unless they provide affirmative evidence or proof that they comply with U.S. law.

DR. HICKEY: Right.

COMMISSIONER GOODWIN: If it is a nutritional supplement, what sort of requirements are imposed by U.S. law that they would have to satisfy to get in?

DR. HICKEY: Right. Well, I'm not familiar with the complexities of requirements for dietary supplement ingredients themselves, but what I can tell you is that when we put a firm on import alert, when their products arrive in the United States--in most cases it's an academic question-- they don't. In many cases, they don't continue to try to send products to the United States, but if they do, there are then a very clear set of requirements for any specific import alerts of what evidence they must provide.

And I don't recall in this particular case exactly what they needed to provide, but I can say, just for instance, in another example of let's say food, aquaculture, firms from China currently need to show that their product is free from antibiotic residues that are carcinogenic. So it's just an example. Over in the dietary supplement area, there would be specific requirements of what they would need to, what pieces of evidence they would need to provide.

COMMISSIONER GOODWIN: All right. Thank you.

CHAIRMAN SHEA: Okay. We have two sets of questions. I have a few questions, and Commissioner Fiedler, has some questions, and we're running a little short of time, but you traveled a far distance so I don't mind if we go over a few minutes.

Just a quick, couple of quick questions. One, we talk about inspecting facilities in China. Can the Chinese regulators inspect a U.S.-based facility?

DR. HICKEY: Yes.

CHAIRMAN SHEA: So they have access to our U.S.-based manufacturing facilities for regulatory oversight and inspection?

DR. HICKEY: Yes. I will just only say that we are much more active in this area than they are, but they do inspections in the U.S.

CHAIRMAN SHEA: Thanks.

Now, the point has been made here, most recently, I think, by Commissioner Goodwin, that we rely on the Western companies to have supply chain security. We also rely on the Chinese FDA for their regulatory oversight. We met with the Chinese FDA last year, and my recollection was that they rely a lot on the provincial FDAs. It's very decentralized in China. It's not, they're not some sort of massive force at the top imposing their will. They rely on information and the work of the provincial level FDAs. It that

right? Or is my impression correct?

DR. HICKEY: You're right. And I think I referenced it briefly in my testimony that this is one of the big challenges for China. I think the numbers are that central authorities have somewhere in the range of about 400 staff countrywide. There are somewhere in the range of 200,000 staff. So it is one of the challenges in China always.

CHAIRMAN SHEA: Okay. I'm going to borrow a question that my colleague, Commissioner Slane, often asks because I think it's a particularly good one in this instance. What keeps you up at night?

DR. HICKEY: Well, this week, jet lag.

[Laughter.]

CHAIRMAN SHEA: Okay. Besides jet lag? What do you worry about?

DR. HICKEY: Well, our office was created, as many of the Commissioners here will recall, in the context of 2007 and 2008 when it seemed like every week there was a new product safety scandal coming out of China.

We have been fortunate in the five-and-a-half years since I arrived that there has not been another set of incidents along the scale of a heparin or something like that.

However, my focus is on the big picture. My focus is on long-term, and I think our relationship with the Chinese has improved over time, and if there is another crisis that comes, I think we have better communication channels.

But the challenges are out there, and they remain, and so I think even in weeks when I'm not jet lagged, I occasionally have a thought or two about those kinds of issues.

CHAIRMAN SHEA: Okay. Great.

Commissioner Fiedler.

COMMISSIONER FIEDLER: A couple of quick questions. When a container load of active ingredients lands in Long Beach, and you find it's bad, can you seize and destroy it?

DR. HICKEY: We can, yes.

COMMISSIONER FIEDLER: Or do we also let them take it away?

DR. HICKEY: With new authorities given to us, we have the ability to seize and destroy product. There have been concerns, I think, certainly from a number of people related to--

COMMISSIONER FIEDLER: Port shopping.

DR. HICKEY: Port shopping.

COMMISSIONER FIEDLER: Yeah.

DR. HICKEY: And these kinds of things.

COMMISSIONER FIEDLER: That was my--

DR. HICKEY: So Congress has sought to close some of those loopholes in recent years.

COMMISSIONER FIEDLER: Are we seeing when you sanction

or bar or put an alert on a manufacturer in China consequent rises in imports from countries that are not known to produce drugs?

DR. HICKEY: Uh-huh. Right. Well, so, transshipment is--

COMMISSIONER FIEDLER: You send it to Indonesia and then send into the United States under another name. A place where you're not.

DR. HICKEY: Right. Right. Certainly a significant issue that, you know, as I emphasized in my testimony and I think in response to one of the questions earlier, this is one of the reasons that we try to focus on other risk profiles I haven't mentioned yet, but maybe this is the time to do it.

Our system, which goes by the acronym PREDICT, which contains an algorithm to try to quantify risk, and as I said the focus tends not to be on where it's coming from but other known risk factors, like volume of product or past, past history. So we try to get around those issues and address those issues through a more robust screening program.

COMMISSIONER FIEDLER: Thank you very much. Last quick question I have is if bad product finds its way through the border and into the stomachs and bodies of the U.S. people, who's liable in the end? I'm a non-lawyer. Is it the importer who's in the United States? Is it the retailer who sold it to him? Is it the U.S. drug company with its name on it or is it the elusive manufacturer in China? Or is there a string of liabilities?

DR. HICKEY: Right. I'm also not a lawyer, but the responsible party--

CHAIRMAN SHEA: Who has the money? That's the answer.

[Laughter.]

COMMISSIONER FIEDLER: Well, no, I mean the question is what success they had, you know.

DR. HICKEY: Yeah, the responsible party at the point of import is the importer, and they take responsibility for product coming into the United States. But there could be other--

COMMISSIONER FIEDLER: They take responsibility for its safety in civil action.

DR. HICKEY: There could be other levels of responsibility depending on the case. If it's a large U.S. firm.

COMMISSIONER FIEDLER: Thank you very much.

CHAIRMAN SHEA: Commissioner Slane has a quick question.

COMMISSIONER SLANE: Does the U.S. importer Baxter Laboratories, Wal-Mart, have any duty to do quality control on imported active ingredients, for example, from China, under the law?

DR. HICKEY: They do have responsibility. I mean if you're talking about a pharmaceutical firm that's importing, let's say, active pharmaceutical ingredients for further use in a finished product, the manufacturer of the finished product ultimately is responsible for its entire supply chain. So there is responsibility.

COMMISSIONER SLANE: So that's another check for you in the process.

DR. HICKEY: That is.

COMMISSIONER SLANE: Thank you.

CHAIRMAN SHEA: Well, thank you very much, Dr. Hickey, for making the trek out here.

DR. HICKEY: Thank you.

CHAIRMAN SHEA: You are excused, and you can relieve yourself of your jet lag.

DR. HICKEY: Thank you.

CHAIRMAN SHEA: Thank you very much for your time.

DR. HICKEY: Thank you.

CHAIRMAN SHEA: We will reconvene at 9:45.

[Whereupon, a short recess was taken.]

VICE CHAIRMAN REINSCH: Let's convene the second panel--

COMMISSIONER TOBIN: The first panel.

PANEL I INTRODUCTION BY VICE CHAIRMAN WILLIAM REINSCH

VICE CHAIRMAN REINSCH: I'm sorry--yes, Panel One. I think we misnumbered, but anyway Panel One. This panel is going to look at China's healthcare sector.

Our first witness is Karen Eggleston. She joined the Walter H. Shorenstein Asia-Pacific Research Center at Stanford University in the summer of 2007 and leads the Center's Asia Health Policy Program.

She's also a fellow at Stanford's Center for Health Policy/Primary Care and Outcomes Research, and a Faculty Research Fellow of NBER. Her research focuses on comparative healthcare systems and health reform in Asia, especially China; government and market roles in the health sector; payment incentive; healthcare productivity; and the economics of the demographic transition.

Dr. Eggleston teaches through Stanford's East Asian Studies Program and is also affiliated with Stanford's Public Policy Program. She earned her Ph.D. in public policy from Harvard. We won't hold that against you.

Our next witness is Dr. Yanzhong Huang. Dr. Huang is a Senior Fellow for Global Health at the Council on Foreign Relations where he examines issues of emerging powers, global health governance, health-related development assistance, and universal health coverage.

He is also an Associate Professor and Director of the Center for Global Health Studies at the School of Diplomacy and International Relations at Seton Hall University.

Dr. Huang is the Founding Editor of Global Health Governance: The Scholarly Journal for the New Health Security Paradigm. His latest book, Governing Health in Contemporary China, looks at China's healthcare reform, the government's ability to address disease outbreaks, and food and drug safety.

He received his B.A. and M.A. degrees from Fudan University and his Ph.D. from the University of Chicago, a wonderful institution. My son is getting his Ph.D. from there, too, I hope.

[Laughter.]

VICE CHAIRMAN REINSCH: One of these years.

Our final witness on this panel is Xiaoqing Lu Boynton. She is a Director at Albright Stonebridge Group where she advises clients on government affairs strategies to support their success in the China market, particularly in the healthcare and life sciences sector.

Ms. Boynton most recently served as a Fellow with the Global Health Policy Center at the Center for Strategic and International Studies. She coauthored several CSIS reports on health and environmental issues in China, including "Implementing Health Care Reform Policies in China: Challenges and Opportunities" in 2011; and "China's Health Amidst the Global Economic Crisis: Potential Effects and Challenges" in 2009. She holds an M.A. in sustainable international development from Brandeis

University.

As I said in the beginning of the hearing, your statements will automatically be put in the record so please do your best to stay within seven minutes for your oral statements, and we'll go in the order in which I introduced you. So Dr. Eggleston, please begin.

OPENING STATEMENT OF DR. KAREN EGGLESTON
FACULTY DIRECTOR, ASIA HEALTH POLICY PROGRAM, STANFORD UNIVERSITY

DR. EGGLESTON: Thank you very much.

Chairman Shea, Vice Chairman Reinsch, and other Commissioners, thank you for the opportunity to testify before you today about the important topic of China's healthcare sector.

I will make three points--about trends, policy and prospects.

China obviously is a large and diverse country, but even in rural areas, China's primary disease burden now arises from chronic non-communicable diseases, such as cancer, heart disease, stroke and diabetes, but with important lingering problems from infectious diseases, such as hepatitis and tuberculosis, increasingly drug resistant.

Hypertension--often undiagnosed and untreated--is a leading preventable risk factor. Others include male smoking, increasingly high-fat and calorie-rich diets, air pollution, and physical inactivity as China rapidly urbanizes.

China has also experienced demographic transition to relatively low mortality and low fertility, with its population now rapidly aging. The need to finance medical care and pensions for the burgeoning elderly population challenge China's developing social support system.

These shifts in a sense represent triumphs of earlier investments in mortality reduction, but also place some constraints on China's future development. They challenge economic growth to continue without the benefit of a so-called "demographic dividend" from a large bulge in the working-age population.

They challenge communities and authorities to address the non-medical determinants of health, and they challenge the health system to reorganize to emphasize prevention and management of chronic disease.

Regarding policies, the five goals for China's 2009 national health reforms were extending basic government-subsidized health insurance started earlier in the decade, expanding the population health benefit package, strengthening primary care, implementing an essential drug list for all grass-roots service providers, and piloting reforms of government-owned hospitals.

One of the major successes of the 2009 reforms was extending basic health insurance coverage to over 90 percent of the population although current separate health insurance systems for urban and rural residents offer modest financial protection from catastrophic medical spending and imperfectly cover the vast migrant population.

Initiatives to strengthen government financing of population health and primary care have made significant strides.

However, strengthening primary care is a difficult and long-term process since patients have a well-founded distrust of the quality of village doctors and local clinics.

Another challenge arises from the distorted incentives imbedded in the fee-for- service price system. Providers can make money from high-tech diagnostic procedures and a mark-up from dispensing pharmaceuticals directly to their patients, while basic curative and public health services are often unprofitable.

Physicians throughout East Asia have long made much of their revenue from dispensing medications to patients, and China's current incentive structure reflects that legacy. Incentives to overprescribe have negative implications for Chinese and the rest of the world, arguably, the most prominent example being the overuse of antibiotics and its threat to the global public good of antimicrobial effectiveness.

However, government reform policies have taken steps to ameliorate the underlying incentive distortions, for example, by removing the drug profit mark-up from grass-roots providers as part of the essential drug list policy.

And a case can be made that some important drugs are underused rather than overused in China, such as drugs to control blood pressure. This may also be related to the distorted incentives. Especially for asymptomatic conditions like high blood pressure, patients may disregard doctors' advice for taking drugs, assuming that profit-seeking is distorting the doctor's judgment.

Policy remedies are themselves complicated. Efforts to reduce overprescribing often lead to patient dissatisfaction, reduced confidence in primary care, and doctors referring higher-severity patients to hospitals precisely when China's health system needs to reduce overcrowding in its large urban hospitals.

Probably the least successful of the five articulated reforms, and hence the current focus of the next phase, was public hospital reform. Government roles of owner, regulator and purchaser are not well differentiated. Improvement of governance structures has the potential to clarify rights, responsibilities and accountability.

Regarding prospects, recent policy statements reveal considerable continuity with earlier announced reforms. Xi Jinping has emphasized that reforms must accelerate in the social sector, including social security and public health. The Report on China's 2014 Plan for Economic and Social Development adopted in March by the 12th National People's Congress emphasizes that the government will expand the comprehensive trial reform of public hospitals, trials to reform services for the elderly, and other initiatives.

Additional priorities include raising the government subsidies for rural insurance and for population health and improving doctor-patient relations, which are currently quite tense in many areas.

Some provinces are merging the city level non-employed and county-level rural, or NCMS, health insurance systems. Such initiatives may improve risk pooling and start to raise the risk protection for those with the weakest coverage currently such as the rural poor.

Prospects for health improvement may be even greater from initiatives outside the health sector, such as providing safe drinking water to all rural residents and efforts to reduce pollution.

Of course, there are also risks of stagnation if local officials' attention is focused on other aspects of reforms rather than the health sector or even of a public health crisis, which may precipitate further reforms.

However, cautious optimism seems warranted. A critical next step will be reforming healthcare delivery and payment incentives to improve value for money. Health sector reform, in turn, can help China rebalance its economy towards greater domestic consumption, reduce precautionary savings, and invest in the human capital needed to continue robust if more moderate economic growth.

Thank you for the opportunity to testify today.

VICE CHAIRMAN REINSCH: Thank you.

Dr. Huang.

PREPARED STATEMENT OF DR. KAREN EGGLESTON
FACULTY DIRECTOR, ASIA HEALTH POLICY PROGRAM, STANFORD UNIVERSITY

Testimony of Karen Eggleston, Stanford University
Asia Health Policy Program Director, Shorenstein Asia-Pacific Research Center, FSI
April 3, 2014

Testimony before the U.S.-China Economic and Security Review Commission Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products

Chairman Dennis C. Shea, Vice-Chairman William Reinsch, and other Commissioners of the U.S.-China Economic and Security Review Commission, thank you for the opportunity to testify today on the important topic of China's healthcare sector.

China's healthcare system faces challenges common around the globe: safeguarding public health, expanding health-care coverage, and improving quality while controlling costs and balancing government and market roles in the health sector. My research on China's health system in comparative international perspective uses the lens of microeconomics. As you know, microeconomics explores choices under scarcity, and few other areas pose the social dilemma of choice under scarcity more starkly than that of health. In the extreme, such decisions determine "who shall live," the title of the 1974 book by pioneering health economist Victor Fuchs. Individuals – currently healthy or not – as well as medical providers, managers and regulators all make decisions shaping health and welfare; none are immune to influence from economic incentives. As Chinese policymakers experiment with reforms, a health economics perspective can help understand how to design incentives to promote "healthy choices" for individuals and for society: choices that increase human capital, spur economic development, and promote an efficient and equitable healthcare system.

My written testimony is based on fieldwork and empirical analyses summarized in several recent research papers cited in the reference section, as well as the contribution of many other health economists and other analysts of China's recent health sector reforms.[6] The references provide fuller citation of that literature.

In responding to the specific questions sent me by the Commission, I draw on health economics analysis and put less emphasis on the political economy of reforms or the governance process, since those are not my research focus. My testimony is guided by the

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[6] My testimony draws extensively from Eggleston (2010, 2012ab, 2013) and co-authored work cited in the references (e.g. Eggleston and Fuchs 2012, Eggleston et al. 2013, Chen and Eggleston 2014). Views expressed here are my own and do not reflect the views of Stanford, the Asia Health policy Program, the National Bureau of Economic Research, the Asia-Pacific Observatory, or any other organization with which I am affiliated. I extend sincere thanks to colleagues for their input through discussions and their published research on these topics.

view that it is important (i) to strike a balance, not focusing exclusively on the shortcomings of China's system nor extolling its progress while neglecting its challenge and (ii) to keep a comparative perspective in mind. China's health status and health system performance fall short compared to some high-income countries, or (perhaps most importantly) compared to the aspirations of China's people. But China's health reforms can be considered a success compared to some lower-income countries, and a model for some developing countries aspiring to universal coverage. Consider for example the insights of Nobel laureate Amartya Sen (as articulated in a *New York Times* editorial "Why India Trails China" on June 19, 2013):

> The far greater gap between India and China is in the provision of essential public services — a failing that depresses living standards and is a persistent drag on growth. Inequality is high in both countries, but China has done far more than India to raise life expectancy, expand general education and secure health care for its people…. India may be the world's largest producer of generic medicine, but its health care system is an unregulated mess. The poor have to rely on low- quality — and sometimes exploitative—private medical care, because there isn't enough decent public care. While China devotes 2.7 percent of its gross domestic product to government spending on health care, India allots 1.2 percent. …. In China, decision making takes place at the top. The country's leaders are skeptical, if not hostile, with regard to the value of multiparty democracy, but they have been strongly committed to eliminating hunger, illiteracy and medical neglect, and that is enormously to their credit" (Amartya Sen 2013).

A third critical distinction that guides my testimony is that between the healthcare system and the broader determinants of health. The goal of health reforms in most countries is not exclusively (or even primarily) to raise life expectancy, but to address critical barriers to accessing quality, affordable medical care. Extending life involves a much broader set of factors than medical care, such as air and water quality, sanitation and waste disposal, lifestyle choices about physical activity and smoking, traffic safety, and other factors.

- ***Your work has looked at diverse aspects of sickness in China, from TB in poor rural areas to demographic aging and diabetes. How has the nature of disease in China changed in recent decades? What kind of burden might it place on China's future development? Also, if providers are "inducing" demand by overprescribing drugs, is this a public health crisis in the making?***

The nature of disease in China has changed from a primary burden of infectious disease to a disease burden dominated by chronic, non-communicable diseases such as cancer, heart disease, and diabetes, but with important lingering problems from endemic and re- emerging infectious diseases such as hepatitis (a primary cause of liver cancer), multi- drug-resistant tuberculosis, and HIV/AIDS. At the same time and as part of the related demographic transition, China's population age structure is becoming more and more like high-income countries with low fertility, increasing longevity, and an increasing proportion of the population over age 60. In a sense, this shift in the burden of disease represents a natural progression of economic development and a triumph of earlier efforts to control infectious disease. However, the shift also places some constraints on China's future economic and social

development—challenging economic growth to continue without the benefit of a "demographic dividend" from a large bulge in the working-age population; challenging the health system to better identify and manage chronic disease; and challenging communities and authorities beyond the health sector to address the broader social determinants of health, from clean air and water to tobacco control and active rather than sedentary lifestyles as China rapidly urbanizes.

China's leadership has launched major initiatives to correct perceived dysfunction in the health sector and meet the expectations of a population with ever-increasing per capita income. To understand the prospects for newly infused government funds to translate into effective health care service delivery and improvements in population health requires understanding the starting point: how China's health sector evolved over the Mao era and the last 30 years of reform.

China's epidemiologic and demographic transitions

China's growth in life expectancy between 1950 and 1980 ranks as among the most rapid sustained increases in documented global history. However, no study has quantitatively assessed the relative importance of various explanations proposed for these gains. Babiarz, Eggleston, Miller, and Zhang (2014) create and analyse a new province-level panel data set spanning 1950-80 using historical information from Chinese public health archives, official provincial yearbooks, and infant and child mortality records contained in the 1988 National Survey of Fertility and Contraception. Although exploratory, results suggest that increases in educational attainment and public health campaigns jointly explain 50-70 per cent of the dramatic reductions in infant and under-five mortality between 1950 and 1980. These results are consistent with the importance of non-medical determinants of population health improvement – and under some circumstances, how general education may amplify the effectiveness of public health interventions.

Because of the overall health improvements during the Mao era (despite the tragic disaster of the Great Leap Famine), China began the reform era in 1980 as an international outlier, having achieving high population health status for its relatively low per capita income level. One might have hoped that China's above-average economic growth would have reinforced China's previously above-average health indicators.
Instead, compared to unprecedented economic growth, health status measures improved more slowly in the 1980s and 1990s, with growing population disparities. By 2000, life expectancy, infant mortality and under-five mortality rates were all about average for countries of similar per capita income.

While in principle this pattern need not signal failure—certainly the previous health improvements helped to fuel rapid economic gains, which in turn may be just as valuable as increased health improvements—it does pose a challenge to those who assume that economic growth is the key to longer, healthier lives. At a given point in time, health tends to be positively correlated with per capita income in a given country. However, there are wide variations in health outcomes for populations at a given level of per capita income, and changes in health spending are often not directly correlated with changes in population

health.

Why did China make such dramatic health gains when it was relatively poor and then stop making large gains during a period of rapidly rising income? Eggleston, Wang and Rao (2008) discuss several not-mutually-exclusive explanations for this "regression to the mean": the social and economic stresses of systemic transformation from central planning to a market-based economy (which has been associated with dramatic health declines in Eastern Europe and the Soviet Union); reverse causality from health to subsequent growth; and changes in health care financing and delivery.

It is also important to recognize that China's changing environment for health outside of medical care *per se* has had a large impact on health outcomes. To blame market reform of medical care for 100 percent of the stagnation in health improvement in the 1990s and 2000s would be to exaggerate the role of medical care. The stress of economic reforms that destroyed China's infamous "iron rice bowl," the increase in environmental pollution and traffic accidents, the continuing high prevalence of smoking among Chinese men— these factors certainly contributed to a slower reduction in premature mortality than would have occurred even if every Chinese citizen had ready access to basic and acute medical care. Just as medical care cannot take all the credit for health improvement, it also cannot take all the blame for poorer-than-expected health outcomes.

Since the late 1990s, China has gradually continued to move up the socio-economic gradient in health, with wide disparities but clear progress for most segments of the population. Life expectancy increased between 1990 and 2010 from 69.9 to 76.7 for women, and from 66.9 to 72.5 for men, levels slightly above those expected for China's per capita income.[7]

Studies on the causes of mortality and morbidity in contemporary China confirm the dominant and growing role of chronic non-communicable diseases. According to official statistics (China Health Statistics Yearbook 2012), the leading cause of death in rural areas in 1990 was respiratory disease for both males and females, with heart diseases only number 4, and tuberculosis and other infectious diseases within the top 10 causes.
By 2011, the leading causes of death in rural China were cancer, cerebrovascular disease (stroke), and heart disease, with tuberculosis and other infectious diseases no longer among the top 10 causes of death. In 2011, these top 3 chronic diseases accounted for 69% of urban deaths and 65% of rural deaths.

According to the estimates of the Global Burden of Disease Study 2010[8], the leading risk factors for mortality in China include high blood pressure, dietary risks, and smoking; interestingly, the risk from air pollution has two components, one (outside air pollution) has increased, while indoor air pollution (from cooking) has decreased. Physical inactivity did not appear as a risk factor in 1990, but was among the top 10 by 2010.

Clearly, China's burden of disease is changing from that of a low-income country to one more closely resembling a high-income profile, especially in urban areas. Hypertension – often

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[7] The specific figures are from the U.S. Census Bureau (retrieved from life tables, April 2011).
[8] See http://www.healthmetricsandevaluation.org/gbd.

undiagnosed and untreated -- is the leading preventable risk factor for premature mortality in China. He et al (2005), based on a national survey of adults 40 and older, found that the leading causes of death (between the 1991 baseline and the 1999-2000 follow-up surveys) were cancer, heart disease, and cerebrovascular disease, but that infectious diseases were also among the top 5 causes for both men and women. Leading risk factors besides hypertension were smoking and physical inactivity, but also included underweight (i.e., body mass index below 18.5). Fueled by increases in high-fat and calorie-rich diets, reductions in physical activity, and other environmental factors, there is also high and rapidly increasing prevalence of diabetes among adults in both rural and urban China (Yang et al., 2010), with the age-standardized prevalence 9.7% in 2007-2008 (20.4% among the elderly). Diabetes prevalence is higher among urban residents than among rural residents (11.4% vs. 8.2%), although the prevalence of pre-diabetes is greatest in rural areas (Yang et al., 2010).

As a result, China now faces a "double burden" of diseases, including those common in both developing and industrialized economies. Reducing behaviors that lead to chronic disease—including smoking, unhealthy diets, and sedentary lifestyles—will be key to reducing the burdens of future morbidity and mortality.

In addition and causally related to this epidemiologic transition, China has experienced rapid demographic transition from high mortality and high fertility to relatively low mortality and low fertility. The total fertility rate declined from around 6 in 1950-55 to around 2 in 1990-95, with the most rapid decline in the 1970s prior to the beginning of the one-child policy. The total fertility rate is now below replacement level (Peng 2011), and is likely to remain low even with the recent relaxation of China's strict family planning policies. As a result, China's population is aging rapidly. The 2010 census revealed a population of 1.34 billion, 50 percent urban and 13.3 percent above age sixty. The median age will exceed that of the United States within this decade, and the proportion aged sixty-five and above will increase to 25 percent by 2040, totaling 300 million strong (Peng 2011). How will the graying of China shape its rise? Eggleston and colleagues (2013) argue that demographic change—including gender imbalance and population aging and how they interact with rapid urbanization—will constrain how China copes with a slower rate of economic growth.

Moreover, as in many other middle- and high-income countries, improved health and survival in China no longer play a large role in increasing lifetime labor force participation and instead contribute to longer retirement lives. In a relatively young population at an earlier stage of the demographic transition, such as in India, health improvements reduce infant and youth mortality, keeping more people alive into their working ages. Of the increase in India's life expectancy over the past two decades, three- quarters accrued to those younger than age sixty-five. Just the opposite was true in sixteen European countries and the United States: more than 75 percent of increases in life expectancy came after age sixty-five (Eggleston and Fuchs 2012). China is catching up quickly: the share of years lived past age sixty-five as a percentage of increase in life expectancy at birth was 52 percent for men and 41 percent for women in the most recent twenty-year period (Eggleston and Fuchs 2012). In only the most recent couple decades, China has shifted from a distribution of death rates with largest decreases in infancy to a distribution with the largest decreases after age 60—a shift that took place over a much longer period in the west (ibid). As a result, except for the poorest rural

areas, improvements in longevity tend to lengthen retirement rather than working lives. Although grandparents do provide substantial childcare and other nonmarket services in China, the longevity transition implies a decrease in working years as a percentage of life expectancy and a challenge to social support systems because of the growing needs to finance medical care and pensions (Eggleston et al. 2013).

Challenges to China's health system from the changing burden of disease

China's health financing and delivery system—originally designed to control infectious diseases and treat episodic, acute medical conditions—needs to reorganize to emphasize primary and secondary prevention of chronic disease, patient education in self- management skills, and community-based primary care.

One strong challenge for China is addressing the underlying causes of health disparities. Controlling infectious disease often disproportionately benefits the poor. Managing chronic disease, by contrast, brings out differences in risk factors, affordability and ability to self-manage with sometimes complicated treatment regimens (e.g. for diabetes). The decrease in under-nutrition and the increase in over-nutrition have been most rapid among China's poorest. China's least advantaged are catching up rapidly in terms of "diseases of affluence." The poor are less well nourished, less able to attend and concentrate in school, and most challenged to understand the importance of adhering to specific treatments. Educational gradients have been documented in China for prevalence of hypertension, diabetes, and pre-diabetes; having difficulties with activities of daily living; having depressive symptoms; micronutrient deficiencies and anemia; and general self-reported and objectively measured health. Thus, attention to educational and health disparities can jointly address root causes of social deprivation in China; with sufficient policy attention and rigorous evaluation of effective programs, such investments in the human capital of the vulnerable could have manifold returns for China's future social and economic development.

Despite the large returns to health and social well-being from investments in simple health interventions like vaccinations and improved primary health care, China's widening disparities in income and educational attainment translate into a wide disparity in healthy lifespan. Inter-generational transmission of relative deprivation further exacerbates this trend. Thus, while China confronts the "standard" health policy challenges of middle- and higher-income countries (such as robust health insurance coverage with sustainable financing), China must address the stagnation of health improvement among those most vulnerable. Recent reforms that significantly increased health insurance coverage are a notable step in that direction, but China's current separate health insurance systems for urban and rural residents offer modest financial protection from catastrophic medical spending and imperfectly cover the vast migrant or floating population. In the decades to come, addressing inequalities in health and education and in the inter-generational transmission of human capital are likely to be even more important as China transitions to ever more human-capital-intensive mode of development (Eggleston 2012b).

Part of the problem facing China's health system stems from the administrative prices set for medical services in China, based on fee-for-service (FFS) payment, which does not

necessarily align well with the goal of cost-effective management of chronic disease. Providers can make money by over-treating patients with costly diagnostic procedures (such as CT and MRI scans) and prescribing drugs, while skimping on unprofitable basic curative and public health services. The risks of this kind of supplier-induced demand – a controversial phenomenon documented to some degree in the U.S. and other high-income countries – are even greater in developing countries where consumers are more vulnerable vis-à-vis providers (except that wealth and liquidity constraints preclude many from following advice for expensive treatment). Moreover, China faces large opportunity costs of excessive spending on high-tech medicine, since the burden of disease is primarily in areas addressed cost-effectively with public health and lower-tech services. The unintended, but hardly unpredictable, supply-side reaction to distorted FFS reimbursement spurs cost escalation and exacerbates the very access problems that distorted prices were meant to prevent. I return to this issue in discussion of the recent and current initiatives for reform, below.

If providers are "inducing" demand by overprescribing drugs, is this a public health crisis in the making?

The incentive structure that underpins over-prescription of pharmaceuticals has a long social and cultural legacy throughout East Asia, not only in China. This propensity to over-prescribe certainly has severe and long-lasting implications for Chinese and the rest of the world—the most prominent example being the over-use of antibiotics and its threat to the global pubic good of antimicrobial effectiveness. "Supporting medical services through drug sales" (*yi yao yang yi*) has been widely criticized amongst mounting evidence that such financial incentives distort prescribing and contribute to rising expenditures. In one study, Currie, Lin, and Zhang (2010) audit the antibiotic prescribing behavior of hospital-based physicians in two cities and one rural area using student "simulated patients" during the 2008 and 2009 flu seasons. They find that Chinese physicians prescribe antibiotics for a startlingly high proportion of patients (averaging 62 percent), even when patients report symptoms that do not warrant antibiotics; and 39 percent of physicians still prescribed antibiotics when the simulated patients signaled to doctors that they knew that taking antibiotics would be inappropriate. These results provide strong evidence of physician-induced demand in China, with adverse consequences not only for medical spending but also for patient health and development of antibiotic resistance. They also illustrate the kinds of distortions introduced by FFS payment with higher fee margins for some services relative to others.

However, "public health crisis" suggests a sudden onset and devastating scope, such as a pandemic like the Severe Acute Respiratory Syndrome (SARS) crisis of 2003 or the potential for an avian influenza pandemic. Over-prescribing of drugs in China is not a public health crisis in the same sense. First, it has long roots and has been ongoing for decades; second, the government reform policies have taken steps to ameliorate the underlying incentive structure (for example, by removing the drug profit mark-up from grassroots providers); and third, a case can be made that some important drugs are *under*- used rather than over-used in China, such as drugs to control blood pressure.

The public health challenge from over-prescribing goes beyond contributing to development of drug-resistant "superbugs," because it leads to a pervasive and deep distrust of healthcare providers, with patients suspecting that they do not prescribe in the best interest of their

patients. Especially for asymptomatic conditions like high blood pressure, patients may completely discount providers' urging to take drugs, assuming that profit-seeking is distorting the physician's judgment. While more research is warranted, I hypothesize that the over-prescribing "inducement" incentives of China's physicians, combined with the real affordability problems of long-term drug adherence facing the less fortunate segments of China's population, plays an important role in the low diagnosis and treatment of high blood pressure. This impact may be especially large, since hypertension is a leading risk factor contributing to the large burden of chronic disease in China.

Policy remedies are themselves complicated. Efforts to reduce over-prescribing can lead to patient dissatisfaction and reduced confidence in primary care, precisely when China's health system needs to enhance confidence in primary care to reduce the over-crowding in large urban hospitals (e.g. Wang et al. 2011). Reducing primary care providers' profits from drug sales (as under the Essential Medications List system introduced in the 2009 reforms) may reduce over-prescribing in primary care, but shift high-severity patients to higher-level providers, so that overall spending may even increase (ibid; and as Chen and Eggleston (2014) also found in a study of EML implementation in Shandong). More encouragingly, a recent study by Yip et al. (2014), based on a randomized experiment in Ningxia Province between 2009 and 2012, found that capitation payment with pay-for- performance helped to reduce prescribing of antibiotics and slightly reduced spending per visit to village posts, with no effect on other outcomes.

- *For many sectors of China's economy, Western economists advocate privatization and liberalization. But as you note in your research, for example, private hospitals do not always outperform public hospitals in China. Moreover, after years of market reform, healthcare providers in China rely too heavily on drug sales. Can you outline the pros and cons of market reform in China's healthcare sector? What might be the proper role of the state in improving healthcare delivery?*

The distribution of public, private for-profit, and private nonprofit health care providers in any given country reveals the tracings of history and ideology, with the evolution of ownership patterns heavily path-dependent. While there are identifiable benefits from privatization and liberalization in many parts of the economy, most experts in the health sector agree that privatization and liberalization are no panacea or magic pill.

For China, rigorous evidence is lacking about differences in performance by private and government-owned healthcare providers, and what evidence is available provides a somewhat mixed story. This result is not surprising, since many factors aside from ownership are powerful determinants of provider performance, including the payment structure, competition, and regulatory context. For example, Eggleston and Yip (2004) calibrate a simulation model of the impact of China's 1990s ownership and pricing reforms on cost, quality and access. Both theoretic and simulation results show how providing implicit insurance through distorted prices leads to over/under use of services by profitability, which in turn fuels cost escalation and reduces access for the poor. The authors suggest that regardless of ownership structure, broadened insurance coverage and mixed payment are better options than continued implicit

cross-subsidies through distorted FFS.

Based on economic theory as well as empirical evidence from a range of countries, a strong case can be made that the proper role of the government in healthcare includes regulatory oversight and promotion of population health services either through direct delivery or "contracting out" to assure access to basic public health services for the whole population. The role of government in personal medical services in less clear cut, as summarized by a systematic review that Yu-Chu Shen and I (in our 2007 and 2008 publications) completed synethsizing the conflicting findings in the voluminous empirical literature on differences between not-for-profit, investor-owned and government-owned hospitals. In pursuing this ownership meta-analysis, a key objective was to provide a comparative evidence base for policy debates about ownership structure in China and elsewhere. Consistent with that review and much of the international evidence, an empirical study of Chinese hospitals (Eggleston et al. 2010) found that public and private hospitals in Guangdong, China, were surprisingly similar once the analysis accounted for other important determinants of cost and quality such as size and teaching status.

Although China's recent health reforms call for non-discrimination against private providers, the legacy in China that the government directly owns and manages the most- reputable providers—the large tertiary and teaching hospitals in all China's urban centers—shapes the market niche of private providers. For example, Wang at al. (2013) find that residents in the communities served by private community health centers are of lower socioeconomic status (more likely to be uninsured and to report poor health), compared to residents in communities served by a government-owned community health centers. Government and private community health stations in Weifang, Shandong province did not statistically differ in their performance on contracted dimensions, after controlling for size and other characteristics.

Certainly one of the most challenging aspects of China's 2009 national health reforms has been the professed goal of reforming public hospitals. Improvement of governance structures for government-owned hospitals has the potential to clarify rights, responsibilities, and accountability in such a way that could significantly improve the health system.

In terms of the locus of service provision, China has inherited a largely hospital-based delivery system managed through the Ministry of Health and local governments, supplemented by a vast cadre of village doctors and a newly developed system of grassroots providers in urban areas (Eggleston 2012a). Like many other health systems in Asia (including Japan and Korea), a large share of outpatient visits, even for relatively minor conditions and first-contact care, is to secondary and tertiary hospital outpatient departments.

China's recent reforms promote development of a primary health care system of "grassroots providers," strengthening the quality and funding for village clinics, township health centers, urban community health centers, and launching a new program for GPs designed to bring "barefoot doctors" into the 21st century in terms of training and quality.[9] The effort to build up

[9] The official definition of "grass-roots health care institution" includes community health

a reliable network of non-hospital-based primary care providers is a difficult and long-term process, since patients have a well-founded distrust of the quality of primary care providers. Unlike in some other developing countries, however, China does not face the same challenges of rampant absenteeism and crumbling infrastructure.

China's hospitals, and a large share of its grassroots providers, are government owned and managed. The latest available statistics, covering January through October 2013, show that government hospitals accounted for 90% of inpatient discharges and 89% of outpatient visits (although government hospitals account for 55% of hospitals).[10] Government-owned provider organizations also account for the majority of services at the grassroots level, including 90% of visits to community health centers and stations and 99% of visits to township health centers, although almost half of all visits to grassroots providers were to village clinics, most of which are private.

Arguably more important than ownership per se is the structure of governance (who appoints the managers, whether there is a board, how the hospital interacts with the local health department and other agencies of the municipal government), as well as the incentives of the hospital's payment system and regulatory environment. For example, a "purchaser-provider split" (or in China, "separation reform") can be key in differentiating the roles of government agencies as regulatory bodies versus owner/managers of local government hospitals. These reforms can be viewed as an important constituent component of China's overall reforms of public service units (PSUs) and state-owned enterprises (SOEs). Several cities have established hospital management oganizations as separate units from the department of health. These non-profit corporate entities contract with the health bureau for hospital services. Shanghai's reforms along these lines were pioneering; Beijing and several other cities (e.g. Suzhou and Wuxi in Jiangsu province; Weifang in Shandong province; Chengdu in Sichuan province) have adopted variants of these governance reforms for public hospitals. Whether these reforms will succeed in their professed aims without unintended effects has yet to be determined, although some early evidence seems encouraging (Liu and Ke et al. 2014).

Regarding the role of the state, government investment in prevention and population health services is critical, as well as regulation of qualifications of primary care providers so that patients have confidence in the quality of their services. Primary care needs aligned incentives to be the quality foundation for a health system, especially with population ageing and need for cost-effective management of patients with chronic disease.

Although ownership form has not been found to be the primary determinant of health provider performance, there is some evidence of more alacrity among private providers in responding to incentives (for good and ill), and of a more severe "soft budget constraint" (Kornai 1986)

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centers, community health stations, sub-district health centers, village clinics, freestanding outpatient departments, and other clinics.

[10] See the National Health and Family Planning Commission website for current statistics, such as http://www.nhfpc.gov.cn/mohwsbwstjxxzx/s7967/201312/b9d67fd3299241ed990084ad5acc11e8.shtml.

phenomenon among government-owned providers.[11] There can be benefits of contracting with public and private providers on an equal basis, if outputs and outcomes can be clearly defined and evaluated.

- Kan bing nan, kan bing gui *(inaccessible and unaffordable healthcare) is one of the top concerns of ordinary Chinese. Which groups are most affected? If this is a global problem, what lessons can we learn from China?*

The ubiquitous slogan "*kan bing nan, kan bing gui*" (getting health care is difficult and expensive) captures the average Chinese patient's concern about access to appropriate and high-quality care. Indeed, surveys consistently shows that this "*kan bing nan, kan bing gui*" problem is one of the top concerns of ordinary Chinese. Alongside issues of affordable housing and education, healthcare is one of the contributors to China's high savings rate, and families rely on "precautionary savings" to allay the concerns that they may be only one major hospitalization away from illness-induced poverty. The most affected groups are the poor (with the least cushion from catastrophic medical spending and the highest risk of foregoing medical care recommended by medical professionals because of affordability), as well as the rural population and the large "floating" population of migrant workers. Their social benefits are least generous, albeit improving, over time, and thus they are most vulnerable to the uncertainties from loss of health and livelihood, compounded by large out-of-pocket payments for medical treatment.

Before the 1980s, universal affordable basic health care had been provided in rural areas by the Cooperative Medical System (CMS), a government insurance scheme for government employees and teachers. In urban areas, employees and their dependents received their health care through firm-based schemes. CMS covered 90 percent of the rural population in the late 1970s (Yip and Hsiao 2008). As a result of rural economic reform in 1979, CMS disappeared, and 90 percent of peasants suddenly became uninsured. In urban areas, a social health insurance scheme financed by employer and employee contributions replaced the previous government and worker schemes, but only formal employees, not their dependents or migrant workers, were eligible (Yip and Hsiao 2008; Eggleston 2008). In 2006, only 27 percent of urban residents received coverage under the scheme (Ministry of Labor and Social Security 2007).

Under this system, the average cost of a single inpatient episode represented 60 percent of

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[11] In "Soft Budget Constraints in China: Evidence from the Guangdong Hospital Industry," Eggleston and co-authors ask a simple question, using data on about 300 hospitals in southern China over the early 2000s: Are hospitals that were struggling financially in previous years more likely to receive government financial support in subsequent years? Yes, according their analysis: controlling for hospital size, ownership, and other factors, the probability of receiving government financial support is inversely associated with the hospital's previous net revenue. This is consistent with soft budget constraints. However since the sample is not nationally representative and is now dated, given the rapid pace of change in China, further studies of this nature are warranted. In the future it would be important to examine not only the extent of hardness/softness of hospital budget constraints, but also the impact on how hospitals operate and the outcomes for their patients.

annual household per capita consumption (Wagstaff and Lindelow 2008). According to one study, health care expenditures in the early years of the 21st century led to the impoverishment of 5.2 percent of China's households, or 67.5 million people, disproportionately in rural areas (Evans and Xu 2008). Out-of-pocket payments have been common even for preventive public health services (Wagstaff and Lindelow 2008).

The structure of China's health expenditures has changed significantly since dawn of the 21st century and introduction of government-subsidized social health insurance programs. Patients' out-of-pocket spending peaked in 2001 at 60 percent of total health expenditures in China, subsequently declining to 34.9 percent of health spending by 2011 (2012 Health Statistical Yearbook). The ratio of urban to rural per capita health expenditures decreased from 4.09 in 1990 to 3.09 in 2011. Nevertheless, that urban residents spend more than 3 times what rural residents spend on health care represents a large disparity, as large if not larger than that of urban and rural incomes (depending on how incomes are measured).

To gain an understanding of the *Kan Bing gui* (unaffordable healthcare) problem, consider the average spending for an inpatient admission in China was 4733.5 RMB yuan in 2007, rising to 6632.2 RMB yuan in 2011 (according to the China Health Statistical Yearbook 2012). Such a hospitalization represented 32% of average urban income, and 82% of average rural income, in 2007. By 2011, an average hospitalization represented 28% of urban and 67% of rural average per capita income. Even with part of those expenditures now covered by health insurance, these figures illustrate the large risk that households still face regarding medical spending in China. Compare these figures to the US, where in 2010 the average hospitalization cost of about $9700 represented 24% of average per capita personal income, and insurance would cover a larger share of that hospitalization expense for the average household. Further strengthening of quality, and encouraging greater access through deeper health insurance coverage, would increase healthcare expenditures further in China, highlighting the importance of simultaneous efforts to control cost.

To a certain extent, of course, "*kan bing nan, kan bing gui*" (inaccessible and unaffordable healthcare) is a global problem. The remarkable capabilities of medicine and new technologies to improve quality of life and extend life come with an increasing price tag. Most economies are struggling to make quality care accessible with sustainable financing. And China's challenge in this regard is especially daunting because of the large population, the dramatic regional disparities, and the rising expectations of a generation that has only known rapid economic growth and improving living standards.

China's success in reaching almost universal health insurance coverage at a relatively low per capita income level does have lessons for many developing and middle-income countries attempting to achieve financially sustainable universal coverage. But as the Chinese authorities themselves acknowledge, basic coverage is only the beginning of a long process, an incremental achievement along the way to an accessible and affordable health system that meets the reasonable expectations of China's population.
Strengthening the risk pooling of health insurance, filling in the remaining gaps in coverage for selected groups and catastrophic diseases, and reforming healthcare delivery to improve "value for money" will all be critical. And health sector reform in turn can be a critical link as

China rebalances its economy toward greater domestic consumption, reducing precautionary savings and investing in the human capital needed for China to avoid a "middle income trap" and continue robust if more moderate economic growth.

As I have argued elsewhere (Eggleston 2013), China's health system challenges need to be understood against the global backdrop of medical technology innovation and the difficult social trade-offs implied by China's current stage of economic development. The ultimate success or failure of China's health system reform process lies not with the broad outlines of reform, as important as those are. Rather, "the devil is in the details," especially regarding governance and incentive structures. To truly resolve the *kan bing nan, kan bing gui* problem, policymakers must pay close attention to payment incentives (including provider reliance on drug dispensing revenue, or *yi yao yang yi*), quality assurance, efficient insurance management, accountability, patient satisfaction, and responsiveness.

Increasing government financing and achieving risk pooling on a national scale, while tremendously important and laudable, are only half of the solution. Without reform of the payment and delivery system, the financing reforms will not be sustainable. Patients' ability to pay out of pocket put some demand-side constraints on the system, but as insurance coverage expands, those constraints will loosen. The difficult task of constraining health expenditures will then fall to the organized payers: social insurance schemes and policymakers allocating tax financing.

The rhetoric in China tends to oversimplify and sometimes directly blame providers for exploiting asymmetric information to manipulate patients and thus inflate health-care expenditures. Just as it is wrong to say that providers are immune to economic incentives, it is equally misleading to allege that supplier-induced demand is the only factor driving healthcare spending increases. China's access problems extend beyond the greed, incompetence, or malfeasance of some "bad apples"; analysts' and patients' ire would be better focused on system-wide incentive problems, though these are not easy to capture in media sound bites or policy statements.

- *The pharmaceuticals industry features in China's Medium and Long-Term Plan for Science and Technology (2006-2020), as well as in more recent measures to promote indigenous innovation and industrial upgrading. Is it fair to say that the Chinese government is prioritizing domestic pharmaceutical companies, which foster economic growth, over the welfare of patients?*

It might be fair to say that some agencies within the Chinese government prioritize domestic pharmaceutical companies' development to foster economic growth and innovation, while other agencies within the Chinese government prioritize the welfare of patients and access to pharmaceuticals. But whether policies to date and going forward unambiguously favor one over the other is not as clear. Indeed, the development of affordable domestically-produced generic medications is not contradictory to the goal of improving patient welfare, and the tensions inherent in that relationship can been managed in many economies (including our own) with patent protection and pricing rules.

There is a perennial balancing act of providing access to medications and incentives for innovation. At a given point in time, it is efficient and equitable to provide access to therapeutically beneficial drugs to all patients for whom the benefit exceeds the low user-specific marginal cost. But maximizing access in this way is also myopic. Over time, it is efficient (and, many would argue, equitable) to invest in innovations that bring benefits to patients in the future. Indeed, without past innovation, there would be no current access. The dilemma arises because promoting innovation—dynamic efficiency—requires a price high enough to cover the joint sunk costs of R&D and some return on investment, whereas promoting access—static efficiency—requires a price low enough to cover only user-specific marginal costs. No pricing policy can achieve both goals simultaneously.
This access-versus-innovation dilemma is not an equity-versus-efficiency trade-off, even though some observers frame it as such. In fact, one can argue that promoting access is efficient and promoting innovation is equitable.

Fostering indigenous innovation and industrial upgrading in China can have benefits for patients in the long run if the short-term trade-offs are acknowledged and the welfare of China's poorest patients is kept to the fore in China's overall policymaking. The trade-off is not the same as the global one of access versus innovation, because it is focused on the industry structure and domestic versus multinational market share for a given innovation, rather than overall incentives for innovation per se. Just as India's generic pharmaceutical industry has helped with global access to drugs for the developing world – but has not solved the challenges of access for all of India's own poor – so too can appropriate development of China's pharmaceutical industry contribute to better access. Certainly it is myopic to push prices so low that the quality of medications suffers, and some innovations in China based on traditional Chinese medicine—such as artemisinin-based combination therapy for the treatment of *P. falciparum* malaria—have made significant contributions to Chinese and global health.

- *What were the major successes and failures of the 2009 healthcare reforms? How have those reforms been supplemented by more recent measures (e.g. last November's Third Plenum)?*

The 2009 healthcare reforms

The five articulated goals for China's national health reforms during 2009-2011 were extending basic health insurance coverage to 90% of the population, expanding the public health service benefit package, strengthening primary care, implementing an essential drug list for all grass-roots service providers (including separation of prescribing from dispensing in primary care), and piloting reforms of government-owned hospitals.

Patients' financial burden, in terms of out-of-pocket spending as a share of total health expenditures, increased significantly to a peak of 60% in 2001. The government emphatically reasserted its role in the health sector with government-subsidized basic health insurance in

rural areas (the New Cooperative Medical Scheme, NCMS) starting in 2002/03, the government subsidized urban non-employee insurance program (Urban Residents Basic Medical Insurance, URBMI) starting in 2007, and further national health reforms announced in 2009. These voluntary government-subsidized programs of NCMS and URBMI have lower premiums and less generous benefit packages than the mandatory and longer-standing insurance programs for urban employees and government workers. China has expanded risk pooling through "wide but shallow coverage" that is gradually deepened over time to achieve universal coverage with a more robust benefit package.

One of the major successes for the 2009 healthcare reforms was to provide basic health insurance coverage to more than 800 million people. Other aspects of the 2009 reforms, especially the initiatives to strengthen government financing of population health and primary care, have made significant strides. Probably the least successful reforms, and hence the current focus on the next phase of reforms, was the effort to reform the governance of public hospitals.

It is worth noting that China's remarkable progress with health insurance expansion since 2003 may have been spurred by the SARS crisis, and these reform successes came at a time when many China analysts agree that there was a lack of meaningful deepening of overall economic reforms. China has also announced that a general practitioner (GP) system will be implemented throughout China by 2020. Policies aim to improve GP capabilities in clinical practice, standardize criteria for training, and create strict requirements for licensure and certification. The plan calls for two or three GPs in practice for every 10,000 urban and rural residents. The government will provide subsidies to GPs who are willing to work in remote areas in the central and western parts of the country. The initiative also envisions enabling local residents to establish stable contract-based ties with GPs to receive appropriate and coordinated services.

China has achieved wide, shallow coverage, and is proceeding to deepen coverage while putting in places additional mechanisms to try to assure that the additional health spending achieves "value for money spent," including improvements in personnel training, provider organization governance, clinical service delivery, payment and contracting, and population health services.

China's 2009 health reforms recognize the need to improve incentives throughout the health care system (Yip et al. 2013). For example, a key component of plans to strengthen primary care is improving the performance appraisal system for health workers, starting with government-owned primary care organizations. Furthermore, authorities have urged experimentation with case-based payment methods for inpatient services, focusing on medical conditions that have clearly defined clinical pathways and health outcomes.
Some of the government documents explicitly mention the problems arising in pilot implementation, calling for better supervision and oversight [for example]: "health service providers cannot turn away [refuse to treat] high-cost patients, or without cause reduce length of stay or split treatment across multiple admissions."[12] Clearly, at least some providers have

[12] See http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohbgt/s7692/201104/51217.htm.

responded to the incentives of case payment in the pilots by actively selecting profitable patients, discharging "quicker and sicker," and/or discharging and re-admitting patients so that they can bill for multiple admissions within the fixed case payment ceiling per admission.[13] Although complicated, these problems are not insurmountable, and as implementation experience accumulates, the necessary regulatory context will gradually lay the foundation for mixed provider payment methods to spur better quality care with greater efficiency. Careful evaluation of China's few experiments with pay-for-performance would also make a contribution to making the health system sustainably affordable while still promoting improved quality of care.

The Essential Medications List (EML) policy and prescribing incentives

Physician dispensing and provider reliance on revenue from drug sales have deep historical and cultural roots in East Asia.[14] Supporting hospitals through drug sales (*yi yao yang yi*) has been widely recognized as a problem in China, decried by the former Minister of Health, and was the explicit target of the EML policy reforms. Since at least the 1950s, China's health care providers receive between 15% (the official mark-up) and 40% or more of the retail price of pharmaceuticals that they directly dispense to patients. These margins became significant determinants of provider behavior when prospective budgets declined under the 1980s and health care providers had to earn profits to remain operational.

China's EML policy includes several components.[15] First, the policy required government-owned primary care organizations to implement a zero mark-up policy for dispensing drugs to their patients, and they were proscribed from dispensing drugs not included in the EML. Most local governments allowed providers a transition period in which they could continue to dispense non-EML drugs and retain some drug dispensing revenue.

Second, EML policies required more generous insurance coverage for EML drugs than non-EML drugs. This component of EML involves changing the benefit package of social insurance.

Third, the national EML policy implemented in March 2010 set guiding retail prices and called for provincial-level bidding for medications listed in the national essential medications list.[16] These supply-side reforms may have reduced the price of EML drugs through changing

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[13] See http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohbgt/s7692/201104/51217.htm.

[14] Eggleston (2011) develops a model predicting physician-dispensing prevailed until the perceived social cost from supplier-induced demand outweighed the benefits of the previous self-reinforcing equilibrium, inspiring search for ways to change provider incentives, as embodied in the current EML policy and public hospital reform. The proposition predicts that China will adopt more rigorous separation policies as it commits to universal coverage and (gradually) replaces demand-side constraints with supply-side constraints on spending.

[15] This section draws extensively from Chen and Eggleston (2014).

[16] Provinces could add medications to their own province-specific EML, if they also provide subsidies to compensate provincial government-owned primary care providers for those additional lost revenues. On average provinces supplemented the 307 medications on the national EML with 207 additional medications (Tian, Song, and Zhang 2012).

the industrial organization of the drug market.

Statements by China's officials praise EML as helping to control spending, enhance access, reduce over-prescribing and thereby improve quality of care.[17] However, the health economics evidence is mixed. Several studies showed that instead of increasing utilization in primary care, after EML many patients with more complicated conditions were referred to higher-level providers (Yang et. al., 2012; Wang et. al., 2012; Ye et. al. 2011). Patients may also self-refer to hospitals if they perceive EML medications to be inferior quality (Sun et. al., 2011). Whether from provider selective referral or patient self-referral, utilization at primary care providers in many cases appears to have decreased (Li et. al., 2012), while the number of inpatients in county hospitals and higher-level hospitals increased (in Anhui, by 18% on average; Sun et. al., 2012).
Similarly, Tian and colleagues (2012) suggested that after EML implementation, more patients received care at hospitals and spending per visit continued to increase, albeit with some moderation in the out-of-pocket share of per-visit spending. The evidence is limited by several weaknesses of previous study designs, and ongoing study of the EML policy implementation will help to clarify its relative benefits and correct disadvantages of the policy design. While overall the goal of removing profits from drug dispensing is laudable, it is far from clear that the EML has successfully accomplished this goal, and it remains unclear how prescribing incentives for China's largest drug dispensers, hospital- based physicians, will be reformed. Perhaps the most promising approach is through broader provider payment reform (such as toward clinical-pathway case-based payments combined with appropriate quality bonuses and evaluation structures).

More recent reform measures

The most recent measures call for pushing ahead with the reforms previously articulated, to strengthen the parts of the system (such as social health insurance coverage) that have worked well and to further improve the parts of the system (such as quality and "value for money") that are fundamental to reaching China's goal of a truly equitable and efficient basic healthcare system by 2020. It is too early to say which of the many initiatives mentioned—from enhancing access for private providers and promoting long-term care services for the elderly, to consolidating the essential medications list system and strengthening effectiveness of government regulatory oversight—will thrive, capturing the attention of central and local officials and defining the next phase of China's health sector reforms. But there are reasons for cautious optimism.

Recent policy statements reveal considerable continuity with earlier-announced reforms, with an injected sense of urgency given the overall reform milieu. An NDRC policy statement released in October 2013 called for more involvement of the private sector in health and long-

[17] For example, Minister of Health Chen Zhu stated in a 2012 interview that EML policies clearly reduce people's burden of drug costs, and that prescriptions for antibiotics, stimulants, and intravenous infusions as a percentage of total expenses for outpatient and inpatient care have all declined in varying degrees (Cheng 2012, p.2538 and p.2539).

term care services, and explicitly set a goal for increased spending on the health and long-term care industry in China. General Secretary of the Communist Party of China (CPC) Central Committee Xi Jinping, in his address to the third Plenary Session of the 18th CPC Central Committee in November 2013, emphasized that "reforms must be accelerated in the social sector including education, employment, income distribution, social security and public health." The Report on China's economic, social development plan adopted on March 13 by the 12th National People's Congress[18] emphasizes that the government launched "a pilot program of insurance against major diseases for rural and non-working urban residents in 28 provinces, autonomous regions and municipalities directly under the central government, and carried out trials on comprehensive reform in over 1,000 county-level public hospitals"; that "the social security system will be improved" and "basic public services will be made more equally available"; that the government "will expand the comprehensive trial reform of public hospitals, and consolidate and improve the system of using basic medicines and the new operating mechanisms of community-level medical and health care institutions" as well as expand "trials to comprehensively reform services for the elderly"; and that the government "will move faster to open banking, education, culture, medical care and other services to foreign investment in an orderly way."

Emphasizing improvement in rural drinking water quality, especially to provide safe drinking water to all rural residents in the next 2 years – as mentioned in the government work report by Li Keqiang in the section on agriculture – may have just as large if not a larger impact on rural health than any of the health-sector-specific initiatives. Similarly, the targets mentioned in the section on "effectively promote ecological advancement," such as making polluters accountable for the pollution and environmental damage that they cause, may have significant positive impact on health if effectively enforced.

The National Health and Family Planning Commission meeting reviewing the "*Liang Hui*" results in March 2014 emphasized (1) assurance of high-level policy support for continuing health reforms; (2) reform of government-owned hospitals as a top priority, expanding the pilot reforms of county-level hospitals to 1000 counties nationwide; (3) strengthening the EML and "new operations of the grassroots providers" reforms, having to do with removal of drug dispensing revenues, as well as improvements in incentive and evaluation structures for health care personnel; (4) raising the government subsidy for NCMS to 320 RMB per capita per year; (5) increasing the per capita government subsidy for population health to 35 RMB per year; and (6) seeking to improve patient- physician relations through a better process for dispute resolution and medical malpractice.

Interestingly, these statements to not emphasize insurance program mergers or enlarging risk pools, although some provinces have announced plans to merge the city-level non- employed (URBMI) and rural (NCMS) health insurance systems. In Shandong province, for example[19],

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[18] http://www.china.org.cn/china/2014-03/15/content_31797508.htm
Downloaded 17 March 2014.

[19] See http://sd.sina.com.cn/news/s/2014-02-15/091356848.html and http://www.zgylbx.com/nqocejwhnew60352_1/; accessed 24 March 2014.

integration will take place by municipality, thus starting to aggregate the health insurance system across urban and rural areas by at first equalizing benefits across urban and rural areas of the same sub-provincial administrative region. A guiding principle is that insurance benefits for the urban (non-employed) residents should not decrease – so reforms may entail a significant increase for rural areas for some regions. During the transition, residents may choose between 2 or 3 different benefit levels with different premium contribution rates (although with similar proportions of government subsidy), so that rural residents may still choose the lower coverage if so desired.

Whether any urban residents would choose the lower level – and whether that option may encourage migrant workers to enroll and gain coverage whether in urban or rural areas – is not yet clear, especially since the unification so far is only in a given sub-provincial level, and many urban-rural migrants migrate further away, including across provinces.

Such initiatives may signal the way for later unification of health insurance risk pools at the prefecture and provincial level, which would significantly streamline administration and raise the level of risk pooling to spread medical risk across much larger populations Eventually, China may merge employee and non-employee insurance at the municipal level, but that will be even more challenging since the employee insurance plans typically are far more generous and in principle are compulsory, whereas enrolment in NCMS and urban resident's insurance is voluntary.

There are at least two large challenges for China's health system ahead: reforming the distorted incentives structure of health service delivery (as mentioned several times above); and addressing the disparities of access and life opportunity that lead to wide gaps in health and longevity between the advantaged and the disadvantaged. According to analysis of the 2000 census of China, college-educated Chinese in year 2000 could expect to live 12.5 years longer than Chinese with no formal schooling (Li et al. 2004). Cai (2009) analyzes disparities in life expectancy across counties in China, using county- level lifetables that he carefully estimated from 2000 census data (Cai 2005). He finds that the average years of schooling in a county is one of the strongest correlates of life expectancy, controlling for demographic differences, GDP per capita and other factors. A one standard deviation increase in average years of schooling is associated with an increase of 0.38 standard deviations—about 1.4 years—in life expectancy (Cai 2009, p.146). Analyzing recent large and nationally representative data, Chen, Eggleston and Zhou (2014) find that China exhibits a significant educational gradient in health and survival. Although these are correlations, not causal impacts of education on health, the estimates point to the double disadvantage of those with low education, and suggest synergies in policies that foster both aspects of human capital.

There are also risks of stagnation and crisis. Perhaps most plausible is the possibility of crowding-out policymakers' attention with the initiatives in other areas of social services and broader economic reforms, leaving the health sector to putter along with smaller innovations and failing to address key underlying distortions – until, perhaps, another public health crisis brings those weaknesses too much to attention to be ignored.

However, I think cautious optimism is warranted. Broader reforms of the economy – especially the balancing toward greater domestic consumption as a driver of sustainable economic growth – will contribute fundamentally to improving the socioeconomic basis and

policy context for China's health sector, and may help to lay the foundation for reaching true universal coverage. With renewed effort toward reforms, China's health sector may host greater experimentation and systematic evaluation of different reform approaches. If taking place under a uniform basic safety net and access to basic population health services, local experimentation can avoid "one size fits all" policies that dampen prospects for delivery and financing innovations to improve quality at a reasonable cost.

Finally, reforms in the health sector are inter-related with other reforms in China's safety net, social protection, and strategy of economic growth. Improved health insurance can reduce precautionary savings and contribute to domestic consumption as a driver of economic growth. Improvement in pensions—such as the recent announcement of consolidation of rural and urban basic pension systems—can impact household decisions about health care use for the elderly as well as trickle down to enhance the welfare of the middle-aged and younger generations. For example, in a recent study on the intergenerational impact of China's new rural pension program using a fuzzy regression discontinuity design, Eggleston, Sun and Zhan (2014) find that China's new rural pension program enhances confidence in healthcare access, and promotes migration of labor and off-farm employment in this rapidly aging and urbanizing society. Pension-eligible elderly are more confident that they will be able to be hospitalized if recommended by a doctor, even though self-assessed health and health insurance coverage do not change at the pension-eligible age threshold.

- *What aspects of China's healthcare reform should the U.S. government and U.S. companies pay most attention to? Are there any recommendations you would make to Congress?*

That the USCC takes the time and effort to understand the background of China's tremendous health system challenges is itself a sign of giving appropriate attention to critical issues facing China's development, with implications that spill over to the region and to the world. While many specific issues require greater study before specific policy recommendations can be made with an ample evidence base, there are several arenas where the U.S. government and U.S. companies can play a positive role in enhancing the well-being of those on both sides of the Pacific.

One small but important example comes from the U.S. National Institutes of Health support of new data collection in China, the pioneering China Health and Retirement Longitudinal Study (CHARLS). The NIH support sends a clear signal about evidence- based policymaking and transparency in the collection and sharing of data. This new nationally representative dataset is not only harmonized with similar datasets around the world based on the seminal Health and Retirement Study in the US; the CHARLS data is also setting a new example in China for public release of de-identified data so that researchers need not have close *guanxi* connects to access data, as has been the standard in China to date for most other large and current datasets.

We can also demonstrate the value we place on rigorous ethical review of proposed studies of health interventions and patient privacy issues, as for drug and medical device clinical trials.

In a similar spirit, U.S. companies doing business in China should be open and transparent in their business dealings. There are remarkable opportunities for bringing quality care to China's growing middle class, especially at the nexus of health care and long-term care to serve China's burgeoning number of elderly. U.S. government policies and U.S. companies might demonstrate through their actions that private sector involvement in the health sector can bring benefits to the poor, not merely target the wealthiest segment of the market. And firms should be open to working with government agencies to help shape appropriate regulatory structures, while firms experiment in arenas with currently murky regulation (such as home healthcare).

In another example, on a topic that will be covered in more detail in the subsequent panels at today's hearing, Michael Santoro and Caitlin Liu (2009) examine the complexity and ineffectiveness of drug regulation in China. After discussing recent reforms in drug regulatory structure and evaluating their likely impact, the authors conclude that both China's regulatory system and the current bilateral efforts between China and the United States to provide further regulation may be inadequate to assure drug safety and quality. Santoro and Liu propose reforms to make the pharmaceutical supply chain more transparent, hold responsible parties accountable, and improve safety for global consumers. Both Chinese and U.S. citizens will benefit from efforts to enhance the supply chain of pharmaceuticals in China and avert public health threats from unsafe ingredients.

Thank you for the opportunity to testify today.

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OPENING STATEMENT OF DR. YANZHONG HUANG
SENIOR FELLOW FOR GLOBAL HEALTH POLICY, COUNCIL ON FOREIGN RELATIONS

DR. HUANG: Thank you, Chairman Shea and Vice Chairman Reinsch, and other Commissioners, for inviting me here to talk about China's healthcare sector.

And speaking of China's healthcare, we often talk about terms like cooperative medical care system, "barefoot doctors," three-tiered healthcare system. These were the essential components of the Maoist health system, and this system despite its problems actually contributed to the tremendous improvements in Chinese health status.

Between 1949 and 1975, the average life expectancy increased from 35 years to 65. And if you compare that to the post-Mao era, the average life expectancy rose by 6.9 years between 1981 and 2010. So almost 80 percent of the improvement in the people's health status since 1949 was achieved in the Maoist era.

And there are some other problems we observed in the post-Mao healthcare transition. One is expanding urban/rural gap. By 2004, for example, nearly 80 percent of the government health spending went to urban healthcare institutions, and the government financial support of the health sector also dropped.

Indeed, we found that the government spending as a percentage of total health expenditure dropped precipitously in the post-Mao era from 39 percent in 1986 to 16 percent in 2002. Compare that with the United States, the public spending as a percentage of total health expenditure was between 45 to 56 percent.

So these problems ultimately prompted the government to launch a new round of healthcare reform in 2009. The government so far has spent $371 billion to fix the healthcare sector.

The healthcare reform generated demands for more and better healthcare, and it also expanded the coverage to 95 percent according to the official statistics, but in the meantime, we also found that reform has not been successful in addressing the problem of access and affordability, the two essential objectives of the new healthcare reform.

According to a survey released by an independent consultancy group in October 2013, Chinese people continue to have difficulty in accessing healthcare. 50 percent of the responders actually said that it was becoming more difficult than it was four years earlier to see a doctor.

And on the affordability front, 95 percent of the responders noted that it was expensive to seek care, with 87 percent saying the cost was higher than it was four years earlier.

So why and how did this well-intended healthcare reform go awry? There are several reasons I could point out. First of all, only one-third of the government investment went to the demand side, I mean the patients. The irony is that even though two-thirds of investment went to the supply side, the healthcare providers, the government contributes less than

ten percent of the revenue of public hospitals.

So as a result, the overall benefit level of the health insurance remains quite low. For example, the insurance plan does not cover dental care; does not cover most of the effective medicines for treating non-communicable diseases; the majority of the migrant workers are not covered.And the government investment is unable to leverage the behavior of public hospitals.

And secondly, the Essential Drug List with zero mark-up is only implemented at the township level. So public hospitals at or above county levels are still allowed to sell drugs with 15 to 25 percent profit margin. As a result, 45 percent of the total hospital revenues are still collected from selling drugs.

And total healthcare costs continue to increase at an annual percentage of ten percent.

And third, demand for services of the grassroots healthcare institutions remains very weak despite the billions of dollars invested by the government.

And finally, significant progress has not been observed in reforming the public hospitals. That was widely conceived as sine qua non of the healthcare reform. In fact, a recent speech by the former Minister of Health admitted there is basically no significant progress being made on that front.

So in terms of the Chinese healthcare reform, and the implications for U.S.-China relations, I think Chinese healthcare reform would generate opportunities for the private and overseas investment given the released demand for more and better healthcare.

We know that China is the world's third-largest pharmaceutical market, poised to become the second-largest by 2015. China’s health spending is projected to almost triple to $900 billion by 2020. Given the U.S. advantages in pharmaceutical R&D, as well as in healthcare management, and service quality, Chinese healthcare reform would mean tremendous business opportunities for U.S. biopharmaceutical firms, hospital groups, and insurance companies.

But in the long-run when Chinese government places more emphasis on cost control, and also given the movement toward more affordable and quality healthcare, we would expect that in the long-run, the U.S. and China are going to have growing disputes over issues such as market access, technology transfer, and compulsory licensing.

Thank you.

VICE CHAIRMAN REINSCH: Thank you.

Ms. Boynton.

PREPARED STATEMENT OF DR. YANZHONG HUANG
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Health-care Provision and Health-care Reform in Post-Mao China

Prepared statement by
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Before the
U.S.-China Economic and Security Review Commission
2nd Session, 113th Congress

Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical

Background

Throughout much of China's history, health care was seen largely as an individual responsibility, not a right. The attempts by Mao's regime to build a system of state-sponsored health care thus marked an important departure from the historical norm. The early 1950s saw the establishment of health insurance plans for government officials and state workers and the construction of state-owned hospitals and clinics at the county and district levels. By 1959, China had built a three-tiered health care system consisting of county hospitals, commune health-care centers, and brigade (village) clinics. This system delivered not only medical treatment, but also preventive care.

During the Cultural Revolution (1966-76), an unprecedented number of health personnel were sent to the countryside. "Barefoot doctors,"farmers who were given informal medical training, became popular to treat common illnesses and promote preventive health care. At the same time, a community-based health insurance scheme called cooperative medical care also spread rapidly.

By 1976, China had more doctors, nurses, and hospital beds than virtually any other country at its level of economic development, and as a result, the general health of the Chinese people improved remarkably. Between 1949 and 1975, the average life expectancy increased from 35 years to 65 years.

The Urban-Rural Gap

Mao's death and the ensuing economic reform dramatically changed the landscape of health care in China. The demise of people's communes and the return to household farming in the early 1980s eliminated communal welfare funds, which had been the main source of financing for the Maoist rural health-care system. The number of barefoot doctors and villages implementing cooperative medical care dropped rapidly. Meanwhile, the rural economic reform increased the disposable income of peasants, who could now afford to bypass the village health-care stations or township health centers and seek medical care at urban hospitals. This development not only undermined the three-tiered referral chain in the countryside but also generated strong demand for more and better health care in cities.

When health-care institutions in the countryside started falling apart in the early 1980s, rather than take corrective action, the leaders of the Ministry of Health publicly called for their demise and promoted a policy of modernization to be implemented mostly in the cities.

As a result, the rural-urban gap in health care expanded. By the end of the Mao era, the health resources distribution actually favored rural areas in terms of the share of the hospital beds and health professionals. By the 1990s, the distribution had been reversed in the favor of urban residents; representing only 20 percent of China's population, urban areas had more than 50 percent of the country's hospital beds and health professionals. Compared with rural health units, urban health institutions have better educated health personnel as well as larger budgets for foreign or sophisticated equipment.

The growing demand for urban health-care services, coupled with the rapid urbanization—more than half of the population today live in the cities—created a vicious cycle that encouraged greater investment in the urban health-care sector. By 2004, nearly 80 percent of government health spending went to urban health-care institutions. Also, 80 percent of the urban health resources are concentrated in large hospitals, exacerbating the problem of access. Rural patients seeking inpatient care at large urban hospitals often had to wait for weeks, if not months to be assigned a hospital bed.

Governance Issues

China's miraculous economic growth is often viewed as an indication of its successful domestic governance. Yet if we use health as a yardstick for measuring governance, China's record has been far less impressive. Average life expectancy rose by only 6.9 years between 1981 and 2010, compared to the increase of 32.9 years during the pre-reform era (1949-80). Put it differently, three decades of post-Mao reform is associated with only 21 per cent of the improvement in people's health status in the six-decade history of the People's Republic of China.

Why did robust economic growth fail to translate into similar gains in the health-care sector? In my book *Governing Health in Contemporary China* (2013), I proposed that a polity shift from "bandwagoning" to "buck-passing" accounted for the content and form of health-care reform as well as the final reform outcome. Under Mao, the bandwagoning polity played a major if not the single most important role in health policy process. The concentration of political resources and the marginalzied bureaucratic role led to quick cue taking, decline in strategic concerns, and more policy coordination. As a result, Mao was able to formulate and pursue his preferred health

policy. While there were problems in the quality of services and the sustainability of the health-care institutions and programs, the unprecedented party-state intervention in health-care realm led to significant progress in reducing urban-rural gap and increasing access to health care.

Under the buck-passing polity, central party leaders, health bureaucrats, sub-national governments, even health-care units all had strong incentives to "pass the buck" – shirk their responsibilities in health-care provision. With the death of Mao, health ceased to be a sensitive political issue in elite politics. Single-minded pursuit of economic growth further marginalized public health and health care on government leaders' agenda. In consequence, the party center shook off responsibilities to formulate health policy and finance public health.

As health policy process was no longer characterized by constant and concrete involvement of the political leaders, health bureaucrats were in a more secured position to pursue their own agenda. In fact, since the Maoist health model was premised on the minimized bureaucratic involvement, it was targeted for attack by health bureaucrats purged during the Cultural Revolution and rehabilitated in the post-Mao era. Shirking its responsibility in rural health care, the Ministry of Health chose to promote the modernization of China's health sector. Fiscal and bureaucratic decentralization nevertheless made it almost impossible for the Ministry to mobilize sufficient resources to pursue its modernization agenda. This generated strong incentives for the health bureaucrats themselves to "pass the buck" – shifting the financial burden to other departments, health-care units, and users of health care.

Preoccupied by local economic growth, local governments, especially those at the grassroots level, had few incentives of earmarking significant amount of resources for health care. If there were any incentives, they were further reduced by the 1994 tax reform (in which the central government recentralized tax power while decentralized social responsibilities). Not surprisingly, government spending as a percentage of total health expenditures dropped precipitously in the post-Mao era, from 39 percent in 1986 to 16 percent in 2002.

Dwindling government support, in conjunction with market-oriented economic reform, also changed the behavior of health-care providers. Public hospitals began aggressively selling drugs and providing extra, often high-tech services in order to recoup losses caused by shrinking government support and fuel growth in revenues. Total health spending increased exponentially. And this occurred at a time when there was virtually no social safety net—the 1998 National Health Services Survey found that more than 87 percent of the rural population and more than 44 percent of urban residents had no health insurance of any kind. The cost of health care was ultimately borne by the users of health care, especially those living on the margin of the society (e.g., farmers, laid-off workers, migrant labor). By 1999, the private share of health-care spending exceeded 59 percent. In some cases, rising costs deterred the sick from seeing doctors; 60–80 percent of farmers who were seriously ill died at home because they could not afford care.

The Launch of Health-care Reform

Amid public outcry against problems of affordability and access, a new round of health-care reform was on the government agenda in 2005. Unlike the traditional pattern of decision making, which relies on bureaucratic agencies to come up with policy proposals, the government decided

to solicit reform proposals from a diverse set of actors. Indeed, except for the proposal from a government think tank, all proposals came from non-governmental, external agencies such as universities and international government agencies.

The proposals, perspectives and positions of the experts involved in drafting the reform proposals nevertheless mirror those of vested bureaucratic interests. By September 2005, two reform approaches had emerged. A pro-government approach, inspired by the British model, proposed that government invest in public hospitals to maintain their "public benefit nature" and provide public health and basic health care for free. This approach received support from the Ministry of Health, which is the owner, operator, and regulator of public hospitals. By contrast, the pro-market approach, influenced by the Bismarck model, favors reduced government direct interference in health services provision and the use of the third party to purchase health services. This approach receives support from the Ministry of Labor and Social Security, which is in charge of the administration of national labor and social security undertakings and has a strong interest in building a nationwide social health insurance system.

Since China's decision making emphasizes consensus, it is relatively easy for one involved policy actor to sabotage the adoption of important policies that it does not like. In the initial stage of the reform, the pro-government approach prevailed. Indeed, until May 2007 all the six proposals favored government dominance in the health sector. But apparently encouraged by the ministries supporting a pro-market approach, two additional proposals with different perspectives were later submitted. The crucial difference lies in whether government spending should mainly go to the "supply side" (i.e., public hospitals) or the "demand side" (i.e., the patients). While the first six proposals supported the idea of government financing of health-care providers toward establishing a free health-care system, the two new proposals emphasized the need for financing the demand side and achieving universal health coverage through the spread of social insurance. The latter two proposals were favored by the National Development and Reform Commission (NDRC), Ministry of Finance, and Ministry of Labor and Social Security. With support from powerful central ministries such as NDRC, the pro-government approach was no longer the favorite approach in the health-care reform. The pro-market approach received further support from the top level in July 2007 when the Office of the State Council issued a document endorsing the spread of social insurance in the urban areas. The pro-government approach nevertheless continued to have support from the Ministry of Health. By October 2007, there was a renewed emphasis on government intervention in the health sector. At the 17th Party Congress, President Hu Jintao reemphasized the "public benefit nature" of China's health-care undertakings, and explicated the need to "strengthen government responsibilities and investment."

The draft reform plan, completed in October 2007, reflected a compromise between the two approaches, with importance of government financing on both demand and supply sides written into the document. In part because of the influence of various interest groups, it would take an additional year to finally unveil the document to the public. In January 2009, the State Council approved the new health care reform plan.

An Assessment of the Health-care Reform

In 2009, the health-care reform was officially kicked off with an objective to provide “safe, effective, convenient and affordable” health-care services to everyone. There are five implementation priorities: health insurance coverage, public health, grassroots health-care institutions, essential drug system, and public hospitals. Between 2009 and 2012, the government invested more than $371 billion, accounting for 5.7 percent total fiscal spending. This includes more than $100 billion from the central government budget.

The immediate result of this increased government spending was expanded health insurance coverage. The percentage of people covered by health insurance surged from 30 percent in 2003 to 95 percent in 2011. As a result, the share of out-of-pocket spending dropped from 56 percent to 36 percent in that same period. The reform also generated increased demand for health care, with hospital bed utilization rate up from 36 percent to 88 percent. In addition, significant progress has been made in the equalization of the provision of public health services and improving the financial status of grassroots health-care institutions.

Yet contrary to the rosy picture portrayed by the government and some scholars, the reform has not been successful in addressing the problem of access and affordability. According to a survey released by the independent Horizon Research Consultancy Group in October 2013, Chinese people continue to have difficulty in accessing health care. About 81 percent of the survey respondents said it was difficult to see a doctor, and more than 57 percent said it was more difficult than it was four years earlier to see a doctor (compared to 20 percent who said it has become easier). On the affordability front, 95 percent of the respondents noted that it was expensive to seek care, with 87 percent saying that the cost was higher than it was four years earlier. Despite the overall increase in utilizing health-care services, access and affordability problems have suppressed demand for health care unnecessarily. Of the respondents, 27 percent said that they opted out of hospitalization, with 74 percent attributing this to the high cost of inpatient care and 41 percent attributing it to the difficulty of being assigned a hospital bed.

Why and how did the well-intended health-care reform go awry? First of all, only one-third of the government investment went to the demand side (e.g., the patients). The irony is that even though two-thirds of the investment went to the supply side (i.e., health-care providers), the government contributes less than 10 percent of the revenues of public hospitals. As a result, not only is the overall benefit level of the health insurance quite low, but the government investment is also unable to leverage the behavior of public hospitals. Second, the essential drug list, with zero mark-up, is only implemented at the township level. Public hospitals at or above county levels are still allowed to sell drugs with 15-25 percent profit margin. Not surprisingly, 45 percent of total hospital revenues are collected from selling drugs, and total health-care cost continues to increase at an annual rate of 10 percent. Third, demand for services of the grassroots health-care institutions remains weak, despite the billions of dollars invested by the government. Both outpatient visits and inpatients received by the township health centers dropped, despite the growth in total number of outpatient visits and inpatients at the national level. Finally, significant progress has not been observed in reforming the public hospitals, widely considered the sine qua non of the health-care reform. Government health departments remain the owners, general managers and regulators of public hospitals, which still provide 90 percent of outpatient and inpatient services, even though 43 percent of the hospitals nationwide are owned by non-public

entities. Among the non-public hospitals, 80 percent are controlled and owned by farmers in a small town in Fujian Province. .

China's Health-care Reform and U.S.-China Relations

China's health-care reform has generated demand for more and better health care, with opportunities for private and overseas investment. With sales of $71 billion, China is the world's third largest pharmaceutical market, and, with an annual growth rate between 15 and 20 percent (twice that of the United States), is poised to become the second largest by 2015. Health spending in China is projected to almost triple, hitting $900 billion by 2020. Given the U.S. advantage in pharmaceutical R&D as well as health-care management and service quality, China's health-care reform means tremendous business opportunities for U.S. biopharmaceutical firms, hospital groups, and insurance companies. In 2011, the top ten multinational pharmaceutical companies saw an average growth in sales of over 27 percent in China. In addition, the rapid population aging in China has also led to the growth of a new market: institution-based senior care. Currently, less than 2 percent of the senior population uses institution-based care, but more than 10 percent are willing to receive care in institutions. The number of elderly people who are able to afford senior housing will reach 22 million by 2020. In August 2013, Premier Li Keqiang convened a State Council meeting, signaling that China would relax restrictions on market entry and encourage overseas capital to invest in China's health-care industry, including senior care.

Demographic and epidemiological transitions, as well as movement toward affordable and quality health care, have also raised concerns regarding cost control. As shown in China's investigation of GlaxoSmithKline's involvement in commercial bribery last year, China's health-care reform has also led to stricter government regulation to rein in the unbridled health-care costs. This, in conjunction with population ageing and growing burden of non-communicable disease, has generated strong demand for affordable drugs and "self-developed" medicines. U.S. biopharmaceutical firms still enjoy a competitive edge in terms of size, technology, and R&D investment over their Chinese counterparts, and China still has strong incentives to create an environment attractive to foreign investment in its health-care and biopharmaceutical industry. Indeed, thus far China's protection and enforcement of pharmaceutical-related intellectual property rights has not been a major issue in Sino-American economic relations over the past decade. But China's efforts to develop a robust homegrown biopharmaceutical industry may lead to increased pressures for U.S. pharmaceutical firms doing business with China to trade market access for technology transfers. In the future, we are probably going to see growing disputes between the two countries over issues such as market access, technology transfer and compulsory licensing. U.S. pharmaceutical firms will therefore face a much tougher and more complex business environment in the years to come.

An effective strategy to engage China's health-care sector requires U.S. government to continue promoting business opportunities for U.S. biopharmaceutical firms, hospital groups, and insurance companies. In the meantime, it is also important for the U.S. government and companies to demonstrate the willingness to work with China in addressing health issues of their immediate concern, including population aging, tackling NCDs and their risk factors, and access to effective and affordable medicines.

OPENING STATEMENT OF XIAOQING LU BOYNTON
DIRECTOR, ALBRIGHT STONEBRIDGE GROUP

MS. BOYNTON: Thank you, Chairman, Vice Chairman, Commissioners. Good morning. Thank you for the opportunity to testify before you today.

I want to use my opening statement to highlight four key points. First, the healthcare reform in China takes place in a country that faces very significant health challenges, including infectious challenges as well as a growing burden of non-communicable diseases.

In recent years, China has been a major hotspot for influenza viruses. The country also has the second-highest number of TB cases in the world with a high rate of drug resistance. China also faces a large and fast-growing burden of non-communicable diseases such as cardiovascular diseases, diabetes, obesity and cancer.

It is estimated that there are 200 million hypertensive patients and 90 million patients with diabetes in China today. The World Health Organization predicted that the number of non-communicable diseases among Chinese people over age 40 will double or even triple over the next two decades. The wide range of health challenges has propelled Chinese decision-makers to look for new and efficient ways to meet the growing healthcare demand.

Secondly, China's healthcare reform has achieved some important outcomes over the past five years. Before the reform was launched in 2009, about 90 percent of rural residents and 60 percent of urban residents did not have health insurance in China. Those who were covered by some sort of health insurance had high premiums and limited coverage.

Today China provides 95 percent of its population with basic health insurance, making it the world's largest health insurance scheme in terms of population coverage. The reform was also able to reduce out-of-pocket expenses. For example, reimbursement rates for inpatient treatment expenses increased from 50 percent in 2008 to 75 percent in 2013.

The expansion of coverage and reduction of out-of-pocket expenses are critical as China attempts to build a robust social safety net in order to reduce its high savings rate and stimulate domestic consumption to grow the Chinese economy.

My third point has to do with where the reform is going after its initial stage. So despite the interim achievements, China continues to face very substantial problems in the healthcare sector. The government is committed to continuing and deepening the healthcare reform and has outlined three priorities between now and 2015.

The three priorities are the reform of public hospitals, expanding universal health coverage, and enhancing an essential drug system to provide affordable drugs.

The ongoing reform presents key opportunities and challenges

for U.S. companies. Health regulators in China are looking to expand pilot programs to separate drug prescribing and drug dispensing to reduce costs in public hospitals across the country.

The government also encourages private investment in healthcare sector to alleviate the burden on public hospitals. The growth of private hospitals in China could open space for the increased sales of U.S. innovative drugs and medical devices to meet growing demand of high-quality care, especially among affluent urban residents.

The government's focus on expanding healthcare coverage, particularly in the rural areas, means potentially new and vast healthcare market. For U.S. pharmaceutical and medical device companies, expanded healthcare coverage could prove to be an opportunity to increase exports to China. However, as China attempts to provide affordable medicines to its population, its price-focused approach in procuring essential medicines could create risks for multinational companies which compete in these markets.

Lastly, I want to point out that China's healthcare reform is unfolding at a time when the top leadership has launched a nationwide anti-corruption campaign, which is an important initiative used to consolidate central power. As the Chinese government focuses on cutting down healthcare costs and expanding access to affordable care, it has heightened the scrutiny of the healthcare sector to crackdown on corruption that has largely contributed to the rising costs of healthcare.

Since 2013, a handful of multinational pharmaceutical companies, including GSK, have been investigated by the Chinese government for their operation and pricing practices. While the investigations have put many foreign pharmaceutical companies in the spotlight, they are not exclusively anti-foreign.

A number of domestic companies were also targeted in the anti-corruption drive. Most prominently, Sinopharm, which is China's largest state-owned China drug distributor. The investigations in the healthcare sector have served the reform goals very well in that they have ultimately helped cut down the prices of medical products, which are considered critical to stimulate domestic consumption.

To cite an example, following the highly public scandal, GSK announced last year it would lower the prices of its products in the China market. The heightened scrutiny in sensitive industries, including the healthcare industry, is likely to continue and will certainly make the Chinese healthcare market more complex for multinational companies to navigate.

I will stop here and I'm happy to answer follow-up questions. Thank you very much.

PREPARED STATEMENT OF XIAOQING LU BOYNTON
DIRECTOR, ALBRIGHT STONEBRIDGE GROUP

Xiaoqing Lu Boynton
Director, Albright Stonebridge Group

Testimony before the U.S.-China Economic and Security Review Commission
April 3, 2014

Hearing on China's Healthcare Sector, Drug Safety,
and the U.S.-China Trade in Medical Products

Chairman Shea, Vice-Chairman Reinsch, and other distinguished members of the Commission, good morning. Thank you for inviting me to testify before you today. My name is Xiaoqing Lu Boynton, and I am a director at the Albright Stonebridge Group, a global strategy company, although the testimony today solely reflects my personal opinions.

I understand the Commission is interested in the latest developments in China's healthcare sector and their implications for drug safety and the U.S.-China medical trade. Healthcare sector in China today is indeed undergoing significant changes. In April 2009, the Chinese government unveiled its ambitious plan to overhaul the country's healthcare system with a goal to achieve universal healthcare by 2020. The government also announced an allocation of $125 billion between 2009 and 2011 to invest in the massive healthcare reform that has since been underway. After a successful initial three years of reform and experiment, the Chinese leadership pledged in 2012 to continue its effort to deepen the healthcare reform over the coming years. In particular, the Chinese government stated that the 12th Five Year Plan Period (2011-2015) is a critical timeframe for deepening the reform in China's healthcare sector.

The ongoing healthcare reform in China takes place in a country that has been grappling with significant health challenges in recent years, including rising infectious challenges and growing non-communicable diseases (NCDs). China is a major hotspot for influenza viruses, including the most recent outbreak of H7N9 in 2013 and the H1N1 pandemic or "swine flu" in 2009. The country also has the second highest number of tuberculosis (TB) cases in the world, accounting for 17 percent of the world's TB burden.[20] Notably, drug resistance is becoming rampant in China, where nearly 1.5 million Chinese patients have drug-resistant TB.[21] China today has approximately 780,000 people living with HIV/AIDS.[22] While the prevalence of China's HIV/AIDS epidemic remains low, there are pockets of high infection among specific sub-populations and geographic regions.[23] China also faces a large, growing burden of NCDs, such

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[20] United Nations Health Partners Group in China, *A Health Situation Assessment of the People's Republic of China* (Beijing: United Nations, 2005).
[21] "Calls for More Help in Fight against TB."
[22] *China AIDS Response Progress Report*, UNGASS, March 2012.
[23] *China 2010 UNGASS Country Progress Report (2008-2009)*, UNGASS, 2010.

as cardiovascular diseases, diabetes, obesity, and cancer. It is estimated that there are 200 million hypertensive patients and 90 million diabetes patients in China. According to the World Health Organization (WHO), NCDs currently account for about 85 percent of China's total burden of diseases and its NCD mortality rate is higher than other leading G-20 countries. The WHO predicted that the number of NCD cases among Chinese people over 40 will double or even triple over the next two decades. The wide range of health challenges that China faces has propelled Chinese decision makers to look for new, efficient ways to use resources to meet the growing healthcare demand.

In 2009 before the new reform of China's healthcare system was launched, about 90 percent of rural residents and 60 percent of urban residents in China did not have health insurance.[24] Those who are covered by some sort of health insurance were frequently confronted with high premiums and limited coverage. The lack of health insurance coverage has led to the population's strong proclivity to save for the skyrocketing out-of-pocket healthcare expenses. As Beijing attempts to stimulate domestic consumption to grow the Chinese economy, establishing a robust social safety net has become critical to the government's growth strategy.

To address China's diversifying disease burden and the government's need to drive domestic consumption, reform initiatives have focused heavily on affordability and access in the healthcare sector. The healthcare reform has achieved significant outcomes over the past five years. Today, China provides 95 percent of its population with some kind of basic health insurance, making it the world's largest health insurance scheme in terms of population coverage. Most notably, the country's 833 million rural residents, the majority of whom did not have any health insurance five years ago, are now covered by the New Rural Cooperative Medical System (NCMS). The reform was also able to reduce individuals' out-of-pocket expenses. According to the latest statistics released by the Chinese government, reimbursement rate for inpatient treatment expenses for rural and urban residents increased from 50 percent in 2008 to 75 percent in 2013. Annual per capita government subsidy for the basic health insurance schemes for rural and urban residents increased substantially from $13 in 2008 to $45 in 2013.

Despite the interim achievements, China still faces significant barriers in its effort to revamp the healthcare system. In the new phase of "deepening" the healthcare reform, the Chinese government outlined three priorities in 2012 – the reform of public hospitals, expanding universal health coverage, and enhancing the national essential drug system – with the goal to control healthcare costs and improve healthcare quality at grassroots and community levels.

In particular, continuing the reform of Chinese public hospitals remains a top priority. Due to an outdated personnel compensation system for Chinese doctors and the lack of healthcare resources over the past decades, Chinese public hospitals have been widely criticized for their heavy reliance on drug sales and diagnostic tests for profits. High mark-ups of drug prices in public hospitals have led to rising healthcare costs. To solve this problem, China's top health regulator – the National Health and Family Planning Commission – has launched pilot reforms to separate drug prescribing and dispensing and eliminate drug mark-ups in public hospitals in urban areas and at county levels. In order to meet the growing and diversifying healthcare

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[24] Vanessa Wong, "Health and Wealth," *Insight Magazine*, April 3, 2007.

demand and to alleviate the burden of public hospitals, the Chinese government also encourages private investment in the healthcare sector. The NHFPC has set a target that private hospitals should handle 20 percent of China's inpatient and outpatient volume by 2015, which is now estimated at about 11 percent and 8 percent respectively.

To address the skyrocketing drug costs, the Chinese government has also focused on developing a national essential drug list, or the EDL, which is a catalogue of 520 types of cost effective drugs issued in March 2013. (A prior version of the EDL was issued in 2009, which consisted of 307 drug types.) EDL drugs are permitted to participate in centralized tenders organized by provincial government. With the ultimate goal of reducing drug costs, the EDL tenders are highly price driven and pay little attention to drug quality. According to the Chinese statistics, EDL drug prices have declined by 25 percent on average since the establishment of the national essential drug system in 2009. However, in some provinces, the EDL tenders have led to a shortage of certain commonly used, low-priced drugs. The Chinese government has vowed to improve the price-driven system to ensure drug supply and quality in 2014.

China's healthcare reform is unfolding at a time when the top Chinese leadership has launched a nationwide anti-corruption campaign, an important initiative that the Xi Jinping/Li Keqiang administration has used to consolidate central power. Since taking office a year ago, the Xi/Li administration has used its anti-corruption drive to oust dozens of high-profile businessmen and government officials. As the healthcare reform attempts to cut down costs and expand access to affordable care, the Chinese government has heightened its scrutiny of the healthcare sector to crack down on commercial corruption, especially in public hospitals, that has largely contributed to the rising cost of healthcare. In June 2013, U.K.-based pharmaceutical company GlaxoSmithKline (GSK) was involved in a bribery scandal in China over criminal activities, including Chinese police allegation that the company paid up to $490 million to travel agencies to facilitate bribes to doctors, hospitals, and Chinese officials. A handful of other multinational pharmaceutical companies were also investigated following the GSK scandal. While the investigations in China have put many foreign pharmaceutical companies in the spotlight, they are not exclusively anti-foreign. A number of domestic pharmaceutical companies were also targeted in the corruption probes, most prominently Sinopharm – China's largest, state-owned drug distributor. However, foreign pharmaceutical companies could be easy targets due to the public belief that foreign drugs benefit from the government's pricing policies and their prices are too high. The anti-corruption investigations in the healthcare sector well serves the reform goal to rein in costs of drugs and healthcare products, which are believed to critical to stimulate domestic consumption. For instance, following the highly public scandal, GSK announced last year that it would lower the prices of its products in the China market. Given the Chinese government's commitment to cracking down on corruption, companies in sensitive industries – including pharmaceutical and medical device industries – will continue to face a heightened scrutiny of their operation and pricing practices in the near to medium term.

The ongoing healthcare reform in China presents several key opportunities and challenges to U.S. companies. The U.S. government and U.S. companies should pay attention to the following issues.

- Public hospital reform – Pilot reforms to separate drug prescribing and dispensing are expected to significantly reduce drug mark-ups. This could potentially benefit the U.S.

innovative healthcare companies as the old system favors low-cost drugs which the public hospitals could have large mark-ups. However, hospitals may still prefer lower-end products in order to control costs during the reform process. Yet, the growth of private hospitals in China could also open space for the increased sales of high-end medical devices to meet growing demand of high-quality care especially among the rising Chinese middle class.

- Expanded healthcare coverage in rural areas – The Chinese government's focus on expanding the scope and level of its basic healthcare coverage in rural areas means potentially new vast market for pharmaceutical and medical device companies. For U.S. pharmaceutical and medical device companies, expanded healthcare coverage could prove to be an opportunity to increase exports to China.

- Price-focused approach – While the Chinese market of essential drugs is substantial, it remains challenging for U.S. drug makers due to the heavily price-driven process of the EDL tenders. The government's price-focused approach could mean potential risks for multinational companies.

- Anti-corruption investigations – The heightened scrutiny of the healthcare sector, which is expected to continue in the coming months, will make the China market more complex. It is important for foreign companies to focus on its compliance efforts to minimize potential risks.

PANEL I QUESTION AND ANSWER

VICE CHAIRMAN REINSCH: Thank you.

Commissioner Fiedler.

COMMISSIONER FIEDLER: Sure. Am I right in believing that the Chinese government as part of its own policies is now better at communicating to the populace about health crises, whether it had been the previous problems with SARS and other stuff? Is that correct?

DR. HUANG: I think I could answer that question. In fact, just last week, I presented a paper at the International Studies Association on the issue of disease surveillance and risk communication.

Overall, we've seen improvement in terms of disease surveillance and risk communication. The government has invested tremendously in improving the disease surveillance and response system, and, indeed, it now has the largest disease surveillance network in the world.

It has also improved its skills in risk communication. That we found in 2009 in the H1N1 pandemic, and also in the recent H7N9 outbreak. The government basically communicated the disease situation with the public and with the international society.

That being said, we have seen lingering problems of cover-up, especially at the local level. For example, after last year's H7N9 outbreak, the Shanghai municipal CDC were able to identify a novel type of flu virus, but waited about two weeks before communicating with China CDC.

Similar problem happened in 2008 during the HFMD (the hand, foot and mouth disease) outbreak. The Anhui provincial government waited two weeks before sending the samples of the virus to the Central CDC.

There are some other problems in terms of risk communication, and that shows that in the absence of fundamental changes in state society relations or central-local capacity gap, we expect the government will continue to face such challenges.

COMMISSIONER FIEDLER: Thank you very much.

I want to ask another question about the Chinese government's action public health-wise to respond to what are probably large-scale environmental impacts on the health of people in various communities, and when I say various, I don't mean to diminish it, but rather there are plenty of places that have serious health problems as a result of environmental conditions that represent an immediate health crisis that simple reform of the system doesn't seem to me to be adequate to deal with.

I mean long-term. Obviously getting rid of the pollutants might be a better solution long-term than revising the public health system. But how do they respond to immediate crises like that?

Let me just put it into context-- recently clearly people are responding, whether it be Maoming the other day and the new chemical plant, saying we don't want it because it affects our health. That means to me that the stuff they have already got there affects their health and they don't want anymore. So there's a natural response in people to oppose this.

But that doesn't take care of their healthcare problems.

How is the environmental health problem being dealt with?

MS. BOYNTON: I'm happy to answer this question. So the government definitely is paying a lot of attention to pollution. In the annual Legislative Meeting that happened last month, Chinese Premier Li Keqiang actually officially declared war against pollution, and the pollution definitely goes beyond actually controlling the pollutants. It's also a health issue, it's a stability issue, so it's a very, very critical issue for the government.

One aspect of the healthcare reform that I didn't address in my statement is the focus on public health services. The government is increasing subsidies for public health services for individuals and it also is investing heavily on the capacity of healthcare clinics and community centers at grassroots levels, and the hope is by expanding healthcare coverage and increasing the capacity at very local levels, people with illness can have the access and have the ability to seek care.

COMMISSIONER FIEDLER: Were you going to answer?

DR. EGGLESTON: I would be happy to add to that. I concur, and certainly it's a very large and long-term challenge for China and calls for a multi-sector approach because certainly the medical care industry itself or even population health, in the way it's conventionally defined, does not include every aspect that focuses on health.

And environmental protection is particularly a salient issue when it comes to a crisis level, and it's related to stability issues so that local officials at many different levels focus on a key incident, and that leads to multi-sector response that may only address that certain event but needs to have a longer-term institutional process to look at the roots of the problem longer-term.

COMMISSIONER FIEDLER: Let me give you an example of something more concrete. So if there's a community full of copper smelters or even half of a province, I mean Shanxi Province is a coal-producing place, and Taiyuan has more pollution than a whole lot of other places. We went there.

The byproduct effects of copper smelting will produce in the population renal disease. So what does improvement of the public health system in that province mean? Are there more kidney doctors there? Is there more dialysis? What I doubt is that that is the response.

In other words, that the medical system responds to the crisis with more specialized care that is required because of the impact of the environment on those people. Other places it may be a respiratory problem where you need more lung specialists. It's not enough to say ten percent of the budgets have gone up in one province more than another. It's whether or not they're delivering the services.

That's a real stability problem in the end. They can't get enough care. There are too many people suffering from the same thing.

DR. HUANG: I think you're exactly right, that if you look at the

Chinese healthcare system, the so-called universal health coverage actually only covers the basic healthcare.

COMMISSIONER FIEDLER: Yes.

DR. HUANG: We should also, in terms of the environmental impact on health, recognize that this connection between environment and health is only a very recent phenomenon, and only very recently the government admitted that there's such a link.

And, secondly, the current health system is not yet ready to tackle the problems caused by the air pollution. We know, for example, there's a rapid rise of the cancer incidences in China. Actually 25 percent of the cancer-caused deaths are attributed to one single disease-- lung cancer.

But so far, the NCDs, or the non-communicable diseases, are not yet high on the government agenda, and the health system is not yet ready to tackle these kind of challenges as well.

COMMISSIONER FIEDLER: Thank you.

VICE CHAIRMAN REINSCH: Commissioner Shea.

CHAIRMAN SHEA: Thank you all for being here. Thank you for your very interesting testimony. I'd like to welcome Dr. Eggleston's parents to the hearing.

In the United States, there's obviously a lot of variety as to how healthcare is delivered, but the sort of typical middle income experience is that you have a primary care doctor. You go there for an annual checkup; you should, at least. If someone in the family gets sick, you know, high fever, sniffling nose, you call them. Sometimes you bring your child or yourself into the primary care doctor. The primary care doctor then sends a referral, writes a referral to a specialist.

You have the option, if things get really bad, to go to the emergency room, mostly in a private, more likely in a private hospital.

Could you just give a sense of how that compares with the typical delivery of healthcare in China, say, to a middle income urban family? Maybe tell us what the difference between that experience and those in rural communities is. Just give us a sense of how healthcare is delivered, if you don't mind. Anybody?

DR. EGGLESTON: Well, I'm sure others will add, but just to say, first of all, a lot of people in urban areas are used to going to the outpatient department of hospitals. This is not unique to China. A lot of health systems throughout East Asia are largely hospital-based systems.

In rural areas, going back, of course, to the Mao era, there's been a system that starts with the village doctor. It used to be called the "barefoot doctor," and then there's a system of referrals that the system is supposed to go through, both in urban and in rural areas, where you first go to the community health center in urban areas or village doctors in rural areas, and they're referred, if needed, to the township health center or to the county hospital in rural areas or in urban areas to a higher-level hospital.

But, of course, there are no restrictions on patients in China, and patients can self-refer directly to a specialist at a hospital in Beijing if they

can afford to pay for it, and so there's a lot of crowding at the higher-level providers because patients arguably have money and they realize that going to the local provider might get a missed diagnosis, might actually not be treated effectively.

So people that can afford it go directly to the providers with higher reputation. That's a start of talking about the delivery system in China.

CHAIRMAN SHEA: Thank you.

Pass the baton.

DR. HUANG: Yes, as Karen said, there's supposed to be a three-tiered referral chain, but that chain essentially has lost its effectiveness, due to the improvement of the transportation system, the increase in disposable income of the farmers, and the misdistribution of healthcare resources. When peasants have a health problem, their first choice is actually to go to a county hospital.

They would bypass the village clinic or township health center and go directly to the county hospital. As a result, the county hospital becomes extremely crowded, but you probably won't see that many seeking care at the township health center--

CHAIRMAN SHEA: Really.

DR. HUANG: This occurs despite the government has invested billions of dollars trying to strengthen the grassroots level health care institutions. It has also increased the reimbursement level for peasants seeking care at the township health center, but still my data suggests that that has not changed the demand/supply situation there.

MS. BOYNTON: And if I may add, I think this is a very important question. It points to several very fundamental problems in China's healthcare system. The system is very heavy on hospitals. China is a hospital market. People when they are sick, they go to hospitals.

In rural areas, like Dr. Huang mentioned, when rural residents are sick, and if they can afford it, their number one choice is to go to the largest hospital in the county or even the city near them. The result of this is over-crowdedness in large hospitals, which makes seeking care extremely difficult. I believe that the Chinese government is very serious through its reform efforts to really attract and incentivize residents in rural areas to go to their local community clinics.

There are several ways they are doing this. They are launching a number of pilot programs to test different ways to really channel the patients to the right level of care.

Several examples I can cite is they are trying to allow physicians in large hospitals to practice in local clinics by giving physician incentives to do so, and that way rural patients would have more confidence in the local clinics, and the government is also investing money and infrastructure building in community clinics to really ramp up the capacity.

CHAIRMAN SHEA: Thank you.

VICE CHAIRMAN REINSCH: Commissioner Tobin.

COMMISSIONER TOBIN: Thank you.

Mr. Chairman, will we have a second round of questions, too?

VICE CHAIRMAN REINSCH: Yes.

COMMISSIONER TOBIN: Great.

VICE CHAIRMAN REINSCH: Yes.

COMMISSIONER TOBIN: Thank you.

You've talked about the public hospitals and the crisis there. How are private hospitals doing and why do they only receive a small portion of the Chinese patients? I think it was less than ten percent, and I ask that because last year when we were in Asia, as we looked at the food supply system, we saw that in terms of getting safe food supply, many of the upper echelon and Party leaders had their own kind of private way of getting food to ensure its safety.

So can you fill us in please on the private hospital systems, whoever would like to add to that or respond to that?

DR. HUANG: Okay. Well, you correctly pointed out that so far the public hospitals still enjoy that commanding height in terms of providing the healthcare services. 90 percent of health care services is actually provided by the public hospitals even though if you look at the number of the hospitals, 43 percent of the hospitals in China actually are considered private hospitals.

The problem for those private hospitals is that they are small in size. They also, in terms of the services provided, only take care of certain diseases, like skin disease, sexually transmitted diseases. They don't seem to have the trust of the people. People would still prefer to go to public hospitals than to private hospitals.

Maybe you--

DR. EGGLESTON: I might just add that another challenge for private providers is the system for rewarding physicians. Often they have challenges in recruiting physicians partly because licensure is just to a specific hospital traditionally in China, and the incentive for career progression as well as the social benefits and so on are much greater for most physicians at the providers that have a strong reputation through the government sector.

So private providers sometimes have to step in and hire retired doctors or reach other agreements. Part of the recent reform was to allow doctors to practice in more than one place. The issue with that is that like many issues in China, there will be a national statement that that should be allowed, but then in practice, there are problems with implementation.

So the government hospital has to give agreement if its physician is going to go practice in a private hospital, but then the government hospital manager doesn't necessarily have the incentive to let their best doctors do that. So there are some complications with personnel recruitment.

COMMISSIONER TOBIN: So am I correct, and I'll let others add, too, am I correct to think that the private hospital option is a newer option that's come in at a time of the economy becoming more market based

or is that--

DR. HUANG: Yeah.

DR. EGGLESTON: Uh-huh.

COMMISSIONER TOBIN: Ms. Boynton.

MS. BOYNTON: Yes, absolutely. The government has actually openly and publicly encouraged the development of private hospitals and even private investment in public hospitals to really help with the resources and alleviate the burden.

The official target the government set for the private hospital is for them to handle 20 percent of the inpatient and outpatient volume by next year. It's very ambitious, but I think the government is providing policies to incentivize them.

COMMISSIONER TOBIN: So as we get a sense of how the private system works there, Dr. Huang, you said that specialized areas are addressed. If I was in Xi'an, and I was wealthy, would I be more apt to go to the private or the public?

DR. HUANG: Well, I think overall still, the Chinese people prefer to go to public hospitals. The reputation is certainly the big issue for the private hospitals. We know, as the official media admitted, that most of those hospitals actually are controlled by farmers, in one township, in Fujian Province, and the staff in the hospitals essentially are retired healthcare workers; some just are quacks.

COMMISSIONER TOBIN: Thank you very much.

It's really quite a contrast to our systems. Very helpful, your testimony. Thank you.

VICE CHAIRMAN REINSCH: Commissioner Slane.

COMMISSIONER SLANE: Thanks for your time and your testimony.

It seems to me that a major defect in the system is the Chinese government's lack of any effort to emphasize prevention. For example, the government owns the tobacco industry, and there's prevalent smoking in China, and there doesn't seem to be any emphasis to cut out smoking or reduce smoking.

The diet has changed significantly in China where pork has become heavily consumed with all of its medical problems, and am I missing something here? And if they fail to emphasize prevention, it just seems to me that the whole system is going to get worse.

DR. HUANG: Well, if you look at the Maoist system, actually there's a principle they called "prevention first." Indeed, the emphasis was placed on prevention, providing preventive care services, launching public health campaigns. That contributed to the improvement of the public health standards of the Chinese people.

But in the reform era when the healthcare institutions became a revenue-making machine, the focus changed from prevention to treatment, that is, clinical care. The tobacco use is a very good example. But here, I think the reason why so far they haven't taken any decisive measures in

implementing the FCTC, the Framework Convention on Tobacco Control, in which China is a signatory nation, is because of the vested interests of the tobacco industry.

And interestingly, despite the fact that the Chinese First Lady is the WHO's anti-tobacco ambassador, so far she hasn't convinced President Xi of publicly speaking against smoking. And the WHO actually recently just issued a document urging China to take more decisive actions on that front.

COMMISSIONER SLANE: Thank you.

VICE CHAIRMAN REINSCH: I just have one short question, and we've got several that want to have another round. Tell me a little bit about Chinese medical schools and medical education. Are most of their physicians trained outside of China, and if so, where? And what is the quality of medical education inside China?

MS. BOYNTON: I'm not an expert on the medical school system.

VICE CHAIRMAN REINSCH: I hope somebody is.

DR. EGGLESTON: Well, it's not my primary area of research either--but the majority of Chinese physicians are trained in China. There are many very well qualified medical schools in China. There are many issues with the medical training system, but obviously in such a large and diverse country, one issue is to what extent you have, as the Mao era said, the "barefoot doctors putting on shoes"?

At what point do you balance having a basic training and reaching everybody versus having what we have, say, in the U.S., where you first have an undergraduate degree and then go on to medical school, whereas their medical training can be directly after you graduate from high school, and in some rural areas, it would be just a little bit of extra training after an earlier phase of education?

So upgrading that training and keeping it up to date, phasing out retiring earlier providers, and bringing in the new and encouraging them to go to rural as well as stay in the larger urban areas. There are challenges.

There's also a big challenge in medical practice and dispute resolution and a lot of tense patient-doctor relations. Policies are encouraging physicians with reputations from urban areas to go to other areas to provide treatment, but there's also a question if there's a medical malpractice issue there, how that will be resolved; and many issues like that.

DR. HUANG: Well, if you meet someone from China who claims that he's an M.D., don't think that it's the same M.D. you find here in the U.S. because usually these are the people who go to college, receive five years of medical training, basically at the undergraduate level, butin their CV, you will see they are claiming they have an M.D..

So this is the example of the difference between the Chinese medical education and the U.S. medical education system.

The second actual difference is that here you will see probably the best minds go into medical schools. It's very challenging and very competitive to go to a medical school. But in China, usually you don't have

the best of the best going to medical schools. In the college entrance exam, you could see that difference.

And further, as Karen has just mentioned, the incentive of practicing medicine actually is not particularly strong in China, in part because of the low base salary, and in part because of the growing conflict and violence in the Chinese hospitals. A survey carried by the Chinese Hospital Association found actually there's a dramatic rise in violence in the Chinese hospitals since the launch of the healthcare reform in 2009.

COMMISSIONER SLANE: What do you mean by violence?

VICE CHAIRMAN REINSCH: Yes, can you elaborate on violence a little bit?

DR. HUANG: Violence could take various forms. It could be just verbal. It could also take the form of a physical attack on the hospital/the doctors that leads to death of the healthcare providers.

MS. BOYNTON: If I may add to the hospital violence side, the problem is so severe that the government has just last month passed a new regulation stating that public hospitals are no longer required to provide security services on their own. Rather the hospitals are under the coverage of public security. So the police are required to be there to maintain the order and safety of hospitals.

VICE CHAIRMAN REINSCH: What is the common complaint of the unhappy patients? Why are they violent? They're not getting the care they want?

MS. BOYNTON: Cost is an issue.

VICE CHAIRMAN REINSCH: Cost.

MS. BOYNTON: And hospital bribery is prevalent. So, you know, patients who can afford bribery can get better care. People who can't afford it are denied care.

DR. HUANG: Yes, certainly cost is an issue. The attitude is another issue. And you can't blame the doctors for their attitude problem because they have to see lots of doctors everyday. You only have probably less than five minutes with one patient. You wouldn't expect to have good attitude in this situation, right?

And the high expectations of the Chinese patients would be another issue. They often come to the doctor expecting they're going to solve the problem. If that didn't happen, they can be very disappointed. That can evolve into violence.

VICE CHAIRMAN REINSCH: Thank you.

Commissioner Tobin.

COMMISSIONER TOBIN: Thank you.

Dr. Huang, did I pronounce that right?

DR. HUANG: That's correct.

COMMISSIONER TOBIN: Thank you.

You mentioned that the majority of the migrant workers are not covered by this new universal healthcare system. So then I think several of you mentioned that the reform has brought about just in a few years 90

percent universal coverage.

Can you help me--90 percent of what? And who and how are the migrant workers covered in terms of medical care? And what percent would that be? So you can see them trying to look at the healthcare system and figure out what those numbers means and where migrant workers fit in.

DR. HUANG: This is a very legitimate question. The official statistics say that 95 percent of the population in China is covered by some kind of health insurance, whether that is cooperative medical care system, whether that is the residence-based urban healthcare or employee-based urban healthcare, or the government-provided healthcare.

The problem is that this includes 200 million migrant workers who are nominally covered in the countryside, but because they live and work in the cities, they actually are not covered because their health insurance schemes are still not portable. So if you count these 200 million migrant workers, the actual percentage of coverage rate is about 87 percent.

COMMISSIONER TOBIN: Thank you.

And we're on the second round, so I'd like to hear from each of you. You've painted a robust picture of the healthcare system there. After today, our staff work on what we've learned about the healthcare system, and we think about what recommendations, you know, what does this mean for the United States? What does this mean policy-wise for Congress? What does it mean for the executive branch?

What are each of your thoughts in a nutshell on what we need to urge Congress or the executive branch to tend to policy-wise?

DR. EGGLESTON: Well, thank you very much.

I think a hearing like this is a very important first step to recognize the complexity of the healthcare challenges in China, and that some of those challenges affect people on both sides of the Pacific.

Also to recognize that the issue of "kan bing nan, kan bing gui," which is just unaffordable healthcare, in China is, in some sense, a challenge that systems all over the world are facing. With the increasing capabilities of medicine, there's not a system that's not trying to struggle with sustainable financing for quality care for everybody.

And this is a challenge that China is trying to meet and for various reasons we talked about touches upon social stability. So there are ways where the government and the private sector can work with China in various ways to strengthen the system.

To give one particular example, there are many aspects, particularly at the nexus of medical care and long-term care, given the burgeoning elderly population in China, where U.S. firms can, are, and in the future will be making a contribution. But these are also areas often where the regulation is murky at best in China, and it might be good for people here, the private firms and the government, to work with the developing regulatory system in China to address issues like how to regulate home-based healthcare and other issues like that.

DR. HUANG: Okay. May I follow up on that question?

COMMISSIONER TOBIN: Yes, please.

DR. HUANG: Well, if you look at the over 35 years of cooperation between China and the US on health, I think this testifies to the increasingly multifaceted and complex nature of the U.S.-China relationship. You cannot define the U.S.-China relationship just simply in terms of trade and security. Indeed, I want to point out that U.S.-China cooperation with health is a stabilizer in the bilateral relationship.

On the one hand, we know that HIV/AIDS, pandemic flu, China's food and drug safety issues highlighted the importance of the bilateral cooperation between U.S. and China.

And on the other hand -- this is something I noticed and find it very interesting--
despite all these issues between U.S. and China, like trade related disputes, we find that the pharmaceutical-related intellectual property rights are not a major concern in U.S.-China relations, in part because of the strong incentive to attract foreign direct investment. Here they actually have, I would say, a very good record in terms of complying with intellectual property rights requirements.

That might change in the future, but so far, again, I think this is very positive development in U.S.-China relations.

COMMISSIONER TOBIN: Thank you.

Ms. Boynton.

MS. BOYNTON: My recommendations are I think the Congress should urge the executive branch to engage the Chinese government in dialogues on building an environment in China that fosters innovation. I think expanded health care coverage in China is good news for U.S. business because it means broader markets and more demand, but the Chinese government's focus on prices presents risks for U.S. companies.

And the Chinese government is very much focused on innovation, but there are many, many issues, including the IPR, IP protection, and by engaging the Chinese government to build an environment that has a system of protecting IP and really appreciates innovative products, I think that's very key to the U.S. business interests.

COMMISSIONER TOBIN: Thank you. And on that IP item, perhaps our staff can talk with you further because I think it's key.

MS. BOYNTON: Thank you.

COMMISSIONER TOBIN: Absolutely.

MS. BOYNTON: Thank you.

VICE CHAIRMAN REINSCH: Okay. Commissioner Fiedler.

COMMISSIONER FIEDLER: I have a couple of questions. The doctor shortage, let's talk about real doctor shortage as more equivalent doctors. So we have them. I had a brother-in-law who went to Mississippi and Kansas because there were no doctors in those areas, and he would get a house, he would get this, that, and the other.

Where are the shortages? The principal difference between the United States and China is the agricultural population is much larger in

China than it is in the United States so when you simply say rural shortages, rural shortages may well mean the majority of the population is short of doctors. What's the story in the first instance?

MS. BOYNTON: An area that has a shortage of qualified doctors are in the countryside where doctors do not want to go and because of compensation, because of living environment, but even in urban cities, like Dr. Huang mentioned, because doctors are so unhappy, and their work situation is so contentious that I think, I read a recent survey that said a lot of doctors in urban hospitals are actually looking to either move abroad if they have the qualification or maybe switch to the hospital administrator side.

So I think the shortage is a real problem in both urban and rural areas.

DR. HUANG: Just a quick follow-up of Xiaoqing's comments. I think if you compare the proportion of the Chinese doctors to many other developing countries, the doctor shortage is not a major concern. The problem is this maldistribution of the healthcare workers. This is especially the case for doctors in the countryside, at the township village level.

That is a major concern, because college-trained physicians don't have any incentive of staying at the township level, in part or largely because of these financial incentive issues, because their basic salary is very low.

Their payment is linked to the services provided. Unfortunately, there is not that much demand for their services at the township level, and so they all want to go to the county level and even to--

COMMISSIONER FIEDLER: Well, I mean but that's a classic chicken-egg problem.

DR. HUANG: Exactly.

COMMISSIONER FIEDLER: No competition. I mean there is no demand because there's nobody there either.

Let me ask a question about the leadership. So historically the leadership's access to medical care in Beijing has been PLA Hospital 301 or something; right? And historically, the PLA medical system research-wise was probably the most cutting-edge in the country, and so I think the top leadership still has access to really good care at PLA 301 and similar hospitals in Beijing.

What does the provincial leadership have access to for healthcare that the public does not? And do Party officials actually pay for their healthcare like everybody else in the country?

DR. HUANG: That's a good question. The provincial leaders certainly have access to the good health care for free. They have the Provincial People's Hospitals in each province. In some provinces, they also have the military hospitals that provide similar services. For example, in Jiangsu Province, they could have access to Jiangsu People's Hospital. They could also access the General Hospital for the Nanjing Military District.

So, they have free access to those wards for the--

COMMISSIONER FIEDLER: Can I interrupt? How far down does that access go in the system? I mean, it's not just the Party Secretary, Deputy Party Secretary, Director of Organization at the provincial level? How far down does it go in the Party?

DR. HUANG: Despite the healthcare reform, there's still a percentage of what we call "cadres," or the government officials, that can access healthcare for free. This is what the Chinese call "gongfei yiliao." That is a very small percentage. There may be a couple of million, eight million or so, of the government officials. They have free access to healthcare, but there's also a hierarchy in terms of what kind of services you have free access.

For example, if you are in a minister level position, or a current minister, you would have free access to healthcare and also free access, for example, to the imported patented drugs. That is all for free.

But if you are just a vice minister, or a retired minister, you would have free access to healthcare, but only access to certain imported drugs, not all of them. So there's a clear hierarchy between them.

COMMISSIONER FIEDLER: You have got to figure that's a source of problems in the populace at some point.

COMMISSIONER TOBIN: Yes.

COMMISSIONER FIEDLER: The drug cost issue. I'm not a fan of any drug company in the sense of --

[Laughter.]

COMMISSIONER FIEDLER: No, I'm not, because worldwide, it seems to me that low income people have low access to the drugs that they need to survive, whether it be AIDS in Africa or tuberculosis in China.

VICE CHAIRMAN REINSCH: Remember this when you get sick.

COMMISSIONER FIEDLER: And so I actually always do remember it when I get sick, which scares the hell out of anybody in America. They should be scared too, not just China.

So the cost of drugs for people who have low disposable incomes, and when you start talking about middle class, I have a problem with all the numbers about largest markets and this, that, and the other thing. It's not a question of largest markets. It's a question of a market where people have sufficient income to purchase.

So you talk about rural people who don't have any money and have less access to drugs. Even in the leadership, we're talking about cutting different ranks for access to different kinds of drugs. So how do you lower drug costs in China in a way that gives more people access to lifesaving drugs with all of these maladies we're talking about?

Tubercular drugs are pretty damn expensive as far as I can remember, especially those that are antibiotic resistant tuberculosis.

How does the government get a-hold of the drug cost problem?

MS. BOYNTON: The part of the reform effort is to develop a National Essential Drug List, the EDL. It essentially is a catalog of 520 types of drugs, and they're all cost effective drugs, and the government

orders the provincial governments to conduct centralized tendering all of these drugs to make sure that the hospitals can procure the lowest cost drugs.

And these drugs are supposed to be made available in community clinics and hospitals for patients to purchase, and most of them are under healthcare insurance coverage. But the problem of this EDL tendering is very significant because the government has a very, very heavy focus on price. They don't care about quality, and--I take it back--they care about quality, but not at the expense of prices.

So, you know, actually a problem that has occurred after the EDL tender has launched is a shortage of these drugs, particularly very commonly used low-priced drugs, because Chinese manufacturers have no incentives to producing these drugs because there is absolutely no profit --

COMMISSIONER FIEDLER: One of your testimonies--I wrote it down--was that 45 percent of the income of the hospital could be drugs. I don't know that that even closely resembles equivalent of U.S. hospitals. For all the gouging that we do, I don't think that the overall percentage would be that high of a hospital's income.

So it's not just the drug manufacturers that one has to get a-hold of. We're talking essentially at a retail level in the hospital, they're marking them up, and what's the incentive for the hospital to reduce the price of drugs if 45 percent of their income is from them? That fiat and imposition in a more authoritarian fashion than has been used.

DR. HUANG: Well, the government certainly has incentives to lower the price of the drugs given the high reliance of the hospitals on drug sales, but there are all kinds of problems here: first, the government tends to rely heavily on administrative fiat in lowering the drug prices instead of through marketing mechanisms. So this is the irony. Once you lower the price of certain drugs, immediately they disappear; it's no longer available on the market.

COMMISSIONER FIEDLER: Always the black market.

DR. HUANG: Simply, also, the drug companies don't have incentives then to produce the drug anymore. And, secondly, there's a huge problem in the bidding tender system, or the so-called "double envelope system." You know, they have two envelopes, one focused on quality, the credentials of the pharmaceutical firm; the other on price essentially.

But in the actual bidding process, the focus is on the price. So there's really not much concern on issue of quality. So there's now an increasing call for abandoning that system.

And, thirdly, the government faces a schizophrenic situation that, on the one hand, they have incentive to lower the prices, to rein in this trend of rapid increase of healthcare costs.

On the other hand, they have strong incentives to promote the healthcare industry. That means high healthcare costs. They say that there is more room to increase the price because the healthcare spending in China is only 5.5 percent of the total GDP, but the world average is about nine percent.

So this is what I call the schizophrenic situation the Chinese government has to face.

COMMISSIONER FIEDLER: Thank you very much.

VICE CHAIRMAN REINSCH: Okay. Commissioner Shea. Oh, I'm sorry.

DR. EGGLESTON: Can I just briefly add to that?

VICE CHAIRMAN REINSCH: Please.

DR. EGGLESTON: The issue with drug revenue in China is not just an issue of the prices of the drugs themselves, but the structure of all of the spending. So the prices paid to doctors for evaluating and managing a patient are very low, and it's an explicit policy that basic services prices are often set below average or marginal costs.

And that the prices on drugs are above marginal costs, saying that this will somehow work out in the end, leads to distorted incentives. But you can't ignore the fact that if you're going to take away half of the revenue of a provider, you have to compensate by paying appropriately for other services that they are providing.

COMMISSIONER FIEDLER: But you're also saying it's the policy or I can now afford the diagnosis, but I can't afford the cure.

DR. EGGLESTON: Well, in my studies, the overall prices of drugs obviously depends on which drugs, but the overall prices of many drugs in China are not out of line with the world market, and one of the reasons--there are some positives of having reliance on drugs.

For example, compared to many developing countries, there's a good stock of available medicines even in rural China in many cases because that's how the physicians make their revenue.

There's a population perception that when you go into a doctor, you need to come out with a drug or you're not really being treated. There's a lot of popular perception that if healthcare spending is high that it must be drug prices that are high, but actually as we know in the U.S. and many other cases, drug spending is just one part of a larger picture.

COMMISSIONER FIEDLER: There must be a lot of placebos going back and forth.

VICE CHAIRMAN REINSCH: Okay. Commissioner Shea.

CHAIRMAN SHEA: Thank you.

In the United States, I think there are about 78 million baby boomers who are now beginning to retire. You see something called Naturally Occurring Retirement Communities, NORCs. Everybody is just getting old in the neighborhood.

And most of the people overwhelmingly want to stay in their own homes, as they age. They want to age in place, and that poses great challenges to the housing system because a lot of the homes and the communities were not built around an aging population.

Doors are too narrow. Bathrooms are on second and third floors. So it's become a problem, and it's going to be a bigger problem going forward, and private institutions, public agencies are all focused on how to

respond to this aging in place phenomenon.

Now when I look at China--I think they're going to get older before they get rich, at least on a per capita basis. And I was wondering if you could share your thought--is this something that they are concerned about? How do you deliver healthcare to an aging population? Do most people want to stay at home as they age and how do you get them the care that they need in that type of situation as opposed to putting them in a nursing facility or some sort of retirement home?

This seems to me is an area of potential U.S. cooperation, U.S-China cooperation. Both societies are getting older and that poses challenges about how to deliver healthcare in residential settings or to an aging population. So if you can just give me your thoughts on what I just said, I'd appreciate it.

DR. HUANG: Well, China certainly is getting older before getting rich. That is for sure. It is a rapidly aging society with now more than ten percent of the population aged over 60, and that poses huge challenges for elderly care in China because traditionally they don't have this institutional care system in place.

Usually it's that you raise your children to take care of you when you're getting old, but now with the implementation of the one-child policy, it becomes increasingly impossible to have, for example, one young couple taking care of four, if not eight, older people.

But we also see that there are more elderly people want to receive institution-based senior care, and they increasingly can afford it. Currently less than two percent of the senior population use institution-based care, but more than ten percent are willing to receive care in institutions. The number of elderly people who are able to afford senior housing will reach 22 million by 2020, and so this is still emerging business in China.

I just read a report. There is this lady who had problems in finding a nanny to take care of her old father. She decided to spend 3 million yuan to build a senior care center for her father and other elderly people.

DR. EGGLESTON: If I could add to that?

CHAIRMAN SHEA: Sure.

DR. EGGLESTON: There are a lot of different approaches in different parts of China. Obviously, there's been investment in increasing institutional availability of long-term care, but that represents a very small fraction of the total need. There is a plan to expand provision but also to expand outside-of-institution -- that is, community-based -- long-term care services.

In places like Shanghai, there are a lot of active programs in this area, but even in rural areas, there's a response to this very real transition of demography, and interestingly, it interacts with many other policies in China, again, non-medical system initiatives.

For example, in villages, sometimes they will create a village senior center funded out of the village collective. I've done some field work

that looks into this, and, interestingly, it's related to part of the incentive to consolidate land, and so there are pros and cons.

The elderly people often want to age in place in their own little yard. They're used to being able to raise chickens in their little yard. You can, as part of modernization in rural areas, move them to a high-rise, but they don't want to have to go live up in a high-rise. So you can have a single level senior center, and some places this is funded by the village for everyone above age 60 in that whole village. There are pros and cons, but that's starting to be available.

And one thing to note is that there are a lot of opportunities at this nexus of medical care and long-term care for the private sector, and there is more private sector involvement in that than in medical care per se.

CHAIRMAN SHEA: Have you seen U.S. companies, some big, like Sunrise, who build large retirement communities, look into the Chinese market or--

DR. EGGLESTON: There's an active interest in the China market, and actually there are government providers also interested in this market; so it's expanding in both sectors.

CHAIRMAN SHEA: Ms. Boynton.

MS. BOYNTON: I fully agree with both the panelists, and I think institutional-based elderly care has been historically frowned upon because elderly people should stay at home and be cared for by their children, but because of the one-child policy and the impact on the demography, people can no longer do that.

So I agree that a large number of elderly Chinese are very interested in institutional based care. However, the infrastructure is still very, very limited, and the government is very interested in looking at different models of building this and also, very importantly, the affordability issue.

Part of China's efforts to improve the social safety net is to include a functioning pension system, and I believe that this is an area that the U.S. and Chinese government could collaborate on and share best practices and explore opportunities.

DR. HUANG: Also, you might want to add that the pension system is broke now.

CHAIRMAN SHEA: Say that again. Could you elaborate on that?

DR. HUANG: The pension system--

CHAIRMAN SHEA: In China.

DR. HUANG: --in China is broke essentially.

VICE CHAIRMAN REINSCH: Commissioner Tobin.

COMMISSIONER TOBIN: Just--thank you.

You mentioned 200 million migrant workers, and how do they fit into what we just talked about, this demographic change in the aging population because they too are aging? Are they having access to those communities you talked about, or absolutely not?

DR. EGGLESTON: Well, most of the migrant worker population is younger age, and so the issue with migration is largely that it's the adult children of the elderly that are migrating; and as was alluded to before, there are problems with those adult children in the migrant population being so far away that they can't provide care to the elderly.

And in many cases, affordable housing in the urban area is not built on the scale that they can bring their family. So the elderly and their children are left in villages, while the adult children migrate.

That being said, there are interactions say with the new rural pension system. In one of our studies, we looked at when the new rural pension system is given to those over age 60. It's a moderate benefit, but one of the effects that it has is that the elderly person feels they're more confident they can get healthcare, and that their adult children are more likely to be able to migrate and be part of the migrant population.

VICE CHAIRMAN REINSCH: Okay. Other questions? Good. Thank you very much to this panel. We appreciate your time, and we appreciate the depth and breadth of your responses.

I think we're a little early, which is good. We can pick up some time. I think our witnesses for the next panel are here. So we'll take a shorter break and plan to reconvene around 11:15 rather than 11:30, and thank you very much to these witnesses.

[Whereupon, a short recess was taken.]

PANEL II INTRODUCTION BY CHAIRMAN DENNIS SHEA

CHAIRMAN SHEA: Our next panel will look at market access for U.S. medical goods and services in China.

Our first witness is Ben Shobert, the Founder and Managing Director of Seattle-based Rubicon Strategy Group, a boutique consulting firm that specializes in market access work in healthcare, life science and senior care industries in China and Southeast Asia.

In September 2013, Ben became affiliated with the National Bureau of Asian Research to advise on aging, healthcare reforms and the pharmaceutical industry in China and Southeast Asia.

He is a member of the National Committee on U.S.-China Relations and holds advisory board seats at Indiana University's Research Center on Chinese Politics and Business, as well as IAHSA-China (The Global Aging Network). He writes on China's healthcare for Forbes magazine. Mr. Shobert holds an MBA from Duke University's Fuqua School of Business. Go Blue Devils.

Our second witness is Rod Hunter, Senior Vice President, International Affairs, at Pharmaceutical Research and Manufacturers of America, PhRMA. PhRMA is a trade association representing the leading research-based pharmaceutical and biotechnology companies. During his government tenure, he served as Special Assistant to the President and Senior Director for International Economics at the White House's National Security Council.

From 1989 to 2001, Mr. Hunter was a Brussels-based attorney and partner with the Hunton & Williams law firm.

Our final witness is Ralph Ives. Mr. Ives has served as Executive Vice President of Global Strategy and Analysis at AdvaMed, a medical device trade association since 2004.

Mr. Ives is responsible for the Association's efforts to provide adequate reimbursement, appropriate regulations and open market access for medical technology products, which are described in this very helpful brochure which was distributed, "What is a Medical Device?"

Previously, Mr. Ives was Assistant U.S. Trade Representative for Asia-Pacific and APEC Affairs and Assistant U.S. Trade Representative for Pharmaceutical Policy in the Executive Office of the President of the United States.

And I was hoping, you know, I think you all are aware of the ground rules. We request that you limit your oral statement to about seven minutes, but plus or minus a minute. We're pretty flexible.

So why don't we begin with Mr. Shobert and then continue to your right after that.

OPENING STATEMENT OF BENJAMIN SHOBERT
MANAGING DIRECTOR, RUBICON STRATEGY GROUP AND
SENIOR ASSOCIATE, NATIONAL BUREAU OF ASIAN RESEARCH

MR. SHOBERT: Well, thank you to Chairman Shea, Vice Chairman Reinsch for the invitation. It's a pleasure to join you here this morning.

For pharmaceutical, medical device, and diagnostic life science manufacturers across the U.S., the China market has become increasingly important over the last two decades. China, and it's important to say emerging markets in general, offer the industry a largely untapped and growing market where basic healthcare needs have long gone unaddressed and where a growing middle class exhibits a strong preference for spending on healthcare goods and services.

For pharmaceutical companies in particular, the China market has become a significant driver of growth. In 2010, the domestic Chinese OTC, or over-the-counter, and branded generic market, was approximately $23 billion in size. By 2020, if projections hold, it will have reached over $369 billion. That projection will make China the second-largest pharmaceutical market globally, following only the U.S.

Before China represented this sort of growth opportunity, many life science companies had successfully leveraged China as part of their supply chain. Today, most have come to see the potential China market as slightly different. It is no longer just an alternative geography where you can find a lower-cost supply partner. It's also somewhere you can sell into. Now, they see this as an alternative to many of the revenue and profitability challenges they're facing in their developed domestic markets.

The specific challenges here in the U.S. that life science companies are facing range from how we are going to deal with an aging society here with the many long-term chronic diseases that we're bringing forward and successfully dealing with, but the costs that those are related to, but also a maturing patent pipeline, and the lack of clear blockbuster drugs, many of which were related to cracking the human genome, and the lack of commercial opportunities that have come as a result of that.

Combined, these pressures have meant that China is more important to life science companies than ever before. Reflecting these realities, American life science companies have made China a central part of their growth plants. Early on, the life science industry adopted market access strategies that looked a lot like what other industries, especially high technology industries, have utilized.

This meant that they wanted to bring latent more mature technologies to the market in case IP drift occurred. However, while that had worked well for the last 20 years, it's no longer likely to be a successful strategy because China's objectives have changed.

How have they changed? Well, since 2008, when the New Drug Creation and Development Program was announced, China's appetite for

American therapies has dovetailed with an explicit policy mandate on the part of the central government that the country develop a domestic life science sector.

The 12th Five Year Plan is very clear in these goals. It wants to see that four percent of the country's GDP be derived specifically from the life science sector. What are they doing to ensure that this actually happens? They formed 20 new incubator bases. They have formed multiple alliances between academia and government. There have been significant subsidies created.

To give you a sense of scale, they are investing close to $10 billion by the end of the 12th Five Year Plan purely on novel molecule discovery. That needs to be put in a little bit of context. The NIH here in the U.S. in one year will spend a billion dollars more than that. And China has a very underdeveloped venture capital market in general and certainly specific to life sciences. So that number needs to be kept in a little bit of perspective.

But there are definitely two reasons that these policies are being pursued. The first is a public health reason, which is the country wants to make sure that it has access to a sustainable stream of basic medicines, but the second reason is more problematic and more relevant to our discussion today, and that is that the country wants to make sure that its high technology sector, specifically life science community, is part of what characterizes its economic growth plans.

As a result of this, American firms have found they need to begin to rebalance their global R&D spending. That's a small reason why you saw Merck announce in 2011 $1.5 billion being allocated towards its China R&D.

The pressures to do more R&D in China have potential upside. They allow American companies to look specifically at the demographics of the Chinese people, the unique co-morbidities that they have and develop drugs specifically for the Chinese population.

However, they also recognize that this complicates market access issues. Now, in addition to traditional commercial concerns that have to be managed, U.S. pharmaceutical companies, in particular, are faced with the increasingly clear recognition that they are going to be required to do technology transfer to stay viable in the Chinese market.

On this point, it's necessary to reiterate much of the testimony from the last panel about the broken nature of the Chinese healthcare system and the very political nature of these failings, and it comes as no surprise to you to see that American businesses in many cases are going to be singled out as reasons to blame in the event when people are frustrated with affordability and access in China.

Always concerned about these issues, the Chinese government has been working to make the existing healthcare system more efficient. Thus far these endeavors have emphasized an expansion of the government-provided healthcare insurance and driving prices down. The latter, as we've discussed already, has been achieved through the EDL, but also through

application of the country's Anti-Monopoly Laws, or the AML.

This is particularly problematic for foreign companies because it forces the question of whether or not they can continue to compete fairly in the China market.

Questions of fairness--whether regulations are applied evenly between domestic and foreign players--are not unique to life science sectors. Surveys over the last several years of the U.S.-China Business Council and the American Chamber of Commerce share these frustrations in other industries.

Similarly, the pressure to transfer technology to Chinese counterparts is not new to the life science category. However, the American life science sector encounters China and its policy goals at a slightly different point in both parties' respective development. The life science category is more dependent on China to sustain its growth and profit targets than other industries have been in the past, and China's ability to disrupt global value chains, even those that are higher technology in nature, is more sophisticated today than it ever has been.

In the past, higher technology industries could engage in technology transfer with their Chinese counterparts by offering less sophisticated technology. Today, China expects the best. And this question, more than any other, is perhaps the cause of our hearing today.

CHAIRMAN SHEA: Thank you.

Mr. Hunter.

PREPARED STATEMENT OF BENJAMIN SHOBERT
MANAGING DIRECTOR, RUBICON STRATEGY GROUP AND
SENIOR ASSOCIATE, NATIONAL BUREAU OF ASIAN RESEARCH

U.S.-China Economic and Security Review Commission

Hearing On: "China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products"

April 3, 2014

"Market Access for U.S. Medical Goods and Services in China"

Benjamin A. Shobert

Founder and Managing Director, Rubicon Strategy Group
Senior Associate, National Bureau of Asian Research

For pharmaceutical, medical device and diagnostic life science manufacturers across the United States, the China market has become increasingly important over the last decade. China – and emerging markets in general – offers the industry a largely untapped and growing market where basic healthcare needs have long gone unaddressed, and where a growing middle class exhibits a strong preference for spending on healthcare goods and services. McKinsey's China healthcare practice estimates that the country's healthcare spending would grow from $357 billion in 2011 to $1 trillion by 2020.[25]

For pharmaceutical companies in particular, the China market has become a significant driver of growth: in 2010, the domestic Chinese over-the-counter (OTC) and branded generic market was approximately $23 billion, by 2020 it is projected to have reached over $369 billion in size. If this holds, China will become the world's second largest pharmaceutical market, following only the U.S. Before China represented this sort of growth opportunity, many life science companies had successfully leveraged China as part of their supply chain. Today, most have come to see the potential China market as more than an alternative, lower cost segment of their precursor supply chain. Now, many American life science companies see China as an offset to many of the revenue and profitability challenges they face in their developed domestic markets.

The specific challenges U.S. life science companies face today within their domestic market include price pressures related to an aging society with chronic long-term diseases and the need to save money, which has driven reimbursement rates down on many goods and services; a maturing patent pipeline with an inadequate number of obvious "blockbuster" drugs in the works[26]; cracking the human genome has thus far not yielded the sort of commercial

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[25] Le Deu, Franck, Rajesh Parekh, Fangning Zhang et. al, "Healthcare in China: Entering Uncharted Waters," McKinsey and Company, July 2012, page 2.

[26] Within the pharmaceutical industry, a blockbuster drug is commonly understood to be one that creates over $1 billion in

opportunities many companies anticipated. Combined, these pressures have made success for the life science industry in emerging economies in general, and China especially, more important than ever.

Reflecting these realities, U.S. life science companies have made China a central part of their growth plans. Early on, the life science industry adopted market access strategies that reflected best practices from other un-related sectors; namely, bringing more mature products and therapies the companies could afford to lose to China if IP drift occurred. In general, this approach worked well for much of the last twenty years, until recently, when China's expectations from multinational life science companies became more sophisticated.

Since 2008, when the New Drug Creation and Development program was announced, China's appetite for western therapies has dovetailed with an explicit policy mandate by the central government that the country develop a domestic life science sector. The 12th Five Year Plan is clear in its goals: to ensure life sciences account for at least four percent (4%) of China's GDP.[27] To see that this objective is met, China has allocated government capital into the life science sector, created twenty new "incubator bases," formed multiple alliances between government, industry and academia, at the same time it has pushed forward on forcing its domestic industry to adopt good practice (GxP) standards, a step which provides greater confidence by foreign companies in the capability and integrity of development, trialing and manufacturing from a Chinese partner. Between 2008-2010, the Chinese government invested $2.7 billion into pharmaceutical R&D, followed up with planned spending of an additional $6 billion by 2015.[28] China has twin objectives driving these policies: to ensure the country has a viable domestic manufacturing capacity to produce basic medicines and to create a new export industry that represents higher technology products.

As a result of China's goals, American companies have found they now must begin to allocate funding towards R&D directed specifically at bench science, product development and clinical trials completed in China. Merck's late 2011 announcement that it would be spending $1.5 billion to build a domestic Chinese R&D capacity reflects the new reality of doing business in China. Today, China is not only a potential market for American life science companies to sell into, it is also where they will increasingly be conducting R&D. The pressure to do more R&D in China has potential upside to American life science companies: not only does China have a pool of scientific talent and a policy infrastructure in place to incentivize research activities, there is also a good argument to be made for conducting development and trials in China for unique morbidities within the Chinese population.

American companies understand that the Chinese government's emphasis to see a domestic life science industry take root further complicates market access issues. Now, alongside traditional commercial concerns that must be managed, U.S. pharmaceutical companies in particular are

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annual sales.

[27] Chee Hew, "Prescription for healthier growth: Shaping China's life sciences market," page 9.

[28] Qi, Jingzong, Qingli Wang, Zhenhang Yu, Xin Chen and Fengshan Wang, "Innovative drug R&D in China," *Nature Reviews: Drug Discovery*, Volume 10, May 2011, page 333.

faced with the increasingly clear expectation they engage in technology transfer as part of their ability to sell into the Chinese market, a market dominated by the Chinese government as the provider of public hospitals and the purchaser of pharmaceuticals, medical devices, and diagnostic equipment. On this point, it is necessary to speak to the delivery of healthcare in China because absent this explanation, it can be difficult to understand why the Chinese government's objectives could run counter to those of American life science companies.

Like many emerging economies, China's healthcare system is paid for primarily via out of pocket expenditures on the part of the consumer. These out of pocket payments take two forms: the ubiquitous "red envelope" payments of cash to doctors in exchange for preferential care, and cash payments for prescriptions and procedures – many of which are medically unnecessary, but required for the hospital to fund itself. Even after two rounds of additional healthcare-specific stimulus spending by the Chinese government in 2009 and 2011, the country's public hospitals remain badly under-funded. This historic reality has created a toxic mix of financial incentives where hospital administrators scrambling for revenue, coupled to under-paid doctors hungry for better compensation, prescribe unnecessary medicines and procedures simply to fund the hospital's ongoing operation and achieve incentive compensation by the doctors related to sale of prescriptions and procedures. The Chinese consumer has born the brunt of this inefficient and financially starved system, reflected in high out of pocket payments for healthcare (estimates are that over the last twenty years, out of pocket expenditures for healthcare in China have been in excess of 50%).[29] In the eyes of many Chinese, the country's healthcare system – and the government's inability to fix it – remains one of their three primary sources of discontent (the other two being corruption and pollution).

Always concerned over social stability, the Chinese government has been working to make the existing healthcare system more efficient. Thus far, these endeavors have emphasized an expansion of the government-provided healthcare insurance and driving prices down. The latter has been achieved in two ways. First is the formalization and expansion of the Essential Drug List (EDL). Second is through application of the country's Anti-Monopoly Law (AML) specifically, and more generally, the expansion of anti-bribery campaigns. As a result of these efforts, U.S. medical goods and service providers now face four fundamental challenges in China: price pressure if they wish to be included in the country's tenders for pharmaceuticals and devices, growing expectations they accommodate technology transfer to their Chinese counterparts, un-even enforcement of the country's AML, and a willingness on the part of the Chinese government to divert attention away from its own failings relative to healthcare by drawing attention on non-compliant behavior (i.e. corruption) on the part of domestic and multinational companies selling into China's healthcare economy.

Central procurement via the EDL remains the most obvious form of price pressure that companies face today. The EDL is a list of some 520 drugs whose prices are capped, and the traditional 15% hospital mark-up is not allowed. China's Ministry of Health (MOH) has

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[29] Zhang, Lufa, Nan Liu, "Health Reform and Out-of-Pocket Payments: Lessons from China," *Health Policy and Planning*, Oxford Journals, February 21, 2013, http://heapol.oxfordjournals.org/content/early/2013/02/21/heapol.czt006.full.

established standards for how much of a hospital's prescribing volume should be drugs on the EDL, simply as a means of ensuring hospitals do not look for drugs off the EDL as a way of continuing to make up their revenue short-falls. As becomes obvious quite quickly, absent additional government-sponsored reimbursement schemes for hospitals, the EDL simply accentuates an already-broken funding mechanism within China's healthcare system. There are ways around these constraints – at least for now – such as sub-headings within regional tenders for what are called "off-patent originator products" (OPO) that allow greater pricing flexibility[30]; however, the policy mandate that is driving the EDL forward is to make pharmaceuticals affordable to more people. This emphasis is entirely understandable from the point of view of China's government and its people; the question is whether efforts such as the EDL are going to be adequate to achieve the sorts of public health objectives around access and affordability that are required.

These questions are ones shared by the Chinese government. The EDL represents a formal and structured vehicle within which various stakeholders ranging from public health policy makers in the MOH, to those setting reimbursement policies in both the MOH and Ministry of Finance (MOF) can try to expand access while controlling cost. Yet, the Chinese government also recognizes that the EDL on its own will be inadequate, simply because the list will never be exhaustive, and companies (both domestic and international) may work to stay off the EDL as a way to maintain profits while selling to a market that is admittedly smaller than they could if they were to go on the EDL.

Because of this realization, China's policy makers recognize other approaches will be necessary to make healthcare more affordable. Given the main drivers of healthcare affordability in China are pharmaceutical inputs, the Chinese government has begun a two-pronged strategy outside of the EDL to drive prices down. The first emphasizes China's AML, largely as enforced by the National Development and Reform Commission (NDRC). The second is pursuit of corruption charges such as those leveled against GlaxoSmithKline (GSK) during the summer of 2012. While tactically different approaches, both have been successful at lowering prices for various healthcare goods across China.

The NDRC's AML enforcement capacity includes the ability to fine companies – both domestic and foreign – that are engaged in monopolistic pricing. Most industry analysts expect 2014 to see a spate of similar AML charges from the NDRC that will impact pharmaceutical, medical device and diagnostic equipment manufacturers. Few can question the immediate efficacy of an NDRC investigation: following the NDRC's AML charges against Nestle, its prices were dropped by 11% on average. Similarly, following the NDRC's 2012 focus on four drug classes that included more than 500 different drugs, prices dropped 17%.[31]

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[30] Chen, Helen, Samuel Han, "Insider Analysis From LEK On Tackling China's EDL Challenge: Navigating The Changes And Planning For Success," *PharmaAsia News*, May 3, 2013, page 2, http://www.lek.com/sites/default/files/L.E.K. Tackling Chinas EDL Challenge PharmaAsia May 2013.pdf.

[31] Chen, Shaoyu, John Graubert, Weishi Li et. al., "China Opens Broad Investigation Into Pharmaceutical Pricing," July 19, 2013, page 2, http://www.cov.com/files/Publication/d4f596c8-7e4b-48e7-

Often times – but not always - AML allegations go hand in hand with China's anti-corruption drive. This has led to a certain amount of cynicism about the application of China's anti-bribery standards. The best example of this so far has been the allegations leveled against GSK in the summer of 2013. In July 2013, GSK admitted that certain members of its business in China had engaged in bribery as a means of securing prescriptions from various hospital administrators and doctors.[32] Much of the bribery in question took place through third party travel agents who acted as proxies to redirect money from GSK towards key referral sources within the Chinese healthcare system. Since the allegations against GSK were made public, the company has announced a round of price reductions.

There are at least three ways to understand the GSK scandal in China. First, that the crackdown on GSK is part of the growing anti-corruption program Chinese President Xi Jinping has set in motion. In August of 2013, two senior executives of state owned enterprises (SOEs) were placed under "formal investigation," including Wang Yangchuan, the vice president of China National Petroleum. This way of explaining the crisis points toward a number of anti-corruption initiatives President Xi has rolled out since taking office, of which GSK is only one, and the healthcare sector is but one of several areas receiving the benefit of an anti-corruption drive.

The second way to understand the GSK scandal is specific to healthcare reform. China is in the midst of a once-in-a-generation expansion of its healthcare system. The country is making massive investments in every facet: new hospital and primary care infrastructure is being built at a torrid pace, a national insurance plan has been rolled out that covers almost everyone in the country, providing increasing coverage for basic pharmaceuticals, devices and diagnostic procedures. Yet most, if not all of these additional investments are being built on top of a weak foundation.

Doctors are chronically over-worked and under-paid.[33] Hospital administrators struggle to meet shortfalls between government reimbursement and the increasing costs associated with the levels of service and medical products they are expected to provide. Both hospital administrators and doctors have found alternative means to make up for the revenue not provided by the government. For administrators, their response has been to incentivize doctors to prescribe unnecessary pharmaceuticals, surgical procedures, and diagnostic evaluations. Doctors have supplemented their paltry incomes through the sort of bribes the GSK scandal has exposed, as well as the previously mentioned "red envelope" payments that families make directly to doctors to ensure proper and timely care. The combination of these practices has created pervasive inefficiencies within China's healthcare system that must be dealt with if the massive additional

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93d2-4d8ea7505e93/Presentation/PublicationAttachment/6e573158-f4fe-4171-973e-6153c648acaf/China Opens Broad Investigation Into Pharmaceutical Pricing.pdf.

[32] "Glaxo Executive Says Changes in China to Cut Drug Prices," July 22, 2013, http://www.bloomberg.com/news/2013-07-22/glaxo-executives-may-have-violated-laws-china-ministry-says.html.

[33] Andreas Tschirky and Lee Babiss, "Drug Discovery in China," *AsiaBiotech*, Volume 10, Number 16, 2006, page 875-876.

investment the country's central government is making is going to be used wisely and actually benefit the Chinese people.
Companies such as GSK did not create this environment; rather, they have had to determine how to navigate the complex field where international compliance standards overlap with how healthcare is consumed and paid for in China. The realization that companies such as GSK did not create this situation, but are bearing unequal blame for it leads to the third, and most troubling way to understand the GSK scandal: China is broadly becoming a less hospitable place for multinational companies to operate.

Over the last several years, surveys by of American and European companies with significant investments in China have noted growing concern over what these firms perceive as a less hospitable environment to make investments and grow domestic market share. Many businesses believe they are being held to higher regulatory standards by China's various ministries than are their Chinese competitors, a frustration that is certainly not new but seems more explicit and intense than in previous years. China's efforts to create a consumption and service based economy, rather than simply a manufacturing one, reflect a concern on the part of the country's leadership that absent a domestic consumer economy, China's growth could stall, with social and political instability to follow. While perfectly reasonable fears, the government's practices that have followed this recognition have meant domestic firms receive increasingly privileged positions over international companies.

When measured against these concerns, the GSK scandal takes on a different and more troubling light. Whatever corrupt practices GSK is ultimately found guilty of, the reality is that GSK's domestic competitors are guilty of much more egregious behavior. Recent allegations that China's largest domestic pharmaceutical distributor Sinopharm has two former executives who allegedly engaged in non-compliant behavior has been welcome news for an industry that recognizes domestic Chinese businesses operate much more in the gray area than most foreign companies do.[34] For the GSK crackdown to be taken seriously, and for it to have the right impact on the inefficiencies that persist in China's healthcare system, two things need to happen.

First, China's regulators need to turn their attention equally towards domestic players, and make sure multinationals see their competitors also be held accountable. Second, the reimbursement practices that lead to chronic revenue shortfalls in hospitals, and the ongoing poor pay for public hospital doctors need to be addressed. Absent either change, the only effect of the GSK scandal will be to push corrupt practices further away from companies towards distributors, independent sales representatives, and dealer networks where businesses can claim they have no directly knowledge of, or influence on, corrupt activities. While this position may satisfy the Foreign Corrupt Practices Act (FCPA), it does nothing to change the political realities within China that made the pursuit of GSK and other life science companies all but inevitable.

The NDRC is only one of three regulatory bodies in China that have AML enforcement capabilities. The other two, the Ministry of Commerce (MOFCOM) and the State

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[34] Patti Waldmeri, "Sinopharm executives targeted in China corruption probe," *Financial Times*, January 13, 2014, http://www.ft.com/intl/cms/s/0/31e8a8ec-7bf4-11e3-84af-00144feabdc0.html.

Administration of Industry and Commerce (SAIC) also retain AML capabilities that impact foreign life science companies.[35] The NDRC's power has been challenged in the last year, largely by reformers within China who believe the ministry has become unresponsive to the need for further economic reforms. The March 2014 National People's Congress encouraged interpretations of the NDRC's diminished power, even though nothing has changed with respect to the NDRC's AML authority. In fact, the NDRC still maintains broad authority to go after businesses that it believes are engaged in activities not beneficial to the Chinese consumer. If the NDRC is further weakened relative to its ability to regulate the economy through issuing approvals and key licenses, it will most likely protect what power it still (which remains significant) has by leveraging fines on what the NDRC believes to be misbehaving companies.

For pharmaceutical and medical device companies, the NDRC's new political reality likely means the industry should anticipate more pressure from the NDRC specific to charges of anti-monopolistic pricing, a strategy that has already been used successfully this past summer to go after a number of the largest multinational pharmaceutical companies operating in China. Companies understandably want to gauge whether they can anticipate a NDRC investigation. Beyond a simple fight for relevancy on the part of the NDRC, what triggers the NDRC's wrath? Two factors seem to best explain when the NDRC chooses to pursue such an investigation. Neither of these factors is within the control of the private sector, a troubling realization many life science companies are coming to terms with today.

First, the NDRC's attention will be provoked if domestic consumption of a particular good outpaces domestic production of the good in question, and this good is perceived to be of national importance. In the past, for semiconductor chip production in particular, the NDRC has been used by the central government to reinforce a message to domestic industry (the government "has your back," so increase chip manufacturing capacity so we do not have to buy as much foreign product), at the same time a different message is sent to foreign companies (you have "too much" market share – if you want to keep it, figure out how to partner with a domestic counterpart). This narrative is particularly sensitive in the life science sector given China's stated objective of establishing a vibrant domestic pharmaceutical industry. Here, the threat of a new, or expansion of an old, AML case by the NDRC may carry with it the implicit understanding that the company in question has not been adequately active in the identification of Chinese R&D partnerships.

Second, the NDRC chooses to pursue an AML investigation when political pressures accrue and require some sort of response by the central government. Unfortunately, there is little doubt that China's healthcare economy has been – and will continue to be – in such a precarious situation. The potential backlash against China's government by its people over frustrations with the country's poor healthcare system continues to be an ever-present concern. One way these frustrations can be redirected away from the government is to turn them towards the private sector, of which both domestic and foreign pharmaceutical companies remain front and center. This means that the NDRC's powers are likely to continue to be directed towards life science

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[35] Hao, Sue, John Lenhart, "China's 'Golden Year' of Antimonopoly Investigations," *China Business Review*, December 12, 2013, http://www.chinabusinessreview.com/chinas-golden-year-of-antimonopoly-investigations/.

companies (both foreign and domestic), especially given the unique role prescription costs play in the total healthcare expenditure for Chinese families.

If, either because the NDRC is fighting to retain its legitimacy, or if the central government should increasingly look to use the NDRC's powers to channel general frustrations about China's healthcare system away from it and towards the private sector, the industry will see more crackdowns such as those from last year. The bigger problem is that these crackdowns are likely to be highly volatile, disorganized, and as such difficult to predict. Foreign companies are closely watching what GSK's ultimate penalty will be. The more egregious their fine, the more likely foreigners are going to fundamentally re-evaluate their future China plans. The country's leadership understands this, and while it is not eager to drive out foreign life science companies, it has two other goals (driving costs down and fostering a domestic industry) that remain primary.

What China's policy makers – the NDRC especially - are likely to pursue will be un-even and high profile examples of behaviors that are perceived to negatively impact the consumer. At the same time, the NDRC's actions will drive further behind closed doors a discussion between the Chinese government and individual life science companies about what businesses need to bring to the table in exchange for ongoing market access. The NDRC is uniquely positioned to accomplish all of this through application of the powers it still retains. Businesses should take note of the NDRC's diminished powers, but would do well not to overlook the ways in which the NDRC's ongoing capabilities can and will be used to shape market access.

Questions of fairness – whether regulations are applied evenly to domestic versus foreign players – are not unique to the life science sector in China. Many other industries, as evidenced by surveys conducted by the US-China Business Council and the American Chamber of Commerce attest, also share these frustrations.[36] Similarly, the pressure to transfer technology to Chinese counterparts is not new to the life science category. However, the American life science sector encounters China and its policy goals at a different point in both parties' respective development than other sectors have enjoyed: the life science category is more dependent on China to sustain its growth and profit targets than other industries have been in the past, and China's capability to disrupt global value chains – even those that are higher technology in nature – is more sophisticated than it has ever been. In the past, higher technology industries could engage in technology transfer with their Chinese counterparts by offering less sophisticated technology; today, China expects to get the best.

It is important to recognize that China, unlike the U.S. or E.U., does not have a mature venture capital market. As such, the Chinese government acts as not only the policy agent to establish life science innovation hubs, but also as the primary funder of domestic R&D. This extends even to established Chinese pharmaceutical companies who, despite enjoying torrid growth, have been slow to make R&D investments. This means that the Chinese government is looking for incentives – both formal and informal – to encourage American collaborations with Chinese

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[36] "USCBC 2013 China Business Environment Survey Results," The US-China Business Council, http://www.uschina.org/media/press/uscbc-2013-china-business-environment-survey-results.

partners, regardless of the fears by U.S. companies of IP loss. American multinational life science companies understand these risks all too well, but several have been able to manage this risk while at the same time accommodating the Chinese central government's policy objectives by collaborating with Chinese Contract Research Organizations (CRO). To-date, the best example of this approach has been the partnership between the Chinese CRO WuXi Pharmatech and Bristol-Myers Squib.[37]

In these relationships, the American pharmaceutical company intentionally carves up a body of bench science work that it needs to have completed, typically related to a particular component of the drug discovery process that is labor intensive and not easily automated. This may be as specific as looking at one specific part of a larger molecule and completing the science on how that part of the molecule reacts to a variety of previously defined agents. The division of this piece of work is designed such that each piece on its own is not commercially or clinically valuable. The assembly of the completed work by a variety of strategically chosen Chinese CROs then takes place back in the pharmaceutical company's domestic market. This assembly process then allows the American life science firm to have control of the most valuable piece of the research, and to have a reasonably high degree of confidence that if IP loss specific to the molecule in question does occur, it can trace back to where this was likely to have taken place.

Over the short term, this sort of R&D segmentation is likely to be an effective tactic to address IP drift. In addition, the relative immaturity of core academic and clinical infrastructure within China means that the country will continue to lag the U.S. with respect to its ability to internalize life science IP. However, China has shown itself to be remarkably adept at moving up the value chain, even into high technology sectors such as clean-tech. As such, it would be a mistake to think that R&D segmentation via CROs will be anything more than a temporary solution. Dr. Ling Su, a leading expert on China's drug development policies, points to three types of partnerships he sees taking place between domestic Chinese and overseas pharmaceutical companies: "The first is a licensing scenario. The second is a co-development scenario. The third is even more dramatic: a joint venture is set up to develop a novel medicine in China."[38] As China's domestic capabilities expand and become more mature, life science companies will begin to structure more joint ventures focused on unique medicine development, an important step in China's push towards having a globally viable life science sector.

Among the most important protections of American life science IP are China's patent laws, which to the Chinese government's credit, have been improving. In the U.S. Trade Representative's (USTR) *2013 Report to Congress on China's Compliance with the WTO*, several outstanding concerns related to IP issues were brought forward. Specifically, the language in Article 26.3 of China's State Intellectual Property Office (SIPO) regarding levels of disclosure by pharmaceutical companies that are more burdensome and detailed than what is required in either the American or European equivalent regulatory agency. Not only is the

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[37] "Bristol-Myers Squibb to Partner with WuXi Pharmatech," *ChinaBio*, March 7, 2011, http://www.chinabiotoday.com/articles/20110307.

[38] Su, Ling, "Drug Development Models in China and the Impact on Multinational Pharmaceutical Companies," *The Food and Drug Law Institute*, September/October 2013, page 22.

information more technically exhaustive than what is required for similar U.S. or E.U. filings, but also the information must be presented when the application is first turned into SIPO. Some analysts have suggested SIPO's intentions are not malicious; rather, that the agency is in the midst of creating new law for a sector it – as a regulatory body – and the nation in general – do not fully understand. Other analysts see Article 26.3 as being intentionally designed to force technology transfer.

Regardless of SIPO's intentions relative to Article 26.3, the question of technology transfer in exchange for market access is one that is unlikely to occur within the public discourse. Rather, more companies are likely to find that among the lists of demands from the Chinese government in order for their companies to sell into the public healthcare market in China, will be the understanding that they must allocate more of their global R&D budget towards collaborations in China. These represent important, if hidden, exchanges that many life science companies feel ill prepared to counter. It is here the assistance of the U.S. government will be most important, as an agent actively seeking to protect the interests of American life science companies as they seek to navigate the China market.

Recommendations for Congress

- The policy environment China is crafting for the life science sector holds many similarities to what the country did in pursuit of a globally dominant position with respect to clean-tech. To the extent American policy makers are not content to allow China to be as successfully disruptive in biotech as it has been in clean-tech, the U.S. will need to ensure that we remain the best place to conduct leading edge research in the life sciences. This prioritization should be reflected not only in government funding, but also in addressing long-standing concerns life science companies have raised about drug development costs, commercialization timelines, FDA approvals, and patent longevity.

- Elevate the Chinese government's handling of life science companies – specifically uneven application of AML standards between domestic and foreign companies – within the context of Strategic and Economic Dialogues (SE&D). Many companies have attempted to deal with technology transfer and market access issues independent of bilateral discussions between the U.S. and Chinese governments. As the pressure on price and IP increases, the SE&D forum will become a more important focal point where the life science community needs representation.

- Review the current WTO protocols to ensure they accommodate the unique needs of the life science sector. In particular, because of the predominant role China's government plays in paying for healthcare, the *WTO Government Procurement Agreement* (GPA) needs to be revisited to ensure it provides adequate coverage for the purchase of pharmaceuticals, medical devices and diagnostic equipment by China's Ministry of Health and Ministry of Finance.

- Continue pressure on China's SIPO to modify the disclosure standards within Article 26.3 to align these with international norms. Specifically, address problems created by Article 26.3 when China invalidates patents granted prior to Article 26.3's passage. Those patents that have been invalidated should be reviewed and re-established as warranted by international standards.

- Push for revision of the SIPO language specific to "new chemical entity," a poorly defined phrase that has allowed Chinese pharmaceutical manufacturers to receive approval from the CFDA

before the six year period of protection China's IP laws establish. As currently defined, proprietary data provided by companies to China's regulators is not adequately protected from domestic competition.

OPENING STATEMENT OF ROD HUNTER
SENIOR VICE PRESIDENT, INTERNATIONAL AFFAIRS, PHRMA

MR. HUNTER: Thank you very much and thank you for the opportunity to testify today, and I appreciate your remarks as well, which set a good groundwork for the importance of China for the innovative pharmaceutical companies.

IMS, which is a consultancy, estimates that by 2017 that the Chinese market will represent $190 billion in pharmaceutical sales, making it, as I think you observed, the second-largest market in the world after the U.S.

This is the fruit of double-digit economic growth over decades, which has created a middle class of some 300 million people, and with that rising demands for social services, including healthcare and pharmaceuticals.

It also, I think, is a reflection in the reforms that we've seen over the last several years, a reflection of the rebalancing that the Chinese government has been making and indeed that the U.S. government has been urging the Chinese government to make since certainly the last decade or so.

And since 2009, they've undertaken reforms to seek to achieve universal health coverage, covering as much as 96 percent of the population by 2011. But, of course, the government recognizes, and I think we all--and the prior panel--recognize that this reform agenda is by no means complete.

And the new leadership set out in its agenda in the Third Plenum decision a series of reforms aimed at the healthcare system, both the public health hospitals, which have been the focus of some concern over corruption in the past, as well as strengthening the financing and integrating the rural and urban health systems.

This market has become increasingly important for some of the overall dynamics about the growth, but you've also seen our members make substantial investments in China over the past decade and continuing.

A recent study indicates that the international companies have been bringing as much as 8 billion RMB per year to China in terms of R&D investment, which is more than half of the R&D investment done by private businesses, including Chinese businesses, in the market.

We would expect, given the reform trajectory, the growth of the country, that that trend would only strengthen as we go forward, and particularly as China improves its healthcare system as well as the innovation ecosystem.

You quite rightly pointed out that leadership has identified in its 12th Five Year Plan the biopharmaceutical sector as a strategic sector, meaning allocation of special benefits, subsidies, and the like.

But we've also seen growth in the private sector within China where you have companies such as Luye, Shanghai Fosun, and Tasly making investments internationally and domestically and also making the R&D commitments that are necessary to become innovative companies.

Several of these companies in their public statements attest that

they're spending as much as ten percent of their revenues on R&D, not nearly as high as the U.S. based companies, but that's pretty substantial, and indeed Tasly--Tasly has a product, a cardiovascular product which is in phase three clinical trials here in the U.S., and I think this is--we certainly from PhRMA welcome this development of China becoming a center of innovation.

There are certainly plenty of ailments to be addressed, and having China's participation in meeting human needs around the world is something to be welcomed.

For all of the reforms, for all the advances that China has made over the past several years, there are some areas of opportunity to make progress, and we've noted them in the written testimony.

I'll just highlight a couple, recognizing the limits of time. In the intellectual property space, the patent system in China is largely consistent with international norms. Where we've had difficulties has been largely in the implementation and particularly around some areas of the review of patent applications.

There's a highly technical issue about data sufficiency, the data that's required to obtain a patent. It's been taken up within the context of the JCCT. The Chinese government has committed to implement consistent with international norms. This was done just in December. We hope that this will actually be implemented going forward.

Regulatory data protection. It is very important to our members. The Chinese government committed with its WTO accession to provide six years of data protection. It's formally on the books, but in terms of actual application, not so much.

One of the biggest challenges we have though is manifested in both the regulatory system and in the pricing reimbursement system. But it is reflected in the data point that it takes on average about eight years for a product that has reached the U.S. market and reached patients in the U.S., to reach patients in China.

This is partly driven by the clinical trials approval system, which is a poorly designed, long process, essentially the same process as a full approval, and with a CFDA staff that's not up to the challenges of reviewing as many applications as they have.

API, active pharmaceutical ingredients, I think you've discussed them earlier today. That, too, is a challenge, both for the global supply chain as well as for Chinese consumers.

Pricing and reimbursement. I'll just mention that while pricing and reimbursement lists are typically updated on an ongoing basis or at least on an annual basis in countries around the world, China's reimbursement list was last updated five years ago. That means in practice that you can't get drugs reimbursed and hence they don't get to patients in the market.

So while we see lots of opportunity -- it's become a very important market for our members -- China is not fully able to participate in the global innovation because of its regulatory system, and it doesn't take advantage of the full benefits of modern medicines because of the

combination of the regulatory system and its pricing and reimbursement system.

So thank you.

CHAIRMAN SHEA: Thank you very much.

Mr. Ives.

PREPARED STATEMENT OF ROD HUNTER
SENIOR VICE PRESIDENT, INTERNATIONAL AFFAIRS, PHRMA

Statement of Rod Hunter
Senior Vice President, International Affairs,
Pharmaceutical Research and Manufacturers of America (PhRMA)

Testimony before the U.S.-China Economic and Security Review Commission
Hearing on China's Healthcare Sector, Drug Safety, and U.S.-China Trade in Medical Products

April 3, 2014

Thank you for the opportunity to speak today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a nonprofit association that represents America's leading global pharmaceutical research and biotechnology companies which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

The Innovative Biopharmaceutical Industries: Economic Growth and Patient Health

PhRMA member companies are important economic drivers in the United States and globally. U.S. industry employment (direct, indirect, and induced) in 2011 totaled 3.4 million high-quality, high-paying, and high-productivity jobs, including direct employment of over 810,000 Americans.[39] The U.S. innovative biopharmaceutical industry exported over $50 billion in biopharmaceuticals in 2012, making the sector the third largest U.S. exporter among R&D-intensive industries.[40]

The U.S. innovative biopharmaceutical industry also provides substantial contributions to patient health. With nearly $50 billion invested in R&D in 2012,[41] and having produced more than half the world's new molecules in the last decade, our members are world leaders in medical research.[42] With more medicines in development in the United States than in the rest of the world combined, the United States accounts for approximately 3,400 products in development in 2013, in large part due to intellectual property (IP) protections and other strong incentives that

[39] Battelle Technology Partnership Practice, The Economic Impact of the U.S. Biopharmaceutical Industry (July 2013). Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America.
[40] U.S. International Trade Commission, Trade DataWeb, accessed July 12, 2013, available at http://dataweb.usitc.gov/ (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).
[41] Pharmaceutical Research and Manufacturers of America. "PhRMA Annual Membership Survey." 1981–2013.
[42] Battelle Technology Partnership Practice. Growth Platform for Economies Around the World. Battelle Memorial Institute (May 2012). Prepared for the Pharmaceutical Research and Manufacturers of America.

foster the environment needed to support continued research and development investment.[43]

The innovative biopharmaceutical industry contributed $94.8 billion between 2000 and 2011 towards achieving UN Millennium Development Goals, including a wide array of capacity-building interventions to strengthen local health care institutions and improve access.[44] America's biopharmaceutical companies are one of the largest contributors of funding for development of innovative cures for diseases affecting developing regions in Asia, Latin America, and Africa. In the last decade, biopharmaceutical companies provided over $9.2 billion in direct assistance to healthcare for the developing world, including donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor.[45] Further, in 2012, research-based biopharmaceutical companies were the second-largest funders of global R&D for neglected diseases: $527.2 million (up 44 % from $365.3 million in 2008).[46] (The U.S. government was first and the Gates Foundation third.)

PhRMA Support of China's Healthcare Reforms

China represents an increasingly important market for our members. Due to rising incomes, changing life styles and extended life expectancy, China's pharmaceutical market is expected to become the second largest in the world by 2017, with total sales reaching $160-190 billion.[47] Sales of innovative medicines are projected to rise 14-17 % each year through 2017.[48] Biopharmaceutical products represent a growing net export from the United States to China as well, with exports of medicines growing 28 % every year for the last 10 years to nearly $1.4 billion in 2013.[49] In 2012, China's pharmaceutical sector was valued at $81.7 billion.[50]

Beyond the importance of China as an export and manufacturing market, there is great potential for the research-based biopharmaceutical industry to partner with China in developing innovative solutions to its public health challenges. The Chinese government has prioritized growth and reform in the healthcare sector in recent years. China has committed a total of RMB 850 billion to establishing a basic healthcare security system, improving healthcare services, establishing an "essential drug" system, and exploring public hospital reform.[51] Success in broadening health insurance coverage is evidenced by the fact that 96 % of Chinese citizens were covered by one of

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[43] Adis Insight, "R&D Insight Database" (February 2013).
[44] J. Norris, et al., The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals, Hudson Institute Center for Science in Public Policy, Economic Policy/Briefing Paper (May 2013).
[45] IFPMA Survey, validated by LSE Health and Social Care at the London School of Economics and Political Science.
[46] Policy Cures 2013 G-FINDER Report.
[47] IMS Institute for Healthcare Informatics, The Global use of Medicines: Outlook Through 2017, 34 (2013) (*hereinafter* IMS Institute).
[48] Id.
[49] U.S. Census Bureau, U.S. Exports to China by 5-digit End-Use Code: 2004-2013, available at: https://www.census.gov/foreign-trade/statistics/product/enduse/exports/c5700.html (last visited: Apr. 1, 2014).
[50] Id.
[51] State Council of the People's Republic of China, Opinions on Deepening Medical and Health System Reform, (Mar. 17, 2009), available at: http://www.gov.cn/jrzg/2009-04/06/content_1278721.htm (last visited Apr. 1, 2014).

the three basic insurance schemes by 2011.[52]

China has also identified biotechnology/biopharmaceuticals as one of the seven national strategic emerging industries, meaning that the Chinese government will spend $6.3 billion supporting life sciences between 2011 and 2015.[53] In July 2012, the State Council released the Development Guidelines for the National Strategic Emerging Industries in the 12th Five-year Plan Period, laying out objectives and supporting measures to facilitate the development of biotechnology industry, among six others sectors. According to the plan, the government aims to significantly boost China's innovative drug development capabilities and expand the domestic industry foothold in the international market.[54]

More recently, China initiated the reform of its Drug Administration Law (DAL), the primary legislation governing the pharmaceutical industry in China. The DAL reform presents an excellent opportunity for China to create a more internationally harmonized, science-based framework for drug regulation that could result in a stronger innovative drug industry, including both Chinese and foreign companies, and that ensures innovative therapies reach Chinese patients sooner. In February, 2014, PhRMA submitted comments to the China Food and Drug Administration (CFDA) urging CFDA to revise the DAL in a manner that promotes innovation and patient access to safe medicines.

China's systematic healthcare reforms and strong support for a vibrant domestic innovative biopharmaceutical industry indicate a recognition that (1) innovative medicines improve the quality of healthcare and patient outcomes and have a critical role to play in helping China meet its healthcare challenges; and (2) greater investment in the healthcare system overall will substantially improve Chinese patient access to those innovative medicines and a better quality of life.

The Value of Innovative Medicines

The innovative biopharmaceutical industry is vitally important for the continued medical breakthroughs that are saving the lives of patients around the world. The improved use of prescription medicines can result in better health outcomes, lower costs for other health care services (such as the 833,000 annual hospitalizations avoided through the use of recommended antihypertensive medication),[55] and increased worker productivity due to fewer medical complications, hospitalizations, and emergency room visits.

HIV/AIDS provides a striking example of the progress made in combatting infectious diseases in

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[52] Meng, Qu, et al., Trends in Access to Health Services and Financial Protection in China between 2003 and 2011: A Cross-sectional Study, 379 The Lancet, 805-14 (2012).

[53] National People's Congress of the People's Republic of China, Outline of China's National Economic and Social Development "12th Five-year Plan," available at: http://news.xinhuanet.com/politics/2011-03/16/c_121193916.htm (last visited: Apr. 1, 2014).

[54] State Council Notice on Initiation of the 12th Five Year Plan to Deepen Medical and Health System Reform (2012).

[55] D.M. Cutler, et al. "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation." Health Affairs 2007; 26(1): 97–110.

recent decades. The discovery and development of new treatments have turned HIV infection from a death sentence into a chronic disease. In the United States alone, death rates have fallen more than 80 % since 1995 as a result of the development and introduction of multiple drugs used in innovative combinations, known as highly active antiretroviral therapy (HAART).[56] As of December 2013, there are 394 medicines in development for infectious diseases that plague many developing countries for which new treatments are needed, including: a medicine for the most common and difficult-to-treat form of hepatitis C that inhibits the enzyme essential for viral replication; an anti-malarial drug that has shown activity against a form of malaria that is resistant to current treatments; and a novel treatment that works by blocking the ability of the smallpox virus to spread to other cells, thus preventing it from causing disease.[57] Research-based biopharmaceutical companies are also hard at work developing innovative treatments for chronic diseases, with, for example, some 73 medicines in the pipeline aimed at Alzheimer's.[58] Since 1980, life expectancy for cancer patients has increased by about three years, and 83 % of those gains are attributable to new treatments.[59]

The United States leads the world in the biopharmaceutical R&D that makes this progress possible. While the United States specializes in the creation of the ideas that spur those kinds of technological developments, there are significant benefits far beyond our borders. As traditional territorial boundaries for research, science and investment dissolve, the United States' and Chinese economies are both reaping the rewards. U.S.-based innovative biopharmaceutical companies are investing in China, with, for example, increased R&D investments of 8 billion RMB per year, accounting for more than 50 % of China's large and mid-size pharmaceutical industry R&D spending and creating approximately 3,000 direct high value-added R&D positions.[60]

China's embrace of foreign direct investment (FDI), including from R&D-intensive industries like biopharmaceuticals, has contributed to its extraordinary development success in recent decades. It is well established that developing countries gain from high-quality and high-quantity technology transfers associated with FDI. Such investment brings with it new technologies, higher productivity and wages, and spillovers to other firms that spur modernization and growth. Moreover, analysis by the OECD, the World Bank and others shows that international businesses also take their FDI and R&D to countries that provide supportive IP environments.

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[56] Medicines in Development, "Infectious Diseases 2013," Presented by the Pharmaceutical Research and Manufacturer of America, available at http://www.phrma.org/sites/default/files/pdf/MedsInDevInfectiousDiseases2013.pdf (last visited Apr. 1, 2014).
[57] Id.
[58] Medicines in Development, "Alzheimer's Disease 2013," Prepared by the Pharmaceutical Research and Manufacturer of America, available at http://www.phrma.org/sites/default/files/Alzheimer%27s%202013.pdf (last visited Apr. 1, 2014).
[59] E. Sun, et al. "The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database." Journal of Clinical Oncology 2008; 26:15S (May 20 Supplement): Abstract 6616.
[60] China Association of Enterprises with Foreign Investment R&D-Based Pharmaceutical Association Committee, Building an Innovation-driven pharmaceutical industry in China, 34 (2012) (hereinafter RDPAC).

A recent study by economists Robert Shapiro and Aparna Mathur examined the economic impact of India's current approach to IP rights, as it affects pharmaceutical products and FDI. In comparing the IP regime in India to that in both China and the United States, the authors found that under an IP regime comparable to China's, the increase in FDI to India would result in economic expansion, thousands of additional jobs in the pharmaceutical sector, and a quantifiable increase in access to innovative new drugs for Indian patients.[61] This is not to say that China's innovation environment is ideal (a matter further discussed below). It does provide, however, an informative comparison of two countries with significant health care challenges, burgeoning populations, and substantial goals for economic growth. Of the two, only China recognizes the value of the research-based biopharmaceutical industry – both global and domestic – in helping the country achieve sustainable solutions.

The U.S. economy also benefits from FDI outflows. Research shows that FDI is associated with high U.S. domestic investment and employment or wages as parent companies expand their headquarter operations to service their expanding foreign operations. This is due to the fact that financial resources and production capacity of multinational firms respond to profit opportunities both at home and in other countries through global networks and investments in a foreign market often stimulate demand for goods and services. Economists found a 10 % increase in a multinational's FDI was associated with a 2.6 % increase in their domestic U.S. investments between 1989 and 2004. Similarly, an increase in the wages and other compensation paid by foreign subsidiaries of U.S. multinationals corresponded with an increase in the wages and other compensation paid to those firms' American employees. Finally, higher FDI by U.S. firms is also linked to higher exports by those companies to their foreign affiliates and higher domestic R&D spending.[62]

China's integration into the global biopharmaceutical R&D network is key to the long-term

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[61] Annual pharmaceutical FDI flows to India would grow from $1.5 billion in 2014 to $8.3 billion in 2020, and that increased FDI would generate some 18,000 additional jobs in the pharmaceutical sector by 2020. There is also a relationship between the IP regime of a country and pharmaceutical R&D in that country: if India improved its IP regime to the level comparable to China's, innovative pharmaceutical R&D in India would double from 2014 to 2020, rising from $645 million to $1.3 billion. Finally, the authors estimated that if India adopted an IP regime comparable to China, its access to new innovative drugs should increase by about 5 %. Shapiro, R. and Mathur, A., "How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the IP Rights of Foreign Pharmaceutical Producers," Sonecon, LLC (Jan. 2014), available at http://www.sonecon.com/studies.php (last visited Apr. 1, 2014).

[62] See Desai, M., Foley, F., and Hines, J. R. Jr. (2005). "Foreign Direct Investment and the Domestic Capital Stock."
American Economic Review Papers and Proceedings 95(2), 33-38; Desai, M., Foley, F., and Hines, J. (2008).
"Domestic Effects of the Foreign Activities of U.S. Multinationals." Ross School of Business. Paper No. 1020,
http://papers.ssrn.com/sol3/papers.cfrn?abstract_id=825264 (last visited Apr. 1, 2014).

growth of the market. Further, multinational pharmaceutical companies are helping to build innovative local Chinese companies by developing expertise, seeding talent, and taking them global. The medicines developed by these new Chinese innovators will benefit Chinese and U.S. patients alike.[63] Indeed, finding new and innovative treatments for diseases such as cancer, diabetes, and Alzheimer's disease, is, and should be, a global endeavor.

Building a Biopharmaceutical Innovation Ecosystem in China

Despite these many opportunities, PhRMA's members still face market access challenges in China.[64] As China pursues its goals for improving health care and building a domestic biopharmaceutical industry, the key to achieving both is innovation. Innovation in the biopharmaceutical industry requires a policy environment that protects IP rights, a 21st century regulatory framework that ensures drug quality and safety, and a health system that rewards innovation and provides timely broad patient access to novel therapies.

Protecting IP Rights

The fundamental component in the innovation ecosystem is IP protection. IP is the lifeblood of any enterprise that derives value from ideas. It takes more than a decade, and well over a billion dollars, to bring a new medicine from the lab to the pharmacy, and companies that pursue this work need assurance of a fair opportunity to recoup their investment.[65] A robust IP system provides the assurance innovators need in order to attract the capital and make investments necessary to develop new products and technologies.

China has implemented an IP regime largely aligned with international systems, but some concerns remain regarding patent examination procedures specific to pharmaceutical patent applications, effective patent enforcement by the regulatory agency, and China's implementation of its international obligation to provide regulatory data protection (RDP). Specific recommendations include:

- Data Sufficiency: Ensure that originators are always permitted to submit post-filing data to the State Intellectual Property Office to support their pharmaceutical patent applications;
- Effective Patent Enforcement: Establish procedures for originators to submit patent information to CFDA and for notification to the originator when CFDA is considering approval of a potentially infringing follow-on product; and
- Regulatory Data Protection: Clarify the scope of RDP and provide public access to information about which products enjoy RDP and the duration of that protection.

Establishing a 21st Century Regulatory Framework

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[63] For example, the Tasly Group, based in Tianjin, is successfully bringing their products through Phase II and III clinical trials in the United States. See http://www.tasly.com/en_web/about_tasly.aspx (last visited Apr. 1, 2014).
[64] For example, innovative medicines are not available to most Chinese patients until eight years on average after they reach the same population in the United States. RDPAC, 42-43 (2012).
[65] J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, The Price of Innovation: New Estimates of Drug Development Costs, 22 J. Health Econ., 151–185 (2003).

A second component in the innovation ecosystem is the establishment of a 21st century regulatory framework. The regulatory approval system should be expeditious. The regulatory system also needs to be predictable, consistent, and transparent. Innovators need to know in advance the criteria and procedures that guide the process and all stakeholders should be able to understand the rationale for the decisions that follow. The system needs to be scientifically rigorous. This requires expertise related to the constantly evolving science and commitments that regulatory standards are up-to-date and applied uniformly.

China has made progress in strengthening its pharmaceutical regulatory framework. However, to establish a framework that is harmonized with international standards and best practices, additional efforts are needed to address CFDA's institutional capacity, clinical trial application and drug registration review processes, and the production and sale of unregulated active pharmaceutical ingredients (APIs) used to manufacture counterfeit products. Specific recommendations include:

- CFDA Capacity: Improve institutional capacity of CFDA by increasing financial and human resources that reflect the current workload of CFDA;
- Clinical Trials:
    - Distinguish between requirements for approval of CTAs and registration applications;
    - Introduce efficiencies in the CTA review process by adopting clinical data requirements that are in line with international standards, such as the International Conference on Harmonization (currently, CTA approvals in China can take 10 to 18 months, which is much longer than average international practice[66]); and
- APIs: Establish a more comprehensive regulatory regime for API registration and implementation of good manufacturing practices according to internationally recognized standards as well as the adoption of an internationally recognized system of serialized verification of APIs.

Rewarding Innovation and Providing Timely Reimbursements

A further component of the innovation ecosystem is a health system that rewards innovation and provides timely, broad patient access to novel therapies. Transparent and predictable government pricing and reimbursement systems at the central, provincial, and local levels would improve patient access to new, safe and effective treatments. It would also allow business planning for long-term supply of medicines and encourage investment in R&D.

Despite China's significant achievements in expanding patient access to health care, there remain several issues in the government's current pricing and reimbursement systems that affect both patient access to new medicines and investment in innovation and quality. Specific recommendations include:

[66] See RDPAC, supra, note 22.

- Drug Pricing: Establish pricing mechanisms that adequately allow for direct and open negotiations between sellers and buyers and that are regular, predictable, and timely; and
- Drug Reimbursement: Conduct a timely and predictable update to the National Reimbursement Drug List (NRDL) (under the current government guidelines, the NRDL should in principle be updated every two years; however it last updated in 2009) and establish a regular communication and consultation channel between the appropriate authority and industry.

Conclusion

As nations around the world compete for investment in R&D, China must make policy changes to take advantage of innovation-driven growth. Building on the considerable progress China has made in recent years, PhRMA urges China to develop an ecosystem to support biopharmaceutical innovation. PhRMA welcomes the opportunity to work with the U.S. and Chinese governments to achieve a shared vision of China as a leading global innovation partner and to reach our joint aspirations for the benefit of patients.

OPENING STATEMENT OF RALPH IVES
EXECUTIVE VICE PRESIDENT, GLOBAL STRATEGY AND ANALYSIS, ADVAMED

MR. IVES: Thank you, Chairman Shea and Vice Chairman Reinsch and distinguished Commissioners. I greatly appreciate the opportunity to be here.

I had the opportunity to listen to the earlier testimonies and I found it very interesting and a very good foundation for the major issues you'll be discussing here today.

AdvaMed members produce medical devices, diagnostic products and health information systems. I passed around this little brochure, and this brochure came from actually when I was at USTR.

The medical device industry came to discuss these issues with me, and I did not have a clue about what they were talking about. So I vowed once I came to AdvaMed that at least by showing some of the pictures that my ignorance of what medical devices are would not be allowed to continue to fester. So I hope this diagram and some of the pictures help in explaining what we're dealing with.

AdvaMed members range from the largest companies to very smallest. About 75 percent of our members are small and medium-sized enterprises. The United States has somewhere between six and 7,000 medical device companies. Most of these are very small companies.

The U.S. medical technology industry is the most innovative and competitive in the world. Americans invented this industry. The United States has consistently enjoyed a trade surplus in medical technology.

China has become one of our members' largest and fastest growing markets. My written testimony contains estimates of size, growth rates, and bilateral trade.

I also listed several factors that explain this rapid increase, including: China's fast economic growth and expanding middle class; the Chinese government's focus on improving the healthcare of its people; and China's aging population.

Our members export to and invest in China.
Along with these opportunities, of course, come challenges. China's regulatory agency, the CFDA, has become more sophisticated and demanding in its requirements.

While our industry sees improvements in the CFDA, we believe that we have developed a cooperative relationship with this agency.

The next few years will be pivotal in China's regulatory system. China has just approved a major revision in its medical device law, and it is likely to have significant impact on our industry. We hope to work with CFDA in the implementation of this new medical device law.

Another policy area in which we are working with the Chinese officials concerns payment systems for products. Most medical technology is sold to hospitals and clinics.

The Chinese government is highly focused on controlling

government healthcare costs and has instituted requirements that hospitals and clinics must acquire most of the medical devices through consolidated tendering at the provincial level.

We are seeing policies that are troubling for imported medical devices, including price ceilings and even prevention of some imported products from competing in tenders.

We have raised our concern with provincial tendering officials and with the U.S. government. We hope that we can change China's direction on this issue.

Intellectual property. The protection of IP is important to our industry. Our written statement identifies three categories of IP concern to our members.

Addressing IP in China is a difficult issue, as other industries and the U.S. government have experienced over many years of trying. We don't have an answer.

Ethical business practices. A fourth area of focus for our industry in China is business ethics. We aim to ensure that healthcare decisions are made in the best interests of the patients.

AdvaMed has a voluntary Code of Ethics -- has had one for many years -- and our members must abide by a number of anti-corruption laws, including, of course, the U.S. Foreign Corrupt Practices Act.

We are striving for increased cross-border harmonization of business ethics and compliance issues in China and other markets. We believe this is essential to create a level playing field for our industry in China and around the world.

In conclusion, our members experienced rapid sales growth in China and see opportunities for more. However, we remain concerned about a possible move toward more protectionist policies for indigenous medical technology companies, especially in provincial level purchasing.

AdvaMed remains highly committed to China, and we hope that the U.S. government also continues its high degree of engagement to support our industry in China.

Thank you.

CHAIRMAN SHEA: Thank you very much to all three of you.

The first question is from Commissioner Wessel.

PREPARED STATEMENT OF RALPH IVES
EXECUTIVE VICE PRESIDENT, GLOBAL STRATEGY AND ANALYSIS, ADVAMED

Testimony before the U.S.-China Economic and Security Review Commission
Hearing On China's Healthcare Sector, Drug Safety,
and the U.S.-China Trade in Medical Products
April 3, 2014
By
Ralph F. Ives
Executive Vice President
For Global Strategy and Analysis
Advanced Medical Technology Association (AdvaMed)

Introduction

My name is Ralph Ives. I am the Executive Vice President for Global Strategy and Analysis at the Advanced Medical Technology Association (AdvaMed).

AdvaMed is the world's largest medical technology association. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. By medical technology, I am referring to medical devices, like catheters, pacemakers and orthopedic implants; imaging equipment, such as MRI, CAT scan and X-ray machines; and *in vitro* diagnostics, including tests for conditions like diabetes, cervical cancer and HIV. While our membership includes large multinational companies, about 75 percent of our membership comprises small and medium-size enterprises.

The U.S. medical technology industry is the most innovative and competitive in the world. Americans invented this industry. The United States has consistently enjoyed a trade surplus in medical technology. Our industry employs about two million Americans, directly or indirectly, in well-paying jobs. When I was recruited from the Office of the U.S. Trade Representative for my position at AdvaMed, I was told that this is an industry of which I could always be proud.

I am in charge of AdvaMed's overseas advocacy. In that capacity, my job is to seek fair, reasonable and non-discriminatory foreign government policies on regulatory, payment and other market access programs affecting our members' ability to provide patients the best medical technology available for their respective needs.

China Medical Technology Market

China has become one of our members' largest and fastest growing markets, though the total size of the medical technology market there remains much smaller than that of either the U.S., Europe or Japan. To put the roughly $12 billion Chinese market for medical technology in perspective, the approximate market sizes elsewhere for medical technology in 2013 were, respectively: over

$115 billion in the United States; about $70 billion in Western Europe; and over $30 billion in Japan (our largest overseas market for a single country). However, estimating the exact size of these markets is difficult because of the variety and complexity of medical technology, with estimates of the number of products in the hundreds of thousands.

The medical technology market in China has grown rapidly – consistently by double digits for the past decade or so – and it is projected to continue to do so. For example, the medical technology market in 2006 was about one-third the size of today's market in China, and it could expand by 40% over the next three years.

U.S. bilateral trade with China has increased along with China's demand. In 2012 our exports from the U.S. to China were estimated at roughly $1.7 billion, with strong growth projected to continue for the foreseeable future. The USITC has estimated that orthopedics, cardiovascular and imaging sectors are the largest drivers, accounting for roughly 25% of the growth in U.S. exports to China.

These exceptional growth rates – in Chinese demand for medical technology and our bilateral trade – are due to several factors. Of course, the most obvious contributor is China's rapid economic growth and burgeoning middle class. Various estimates put the Chinese middle class at over a quarter billion people. When people have more income and wealth, they want better health care.

Another important stimulus for the demand for medical technology is the Chinese government's focus on improving the health care of its people and commitment of funds to do so. In April 2009, China announced an ambitious health care reform plan of comprehensive measures to increase access to health care – including broadening insurance coverage, building new health care facilities, increasing government spending, training medical personnel and increasing the role of information technology. This overarching health care reform plan has been implemented to rebuild in China a social safety net for medical services. Under this plan, all citizens have been promised access to basic health care services by 2020, and some reports indicate this goal is close to being achieved. The Chinese government pledged to spend $125 million over three years. A high-level of spending continued after 2011 to help meet the 2020 goal.

A third factor is China's aging population. By 2020, the country's population will actually start to decline. As some have observed, the trend for the population to age and decline before the nation as a whole is wealthy has many implications for China and the world. Just as health care needs tend to rise with age, so does the demand for innovative and high-quality medical technology. This provides an important opportunity for the medical technology industry.

AdvaMed members also invest in China. They build manufacturing plants, establish R&D facilities and purchase Chinese companies. The Chinese market is important because of its size, of course, but also because it can serve as an export platform to other markets, especially in Asia, and as a source of components.

Policy Challenges

Regulatory

As China's medical technology market has grown, so has the sophistication of its regulatory system. China, like the United States, wants to ensure that the medical devices reaching its patients are safe (they won't hurt people) and effective (they perform as intended). These are essentially the same fundamental criteria used by the FDA in the United States.

AdvaMed and its member companies have developed a cooperative relationship with what was, until last year, called the State Food and Drug Administration in China; it is now the Chinese Food and Drug Administration (CFDA). We have been working with CFDA officials to urge their use of internationally recognized, best regulatory practices in their pre-market approval and post-market surveillance systems. In addition, we have pressed for the transparent development and implementation of new regulations; that is, we have been asking for advance publication of proposed regulations, adequate time to provide comments, and reasonable transition periods before the regulations go into effect. We believe we are making progress on most of these issues.

The next few years will be pivotal in China's regulatory system. China has just approved a major revision to its medical device law (previously called Order 276) and we are awaiting the public release of this law. This revision creates a significant opportunity, and also significant risk for our industry.

It is expected that the revision to this law will impact all aspects of China's regulatory system (clinical trials, testing, inspections, evaluations, re-registration, post-market surveillance, etc.). We have already seen more than 20 new requirements with significant impact to our industry over the past year, and expect to see hundreds more as the revision is implemented. So far, China has been receptive to industry suggestions and proposals on these draft requirements and we hope that the revision of China's medical device law continues to be used to modernize the registration procedures, making them more efficient and effective.

An example of a new requirement that is "in play" in China is China's implementation of Unique Device Identifiers (UDI) for medical devices. In simple terms, this is a bar code that will be required on all medical technology products. The purpose of UDI is patient safety – to allow regulators to identify devices throughout distribution and use. For this system to function on a global basis, we need those countries that plan to adopt a UDI system to embrace a common approach. The U.S. FDA recently implemented a UDI rule in the U.S. with estimated costs to AdvaMed members in the millions of dollars.

Fortunately, the U.S. rule is based on international standards – in conjunction with the International Medical Devices Regulators' Forum (IMDRF). The EU is developing similar requirements which would also be based on international standards. We are concerned that China is contemplating a "home grown" UDI system that would not be consistent with the global approach, and that would require our companies to employ china-specific approaches throughout the supply chain. This would be very costly – not only for our firms but also for Chinese companies. More importantly this would undermine patient safety.

We have asked the U.S. government to work through the Joint Commission on Commerce and

Trade, the IMDRF (of which China is a member) and other mechanisms to encourage China to make a commitment that its future UDI system will be based on international standards. We believe it is in China's interest, as well as our industry's interest, to do so.

Payment

As in many countries, there are a variety of ways medical technology manufacturers are paid for their products. Most medical technology is sold either directly or indirectly to hospitals and clinics. These providers may, in turn, be reimbursed by the patient, private insurance or the government. Different countries use varying mixes of these basic systems.

In China, the vast majority of health care has always been delivered through public (government-owned) hospitals and clinics, and the government has always been the primary stakeholder in the payment system. As in many countries around the world, the Chinese government is highly focused on controlling government health care costs. To this end, China has instituted requirements that hospitals and clinics must acquire most of the medical devices they use through consolidated tendering – which is often conducted at the provincial level.

We are increasingly seeing policies that are troubling for imported medical devices. For example, some provinces are requiring foreign manufactures to provide the import price of the product as a condition for entering the tender, and these prices create a ceiling price. There is no such limitation placed on the prices of domestic medical technology, which can be sold at lower prices because of lower costs – including manufacturing, transportation, research and development expenses – and a lack of service.

In some other cases, provincial officials are banning competition by foreign manufacturers for certain product lines. This policy obviously places U.S. medical technology at a disadvantage to domestic firms.

We have raised our concerns with provincial tendering officials, stressing that these practices will limit patient access to the best available medical technology. We have also alerted the U.S. government – the U.S. Trade Representative, Department of Commerce and U.S. Embassy – which is assisting us in our efforts. We hope we can change China's direction on this issue.

Intellectual Property

The protection of intellectual property is important to our industry, which spends an estimated 11% of revenue on R&D – second only to the pharmaceutical industry. Our industry is highly innovative, with the lifecycle of a medical device averaging about 18 months, which is similar to that of a smartphone.

The complexity of medical technology and the relatively rapid innovation cycle offer some degree of protection. Also, the good reputation of U.S. medical devices and diagnostics companies creates an obstacle to piracy. However, as Chinese manufacturers move up the value chain and export more of these products overseas, our members' concerns will intensify.

Our members' IP concerns primarily fall into three main categories. First, Chinese products appear to make use of our members' IP. Such products can sell at a lower price, since they did not entail the same level of R&D costs. This can be a problem in China and in other countries – mainly other emerging markets.

Second, we are seeing Chinese products that look like U.S. products but that do not function like U.S. products. When these make it to market in China, the U.S. or other global markets it creates a threat to public health, and a threat to our members' global reputations.

Third, in the regulatory/registration process in China, our companies are required to submit much more proprietary data to government and government-affiliated organizations than is required in other major markets. We hope to gain greater clarity into the policies governing the collection and protection of this data.

Ethical Business Practices

A fourth area of focus for us in China is business ethics, with the aim of ensuring that health care decisions are always made in the best interests of patients. AdvaMed has had a voluntary Code of Ethics for many years, and our members also abide by a range of anti-corruption laws including the U.S. Foreign Corrupt Practices Act and similar laws of trading partner nations. However, increased cross-border harmonization of business ethics and compliance efforts is essential to creating a level playing field for our industry in China and around the world.

We are working with our members in China on compliance and ensuring that our Code reflects Chinese laws and practices. We also have a memorandum of understanding with the Chinese Medical Device Industry Association to work together on a China-specific code. This effort will help promote practices that assure that the choice of one medical treatment or medical technology over another is made strictly with the interest of the patient in mind, and will also help ensure our industry's long-term reputation and success in China. Our work in China is part of a global effort to see a convergence of codes in the Asia-Pacific region and Latin America.

Conclusion

Our members have experienced rapid sales growth in China. We see opportunities for more. However, we are concerned about a possible move toward more protectionist policies for "indigenous" medical technology companies. AdvaMed remains highly committed to China, and we hope that the U.S. government also continues its high degree of engagement to support our industry in China – ensuring that China lives up to its global trade commitments and pressing for a level playing field for U.S. companies in this critical market. That would be our main messages to this Commission.

PANEL II QUESTION AND ANSWER

COMMISSIONER WESSEL: Thank you, Mr. Chairman, and you may not have appreciated the products when you were at USTR, but I find as I age I am increasingly appreciative and utilize your products. So I have more familiarity with them than I'd like.

Mr. Shobert, just a quick question, and perhaps you should have some government service as well since I got a diplomatese term. You talked about "IP drift." Do you mean IP theft?

MR. SHOBERT: Yes.

COMMISSIONER WESSEL: Okay.

[Laughter.]

COMMISSIONER WESSEL: Just wanted to check because it's a new term. I'm just getting used to Twitter so I want to know that I'm dealing with things correctly.

MR. SHOBERT: You're actually in good company.

COMMISSIONER WESSEL: What's that? Okay. [Laughter.]

COMMISSIONER WESSEL: Mr. Hunter and all the panelists were talking about--and the $369 billion figure was used--there's a bilateral flow here, and I know on the later panel we're going to deal with safety, but can you help me with sourcing issues relating to your members and, then, Mr. Ives, to yours as well?

How many suppliers are your members dealing with, as far as you know? What steps can an individual U.S.-based company take in terms of assessing the security of the supplies, the quality of the supplies, et cetera?

Do you have to take on a partner in China, as we have the JV requirements, as you know, in so many other areas--getting to the IP drift issue, as well? And as you look at those supply chains, with China, I know in the DSHEA field, the--

CHAIRMAN SHEA: That's D-SHEA, D-SHEA.

COMMISSIONER WESSEL: D-SHEA.

CHAIRMAN SHEA: Right.

COMMISSIONER WESSEL: It's DSHEA, but we'll give you some credit. On the dietary supplement side of the equation, there's a significant amount of Chinese-sourced products coming into our supply chains. Are the products that you are selling in China, are they being produced in China or are they being produced in the U.S., and the same thing for the medical devices?

So do you have sort of a local-produced- and-sell-there policy? Do the products that are produced in China by your members, are they sourcing back to the U.S., sourcing to China, or other markets? Are there any differentials, if you will, in terms of all the supply chains? And what's the size of the bilateral relationship, not just the opportunities in the Chinese market?

I know that's a lot of questions, but trying to really understand

the supply chain issue.

MR. HUNTER: Those are interesting questions about the structure of the market, and I'm afraid I'll disappoint in not knowing the data. We can track a lot of that down. Consultancies such as IMS generate a lot of these data.

The real value in the innovative pharmaceutical part of the business is in the innovation. The manufacturing is not, for the small molecules, where the greatest value is. Biologics is quite different. Biologics are, of course, much more challenging products to generate, to produce in a reliable and safe way.

These are just some general observations, but I think as you look at global supply of pharmaceuticals, you'll find that a lot of the R&D is actually done for U.S. companies, European companies, is actually done in the U.S. because that's where the clusters of expertise are (up around Boston and other places in the U.S.), and that the production is done in a lot of other countries.

Now, I don't know the strategies of each of the companies although certainly the number I mentioned about the R&D investment is also reflected by other investments in the markets, both in terms of production and the distribution, the sales and distribution teams within those countries, within China.

So I'll have to see if we can track down some useful data.

COMMISSIONER WESSEL: If you could, please.

MR. HUNTER: But it's not a produce-a-widget-here/ship-it-there model.

COMMISSIONER WESSEL: Right.

MR. HUNTER: It's much more like a lot of businesses these days, it's much more disaggregated.

COMMISSIONER WESSEL: But just following up with data would be very helpful because part of this also goes again to the next panel about concerns about safety. Our concerns, of course, should not only be for the Chinese people, but for our own citizens.

So if one of your companies, Pfizer, Merck, etc., is producing Crestor in China and selling it in China, there's the U.S. issue about IP and some other issues, and hopefully access to the market, but we don't have the safety concerns for an import into the U.S.

So understanding the sales and sourcing issues, and the size of the market, are we talking exports, which is both an opportunity as well as desire of the administration in all business, or is it producing there because that's what China is requiring?

MR. HUNTER: I think we'll find when we get you the data that a lot of it is production for China.

On the global supply, and particularly to the U.S., I think all of us recognize the importance of not just the U.S. regulatory system but also the liability system which always focuses the minds of senior managers.

So I think the companies are obviously all over their supply chains, but they do have concerns about the strength of global supply chain regulation, and hence the concern that we've all reflected, and I suspect that the FDA official also probably talked about concern about API regulation, effective API regulation, which particularly since the Chinese APIs go not just here but all over, and they go to India, and then to here or elsewhere.

You asked about supplements. You know supplements aren't something that are really--

COMMISSIONER WESSEL: No, no, I was referring just to the size it posed--

MR. HUNTER: That was an example.

COMMISSIONER WESSEL: --not for you to respond to.

MR. HUNTER: Right. Okay.

COMMISSIONER WESSEL: As it relates to, and as I recall, the FDA acronym for the safety or the inspection is GMP; is that right? Is the Chinese inspection process of facilities the same in its rigor as the FDA's rigor?

MR. HUNTER: Nobody has a system as extensive as FDA's. The European system is quite strong, but it's a different kind of system and maybe not as intense as the FDA system, different methodology.

China's, I think it would be fair to say, isn't in the same league, and this is a conversation I was having with one of your fellow Commissioners earlier. One of the challenges that China has is building the state capacity of a modern regulatory state.

Even our experience is a relatively recent one of the last several decades that we've built an FDA capacity to the extent that it has now. China is having to do this all within a period of a decade. CFDA is not very well-resourced, either in terms of numbers of people or financially. A lot of the enforcement has to be done at the local level and the regional level where, of course, the authority and incentives may be differently aligned. So I think those are some of the challenges.

And part of the reason why -- and I think you may have alluded to something like this -- one of the reasons why there's been such demand for international pharmaceuticals is there is a recognition of the quality of the products, where because of the weakness of the regulatory system, people don't have the same assurance that Chinese-company-produced pharmaceuticals are of the same quality, even if it's the same molecule.

COMMISSIONER WESSEL: I see my time has expired, but if there's more time.

CHAIRMAN SHEA: Sure.

COMMISSIONER WESSEL: And I do want the follow-up information because I'd hate to have Crestor -- as a product if it's produced in China the standards aren't the same -- it could denigrate those customers who use it around the world--their interests.

CHAIRMAN SHEA: Yeah, I'm going to follow up. If you're going to give us some follow-up information, Mr. Hunter, I'd appreciate it.

I'd appreciate it if you'd take a look at Roger Bates' written testimony to this Commission. He submitted some written testimony for our last panel, and he's from the American Enterprise Institute so as someone with a Republican heritage, I kind of listen to what this guy has to say.

And he says, he quotes a professor in China. He says that the "data show that American and European pharmaceutical companies are misinformed about the identity of the manufacturing site of 39 percent of drug substances they purchase from China." He says that "most alarming, over 90 percent of the audits I have seen of Chinese drug substances bought by Western purchasers are conducted after purchase," which he finds alarming.

And then he says "large manufacturers of inferior quality chemicals are not sanctioned, indeed China's FDA does not have the capacity to assess the products it makes for export nor apparently does any other Chinese agency. U.S. FDA conducts inspections, but it only inspects known pharmaceutical production sites once a decade."

And we learned today they only have two-and-a-half FTE currently employed for inspections.

And then he says the only way to improve product quality in the short-run is for U.S. manufacturers to improve their supply chain quality.

So if you could, you don't have to answer now, but I know that's not why you're here, to talk about supply chain. But if you could look at that and kind of respond to some of his points, that would be appreciated.

Mr. Shobert, you said, just something in your testimony that struck me. You say "the policy environment China is crafting for the life science sector holds many similarities to what the country did in pursuit of a globally-dominant position with respect to clean-tech."

Could you explain that, please?

MR. SHOBERT: Yeah, as the Commission is all too familiar with, when China sets its eyes on a particular sector that it wants to see become a domestic champion, it goes about crafting a whole spate of policy incentives, one of the most basic of which is just the amount of money that's allocated in pursuit of the goal.

So what China has the potential to do, and this is a question that we're actually looking into at the NBR as part of a two-year project is what is China in pursuit of and how does that have the potential to disrupt the global life science sector?

Now, there are some important dissimilarities. Specifically, the life science sector today is already an economic engine for the United States. Clean-tech held the potential to become a part of our economic renaissance, especially in the post-2008 era where we were looking for new high-technology industries that were going to drive growth.

Life sciences are today. And so that poses a very interesting question, given where we are in the U.S.-China relationship. Historically, one of the ways that we've been able to sustain the U.S.-China relationship during moments of difficulties has been by pointing to the mutual benefit

and also the likelihood that high-technology sectors were going to be the ways that we outcompeted China.

As you start to see more bench science get reallocated away from the United States, as you start to see more precommercialization, basic technology analysis, drug discovery, take place in China that could have been done in the United States, you begin to alter the question about globalization. You begin to change a very fundamental component to what has sustained the relationship.

So what we're trying to look at, and we don't have good answers for you today, we're trying to look at specifically what are the cohorts of subsidies, of funding, academic partnerships, the incubators, the specific strategies that are being pursued at these 20 new incubator sites located across the country? The cynical way of looking at those incubator sites -- and this will definitely be the case with a lot of the capacity that gets built -- is those are simply boxes that are getting checked by municipal leaders as part of their annual attempt to get promoted.

But the more long-term opportunity there is that that could be one of the first steps that's taken to actually develop a robust domestic R&D capability that's going to rival what we have in the United States.

CHAIRMAN SHEA: Thank you very much.

Commissioner Vice Chairman Reinsch.

VICE CHAIRMAN REINSCH: Mr. Hunter has--

CHAIRMAN SHEA: Oh, I'm sorry.

MR. HUNTER: If I could comment on that, that train of thought. Surely, the Chinese government has designated this sector as a strategic sector. I mean it's strategic, but this isn't like the IT sector, which I used to work in, where there were also an overlay of security concerns. So that makes it a little bit different.

Second, it's worth remembering that the pharmaceutical sector not that long ago used to be largely a European-based industry, but it migrated. Not because of a series of specific policies aimed at attracting it to the U.S., but it migrated to the U.S. largely because the ecosystem for innovation was much better here.

And that's a combination of a bunch of things which are very difficult to put together; everything from the intellectual property incentives to the relationships with something like the NIH, the universities, the regulatory system, and a regulatory system that's aimed at bringing innovations to patients, and also the pricing and reimbursement system so the financial reward at the end of the day.

Now, it's possible that China can build that, but that's a massive undertaking that it's hard to create just purpose built. Now, perhaps they can subsidize their way to get there, but--maybe. It will be a challenge.

CHAIRMAN SHEA: Sure.

MR. SHOBERT: Yeah, on that point, I think that's a great point, and the person who has driven deepest into the question of whether or not the national economic development model-- the mercantilist model that

China has pursued -- will be effective is Joe Wong. —

One comment to reinforce what was just said, whether or not they will be successful is very important. They will be disruptive. Whether or not they will be successful at actually building this capacity and how that will matter, that's what we don't know right now.

CHAIRMAN SHEA: Thank you.

Vice Chairman Reinsch.

VICE CHAIRMAN REINSCH: Thank you.

I'm encouraged to hear from Commissioner Wessel that somebody here has used more of Ralph's products than I have, and I think that's a contest I intend to lose.

COMMISSIONER WESSEL: We haven't quantified that.

VICE CHAIRMAN REINSCH: Well, we'll have our own sidebar later about that.

I don't know Mr. Shobert, but I do know Mr. Hunter and Mr. Ives, and I want to take the opportunity to thank you for your service to the government when you provided it and also for your continuing interest in good public policy. I think you're both to be commended for that and thanks for coming today.

Mr. Ives, I'm interested in the IP issues. I was looking at your written statement where you alluded to the different categories of IP drift, or theft, whatever we're calling it, that you've identified. And I'm curious in the case of the first two, which are I guess Chinese incorporation of your members' IP into their products; and second, the products that look the same but, in fact, are not the same. What are the remedies that your members have employed in those circumstances in China and what degree of success have they had with those remedies?

MR. IVES: Thank you, Chairman Reinsch, and thank you for your earlier comments.

We have a somewhat different innovation model than pharmaceuticals, and I appreciate Rod taking most of the questions. The innovation model in medical devices is roughly, on average, every 18 months a new medical device comes out so it's a much faster model than drugs, and I won't try to say what Rod would say in terms of the length of a patent. I think it's around probably about 13, 14 years once you get the patent protection.

So that's point one. There's a faster innovation model so it's less opportunity to steal IP.

Secondly, there's enormous complexity in the medical devices, and those pictures are just kind of an example, and we're talking about hundreds of thousands of medical devices. So with a faster innovation model, enormous complexity. There's various patents. It's usually our medical devices do not rely on a single patent, and then you have a blockbuster thingie that's multiple patents over a multiple year period.

And finally, as I indicated in my testimony, the medical devices, particularly the high value medical devices, are sold directly to the

hospitals, and the sales rep, the distributor develops a relationship with a physician, with the hospital, so they know when Company X, one of our members, is selling a medical device. They can rely on that being the medical device.

So those are basically three areas where I think medical devices has somewhat of an advantage over the pharmaceutical or maybe even some of the other industries.

Thank you.

VICE CHAIRMAN REINSCH: I'm still not getting the sense of what remedies your people employ when they run into a problem.

MR. IVES: The remedies. They so far have not wanted to pursue these in terms of--back to my old haunts--USTR. And they have done a number of things. One, their supply chain is very, very sophisticated. Two, they have raised their concerns with the Chinese government officials. And thirdly, when they find these products in the United States, they go to U.S. officials and enforcement officials. So that's the way in terms of particularly products coming into the United States.

And the third, they're particularly concerned about one of the ways in which intellectual property has drifted--is that a verb?--is we're very concerned about products that may look like Company X's product, but it does not perform like Company X's product, because that means there is patient safety at stake. So that's where our companies get particularly anxious, go to authorities, and try to prevent that product from either coming into the country or getting into the U.S. supply chain.

VICE CHAIRMAN REINSCH: In those circumstances, have they found Chinese authorities cooperative?

MR. IVES: To the best of my knowledge, they are cooperative in the sense they say the right thing. As Rod said, there's a lot of--I think you said it--but in terms of implementation of intellectual property protection, and that's difficult. They do find U.S. authorities very receptive when they find the products in the U.S.

VICE CHAIRMAN REINSCH: Okay. I've got more, but I'll save that for another round. Thank you.

CHAIRMAN SHEA: Commissioner Fiedler.

COMMISSIONER FIEDLER: At least in pharmaceuticals--and medical devices, I'm less-- actually I'm not particularly knowledgeable about any of it, but the customer in China in terms of market access is the government; right?

And China hasn't signed the Government Procurement Agreement that they promised to 13 years ago when they came into the WTO. So you've got a problem: they don't have to let you in; right?

Are you looking for a carve-out from the Chinese government for you guys, you know, effective carve-out? In other words, they don't sign the agreement, but they allow you to sell in? What are the particular problems that that presents you ultimately for selling your product inside China?

MR. HUNTER: I take it that was for me. You're right that

China made a commitment on joining the WTO to--I forget the exact phrasing, but basically as soon as possible, which has been not very possible and not very soon.

When our members work to try to get their drugs on the reimbursement list there's a cat's cradle process. The pharmaceutical sector is always complex, but China takes it to a new level in terms of how its reimbursement system works, where you have a national list, and then it has to be implemented through a provincial list, and then you have to do the negotiations at the hospitals and so on.

Now, theoretically, you don't have to be on any of these lists. You could try to persuade either a hospital or otherwise, but, in practice, you won't get the reimbursement, and these reimbursement lists, while they make commitments to update them every two years, they haven't in the last five years, which is very different from international norms.

Now we are disadvantaged from a market access perspective, but ultimately it's also the Chinese consumer who's disadvantaged and means that the therapies that are available to people around the world are not available in China. As I mentioned before, there's, on average, an eight-year lag from the moment a product can be had by an American patient for when that same product is on average available to a Chinese patient. I mean the real loss is to the Chinese citizen.

COMMISSIONER FIEDLER: I mean that argument can be made for lots of other products--

MR. HUNTER: Exactly.

COMMISSIONER FIEDLER: --that they don't allow.

MR. HUNTER: Of course. Of course. So, yes, we can--I'm not sure that going to USTR to complain about GPA is the most effective means, but we certainly engage with MOH, the relevant ministries, and at the provincial level to urge more expeditious updates of the reimbursement list to begin that complicated process. But it is one of the big challenges.

COMMISSIONER FIEDLER: You have the same problem; right?

MR. IVES: Thank you.

We would like China to join the AGPA, but up until fairly recently, while the government has been involved relatively loosely in purchasing medical devices, most of the sales have been either, again, directly to hospitals, or through tendering systems that have not been discriminatory.

So our members are competing with each other and with Chinese manufacturers. As the Chinese government gets more and rmore involved in the purchase of medical devices and more of the funds come from the government, we are concerned about discrimination. As I indicated, we are concerned that the Chinese government will find ways to favor the domestic manufacturers.

But I would say one thing about the AGPA, and I know a little bit about it from USTR, it has a threshold, and the threshold is relatively high. This has been in the WTO and a lot of our free trade agreements. So

we would, as an industry, we would just have to see whether even if China joined the WTO--AGPA, it would be helpful.

COMMISSIONER FIEDLER: Just a quick question. Your companies, and I don't need any identification, what is their experience with Chinese cyber intrusions going after their technology and secrets?

MR. IVES: I can be very quick. I don't have a clue. They haven't come to me. Members come when they have a problem, and they have not come to me. So I don't know.

COMMISSIONER FIEDLER: It would be the only technology they're not stealing.

MR. HUNTER: I think it's a concern, but, again, it's something that concerns them, but it's not the sort of issue that they would take to their trade association. I think they would take it to enforcement authorities more quickly.

COMMISSIONER FIEDLER: Yeah. But I would think you would know; right? The enforcement authorities tend to be in Washington, you tend to be in Washington, people do talk.

MR. HUNTER: Well, these things get taken up within the security side of the companies which are just like in the security sides of government--tend to operate in different channels. But it's a very serious concern.

MR. IVES: And Rod explained much more, much better than I did why I as an association we do not know--that's why I answered I don't have a clue. It's up to the members.

COMMISSIONER FIEDLER: Okay. Thank you.

CHAIRMAN SHEA: Commissioner Slane.

COMMISSIONER SLANE: Thank you.

Mr. Ives and others have made statements that the Chinese government is interested in the health and welfare of its people.

And I really question that. They promote smoking. They create air pollution that prematurely kills 1.2 million Chinese. They have a diet that's getting increasingly more and more unhealthy. They have poor delivery of services. They have corruption. They have aging population overloading the system. 200 million migrants who don't have access to the system. I could go on and on, and it seems to me that their healthcare system is unsustainable and ultimately will collapse or have to be revived in some major way.

Our issue, and I know this isn't your issue, and it probably helps you that it works this way, but our issue is to try to get the Chinese economy to switch over from export driven to consumption, and to do that, we have to get more disposable income to Chinese people.

Chinese people don't have faith in the healthcare system, and a disproportionate amount of their savings is allocated to their own healthcare because they know they're going to get sick, and whatever benefits that they have, they don't really count them as any benefits.

And so I'm just wondering if you would agree with me, or

whether you think I'm completely off base here?

MR. SHOBERT: I think, as you know, and as Commissioners, I'm sure you get tired of all the tropes about China as a teenager and China needing to prioritize economic growth over all else, to develop the balance sheet strength to be able to spend money on healthcare. But I think that's unfortunately one of the only narratives we have to explain how we got to where we are today, which is a chronically overburdened, underfunded healthcare system that is unsustainable.

If you look at the money that's being allocated as part of the 12th Five Year Plan, there are two inherent dangers that could make it fundamentally unsustainable and prone to collapse. One is, as always, in China, the money that's getting spent is disproportionately going to bricks and mortar and towards equipment because, again, as I said earlier, those are the easiest ways to get promoted as a mayor.

The second big danger is that the funding mechanism between the Ministry of Health and the Ministry of Finance that makes the actual delivery of healthcare services, not just goods, which is what we're predominantly talking about today, that funding mechanism is broken, and from an anecdotal point of view, something to keep in mind, a doctor that graduates in Beijing for the first couple of years will make less money than if he were driving a taxicab.

It's very hard to keep good doctors in the profession doing good clinical therapeutic work in that kind of environment.

There is no question that China is coming to this issue late. It prioritized economic growth, and it did so at great cost, and when you look at every major survey of the Chinese population, the three things they're frustrated about are the environment, corruption and healthcare, and there is nowhere that all three of those issues overlap more than in what we're talking about today, and that likely makes this issue one of the fundamental flashpoints that could present a structural problem to China.

MR. HUNTER: I would just add we all know from our experiences in government that governments in big countries are often quite complex, and China is a very big country and exceedingly complex place. At the national level, the government is highly siloed, which makes policy, implementing effective policy in any area challenging, and the area that we're working in, that Ralph works in, is certainly much affected by that.

But then on top of that you have competing interests at the national, regional and provincial levels which explains some of those perverse outcomes that you talk about. I remember when I was in the administration, the EPA Administrator at the time described his single-biggest environmental concern being China--domestic concern being China because of the air pollution.

The shift, the shift towards greater consumption, that is an economy that is not export oriented but has a consumption focus, certainly the leadership talks about it, talks the game, but they have to overcome enormous vested interests, some of the ones that you mentioned and, again,

with a system which is highly siloed and with lots of competing incentives.

One of the studies I thought that was most interesting recently was the joint study with the DRC, the State Council think tank, together with the World Bank with China 2030 program or study, which was aimed at how does China avoid the middle income trap, and I think there set out an agenda which actually I think reflects very much where the leadership is trying to take the country.

But they have all these domestic challenges, which is not to excuse it by any means, but we have to recognize that that is what they deal with.

MR. IVES: Thank you.

And the only thing I would add is what I referred to in my testimony is the Chinese government focusing on healthcare and focusing on pollution, these are relatively new phenomena, I mean in China's history. We're talking about maybe the last five years or so that they're beginning to focus or beginning to see this huge problem they have in both of those areas. Now, whether they can address them given the magnitude of the problems, you may be correct; I don't know. But I'm referring to really a relatively recent phenomena.

COMMISSIONER SLANE: Thank you.

CHAIRMAN SHEA: Senator Talent.

COMMISSIONER TALENT: Yeah. After listening to part of the first panel and then this panel, it just occurred to me that the following question might be a good one.

If you were the CEO of let's take pharmaceuticals because this may be different for medical supply--I don't know, and you can comment on that, Mr. Ives--and a shareholder or board member were to say to you, look, why should we be trying to sell our product in China?

And we have a system whose financial sustainability depends on corruption--right--bribery and deliberate overprescription of drugs; discriminatory regulations--discriminatory against out-of-country providers--right; steals intellectual property; and has now introduced pricing constraints, which is managed by a convoluted and opaque bureaucracy that's highly politicized and very sensitive to domestic power struggles, as everything is in China--right--within the leadership.

And these are not bugs of the systems; these are features of the system. So why do we even want to do business there? And what would you say to them?

MR. SHOBERT: 17 percent growth a year in pharmaceutical sales, demand for pharmaceuticals. I'm not sure I would describe the environment as darkly as you did. You know there are problems with the regulatory system. I don't think it's discriminatory. I don't think it's intentionally discriminatory. Part of this is what I mentioned earlier, building an effective regulatory state.

The pricing and reimbursement system lags terribly. We see that in some other markets, like Turkey, as well. But, you know, this is where

the growth is--and you alluded to this earlier--that where most of the growth in pharmaceuticals and I suppose medical devices is in major emerging markets, and they all bring with them these sorts of challenges.

China is bigger and so those are in some ways more acute, but--and even on the IP side, yes, I think there's a temptation for industrial policy on the Chinese side, but it's not as bad as what I saw when I was in the IT sector. We've had a lot of strong support from the U.S. government through JCCT to get alignment around some of that data sufficiency issue that I mentioned earlier. So it's very difficult, but it is a growing market.

MR. SHOBERT: In my practice, we work pretty hard to get people to say no, and that's not because we're fundamentally hostile to China, but simply we want any new entrant to China to understand at the most basic level within their organization, and this goes all the way to the top, especially when you're talking about compliance risk, that selling into the healthcare economy in China is inherently a political act.

And so you have to understand that. Now that's I think to your point going to be the case in any emerging economy. One of the fundamental tensions that we're circling around today that Professor Eggleston touched on is just this general question that we're all facing: how are we going to manage burgeoning healthcare costs with all these new technologies that we've been fortunate enough to discover over the last hundred years?

This is a fundamental question that goes to the heart of the social contract between people and their governments. So you have to be very clear-eyed about the nature of the risk that you're taking when you go into China, and it's not for everybody, but it is an extraordinary revenue driver.

And I think at the most basic level, the answer to your question is that if they don't have access to China specifically, if they don't have access to emerging markets more generally, the nature of their developed markets, relative to demographics, to central purchasing, to frankly a lot of the things that we're complaining about in China, are already taking place in their domestic market.

So they have to go somewhere else to generate growth. It's an important market for that reason, and I think it's also important to recognize that the Chinese government has a lot of good reasons to want its multinational partners to bring technology, and they're trying to walk a very fine line. What's different about this particular sector is it illustrates a political failing of the party, and that makes it a little bit more acute and a little bit different relative to other sectors.

COMMISSIONER TALENT: And I hear what you're saying. Obviously, there's an opportunity for profit or you wouldn't even be considering it, and I suppose the answer to the question really sort of depends on your theory of business; right?

But I mean there are other places you can try and grow your business through investments. It's all an opportunity cost thing. You're going to put some money and time and effort into it, and I hear what you're saying, and, Mr. Ives, what you're saying is, okay, it's a real question, but

there is a substantial market there, which should drive you to consider doing that, if not now, then maybe at some point when the situation clarifies a little bit better.

Okay. Mr. Ives, you want to say something?

MR. IVES: Well, I was going to add the issue really is relative growth. You look at the U.S. market, the Japanese market, and the European market, those are the large developed markets for medical devices, and the growth rate is just significantly slower. They are more mature markets.

Our members are looking at emerging markets. China is one of the larger emerging markets so they're naturally interested in selling in China. So they sell and invest in China and in other emerging markets.

MR. HUNTER: Just one final point about pharmaceuticals. Also, if you don't take your product to a market, you don't work the patent in a market, and somebody else can use it. So, it's either you use it or lose it.

COMMISSIONER TALENT: All right.

CHAIRMAN SHEA: Thank you.

Dr. Tobin.

COMMISSIONER TOBIN: Great. Thank you.

Mr. Shobert, and others afterwards if you have comments, you painted a picture in your written testimony and today of China developing its life sciences industry and that sector as a countrywide strategy. So assuming it's five years from now or ten years from now, and they've developed some new products that they're exporting, tell us how currently do clinical trials work in China? Are the trials focused on adapting or approving products for the China market? Or are they also being looked at for going to export?

And, then, finally, are the standards for their clinical trials different from or similar to ours? Because--and the driving reason for my question is because if it is five to ten years from now and certain things are coming back, and I as a patient or whatever have some choices, I want to understand how they are doing things.

Thank you.

MR. SHOBERT: The actual mechanism of the clinical trial isn't exactly my expertise. I suspect Rod can probably speak more directly to that. It's worth saying that there were two scandals that GSK got caught in the middle of this past summer.

One of them that got the most publicity was relative to its compliance and its bribery practices. That got most of the traffic, but there was a twin scandal that went by not unnoticed, but didn't get caught up quite as largely, and that was specific to its clinical trial capabilities and some corners that got cut in China.

There are a couple of take-aways from that. One is specific to GSK, and because they've had some similar problems in other markets, including the United States, so there's reasons to not make that a China-specific problem. COMMISSIONER TOBIN: What kind of corners were cut?

MR. SHOBERT: Some fabrication of data is my understanding.

But then the other thing that that points to is also that there was the clinical trial capability in China is just not as new, and I think, Rod, you made this comment earlier, that this is a new sector for China, and so there is a lot of nascent infrastructure that is academic, that is regulatory, that is industrial, that is either just now being formed or really frankly hasn't even gotten started.

And so I think you're likely to see some problems here, which I don't think is a reflection of people intending to be duplicitous. It's a reflection of the system being very new.

MR. HUNTER: I think you were asking in one of the questions or it was framed was whether companies go to China for China or for part of a global system? And I think your question on the clinical trials really hones in on why it's not part of the global system, why it's--China has a clinical trials approval system which is very unusual.

Basically it has the same process, the same procedures for the registration requirement as for clinical trials, and it takes about three years to get a clinical trial approved. And then it takes another couple of years to get a drug approved.

In the U.S., you don't actually get an approval. A company makes a notification. It waits a certain period of time. FDA reacts or doesn't. And then you may go off and do it.

Also, not only is the procedure quite different and the time shorter, what they're looking at is different. Basically, in order to do a clinical trial, you have to generate all the information that you would generate for a drug approval.

So that means you can't include China within a global clinical trial. You have to get the drug approved somewhere else, and then you bring it to China after you've gotten it approved somewhere else, and then you do a China-specific clinical trial, and then you go through this process.

So it in some sense runs counter to their aspiration to make themselves a global leader in this area, and, second, it slows down the entry into the Chinese market of new medicines and new therapies.

COMMISSIONER TOBIN: So even for their development of new products themselves, and I could be getting this wrong, they have to go outside to get the clinical trials and then come back in?

MR. HUNTER: They could do that. I don't know of any cases where they have. Maybe they have. I would imagine if you're a Chinese manufacturer, you probably start at home. And so they just do a Chinese market. And it is a big market so there could be a logic.

For the international companies, you know, that doesn't really make sense.

COMMISSIONER TOBIN: So it would occur internally in China--the clinical trials--if it's a drug they're developing, and if they're choosing to export it, it would likely occur outside?

MR. HUNTER: Yeah, they'd have to get the approval. If they wanted to export it to the U.S., they'd have to get it approved here. So like

what Tasly is doing. They had this cardiovascular drug approved in China. They have now brought it to the U.S., and they're in phase three clinical trials in the U.S.

COMMISSIONER TOBIN: Thank you. That's helpful.

MR. IVES: It's similar but not identical in terms of medical devices. Before we can get a product on the Chinese market, if it's a U.S. product, it has to be approved first by FDA before you can begin the Chinese registration process.

So whatever FDA demands, if you're comparing the FDA's to some of the Chinese system, that product has already been approved by FDA, or if it's a European product, by the European agencies.

COMMISSIONER TOBIN: I may have other questions if we do a further round. Thank you.

CHAIRMAN SHEA: Senator Goodwin.

COMMISSIONER GOODWIN: Thank you, Mr. Chairman.

Mr. Shobert, I want to return to your use of the phrase "a political act." That is the decision to enter the market is fundamentally a political act, and I suppose as good a way to do that as any is to talk about the GSK incident from last summer, at least the one I'm most familiar with, which was the bribery allegations.

In a lot of the briefing materials the Commission had in preparation for today, there's a characterization of that incident as being one reflective of a double standard in China or at least one indicating a decision of selective enforcement, and yet it's my understanding that GlaxoSmithKline actually admitted wrongdoing, acknowledged that they unlawfully bribed officials and doctors in China.

So from my perspective, it's hard to feel much sympathy for a company when they acknowledge that they've committed an unlawful act, certainly one that if an American company committed would violate our own Foreign Corrupt Practices Act.

Yet your use of that phrase makes me wonder--"inherently a political act"--does that mean the desire to participate in what is obviously a growing market, an emerging market with the potential for much growth for pharmaceutical companies? Is that potential for growth so immense that the desire to participate in a market requires companies to play ball in this manner? And if everyone is doing it certainly isn't going to provide a defense in the Foreign Corrupt Practices Act.

But what is the reality on the ground in the People's Republic of China when it comes to accessing that market for Western companies?

MR. SHOBERT: So it's easy to begin the GSK story with the simplest truth, which is also the most confusing, and the simplest truth is what you just said. They did what they have been accused of doing. And they did it to the tune of, you know, over a half-a-billion dollars, and it was explicitly done. And the argument that everybody else is doing it doesn't ring particularly true in the ears of an American FCPA standard.

Having said that, it is always necessary to recognize that

regardless of the industry we're talking about, the FCPA itself is a form of taxation. And when American or European companies do business overseas, it represents a standard they are going to be held to, and this is not specific to China, that is going to be different than what a domestic company is going to be held to.

Now, the question needs to be asked why GSK was doing what they were doing? Again, the simple answer that they were unethical is convenient, but it's also not entirely accurate. There is a longstanding tradition in China of "red envelope" payments, and you pay this money to your doctor to be seen, and you pay that money to see a specialist, and you pay that money to jump to the front of the line. And you pay that money to get drugs that actually are high quality.

Behind the scenes the same type of red envelope payments take place between pharmaceutical sales representatives, dealers, hospital administrators. Why is that? That's because the system is fundamentally starved of revenue.

So what we consider, rightfully so, noncompliant practices are a very real reflection of a long history of the Ministry of Finance not writing checks to the Ministry of Health that allow the Ministry of Health to pay its bills, and so what you create is a culture of economic rent seeking, and so the GSK scandal at one level is very simple to understand because they did something that per the UK Bribery Act, in their case, the FCPA, in the case of the United States companies, they shouldn't have done.

But the underlying reality of doing business in China's healthcare economy means this type of transaction is always going to be part of how you do business.

COMMISSIONER GOODWIN: Well, sure, which really leads to the more important question, not making a moral judgment about what they did, but rather these tensions that are being placed on companies that, you know, the Foreign Corrupt Practices Act and comparable laws on the books in the UK were there for a reason. Policymakers made policy judgments and put them in place to protect consumers and these companies from having to engage in this sort of activity.

If that's the way it's done, or that's the way it's always been done, and they are expected to continue to act that way to gain access to the market, and that runs afoul of a black letter law, that puts in the companies in a tough position.

I think the choice would be pretty clear if I was a lawyer for one of the companies, but my question to you is how do they handle that tension, how do they try to navigate their way through those issues, particularly when, admittedly, I would suspect domestic companies aren't subject to the same level of scrutiny when it comes to those sorts of payments that you refer to?

MR. SHOBERT: So you're seeing a cottage industry of FCPA consulting firms making a lot of money going in and installing even more robust compliance procedures. You're also seeing some companies start to

reevaluate whether or not they should have direct sales people, and so the big fear on the part of the people I'm dealing with is that unless this funding mechanism is fixed, what you're going to see is the corruption get pushed away from the companies themselves down to the distributors and the dealers, and then the FCPA standard of did you know or should you have known is going to be satisfied at a very cosmetic level.

The problem in China is that that is not the reason that GSK got caught. GSK got caught because they ran afoul of the political system, and a point needed to be made.

So how is this actually going to change the behavior of companies on the ground? The most pragmatic answer I can give you is you're going to see sales forces start to be empowered at the distributor and the dealer network, and you're going to see companies start to really try and utilize a different channel to market than what they have done historically. But the problem is not going to go away.

COMMISSIONER GOODWIN: All right. Thank you.

CHAIRMAN SHEA: Thank you.

Commissioner Wessel.

COMMISSIONER WESSEL: Thank you, Mr. Chair, but I am truly enjoying your testimony, and I say that with admiration, IP drift and now FCPA being the Ministry of Finance's fault, and I understand your reasoning but disagree with the result.

Let me ask, if I can, a couple of questions. Mr. Hunter, you, or someone else, referred to Merck's investment in R&D in China, and I believe the number was used, Mr. Shobert, 1.5 billion, was it, in 2010; was that right?

MR. SHOBERT: Yes.

COMMISSIONER WESSEL: What has been the result, Mr. Hunter, of this or other investments by U.S. pharmaceutical entities or medical device companies in China in the R&D? Are we seeing products developed from it? Are we seeing the fruits of it? Are we seeing that Merck, for example, may be able to get more products on the EDL list as a result?

Why are they investing in China? What has--and I know four years is not a very long time in the R&D world, in the pharmaceutical category--what's been the result? Are others doing it? Is there a catalog of it?

MR. HUNTER: There has been a lot of investment by companies in the R&D space, and I think I gave a figure of eight-and-a-half billion RMB per year in recent years. The reasons which companies do it obviously differ between the companies. In some cases, it's associated with some other investments.

When I hear CEOs talk about it, some of the reasons that they point to is that also there's talent. They may not have as robust an ecosystem for innovation as we do, but they do have a lot of very good scientists. If you're going to do clinical trials, and you have to do the local

clinical trials, you'll need to set up some aspects of your R&D in the market, and there are going to be different patient profiles in Asia, and that also makes it interesting.

So I think that there are a mix of reasons. A very reasonable question about what have been the fruits of these investments, I don't know the outcomes yet. It is pretty early. The life cycles for at least what's R&D projects are pretty long, and these are mostly phenomena of the last five, six, seven years.

COMMISSIONER WESSEL: If you could provide, only those that have been announced publicly, a catalog, if you will, or an inventory of the R&D.

Going back to a point you just made and I don't often find myself defending Chinese practices, but I'm going to do that here, or identify what I think is a concern, and you can negate it.

Could the Chinese clinical trial mechanisms be a response to what was 15 to 20 years ago somewhat viewed as foreign firms taking advantage of China? As you know, because of the wealth of their population, many companies went in and did early trials in China, paying agricultural workers what was exorbitant sums for them but very little for the companies, and there was a lot of question about those clinical trials.

I know that most of that has changed, but could China's response be because of what happened earlier?

MR. HUNTER: That's an interesting question. I don't know what the intent, the motivation was at that the time the current drug administration law was drafted. Conceivably there may have been reasons such as that, or it may have been simply just the lack of expertise in the field.

FDA is obviously in a much better place to assess these things, and there's also a very robust liability system, and there's a lot of expertise in the companies to ensure that the clinical trials are done well.

I think that whatever the origins may be, this is having a negative impact on China's ability to participate in the global research and development. The Chinese government has recently announced this year, or within the past year announced, last year they announced that they were going to do an update of their drug administration law, a much awaited update, and we're hopeful that they will make the reforms in that context.

COMMISSIONER WESSEL: And Mr. Ives, as it relates to the medical devices your companies produce, do you have any sourcing information on what the inputs are coming out of China? They have your pacemaker, and a lot of the devices your members make, often have designs that would allow contract manufacturing much like an iPhone.

What kind of production is taking place in China for import into the U.S.? Do you have figures on that?

MR. IVES: Well, you're making an excellent point. Our larger manufacturers source from literally thousands of contract manufacturers. The percent that they rely on China, I don't know, but I think if you look at the

publicly available trade figures, most of the trade figures you'll see are what we would term kind of low value products coming out of China.

So with that as the basis for evidence, I don't think that the higher value products are being made in China to be shipped to the United States. That doesn't mean some of the components might be, but the point that Dr. Hickey made, I think, is very important here, and that is the manufacturer is ultimately responsible for that product. It doesn't matter where the components come from. That manufacturer is responsible for the product.

COMMISSIONER WESSEL: If you have any information on ten or 12-digit flows that would enable us to look at product specific issues, that would be helpful.

MR. IVES: Absolutely. They're available in HTS, but I'll get them.

COMMISSIONER WESSEL: Great. Thank you.

CHAIRMAN SHEA: Vice Chairman Reinsch.

VICE CHAIRMAN REINSCH: Mr. Hunter, we were talking before the panel started about some of your work in India as well, which is also an area of concern to your members. Could you spend a couple of minutes comparing or contrasting the experiences of your members in the two countries?

Attitudes of the government and how they differ? What are the problems that you encounter in each case and whether they're the same or different?

MR. HUNTER: Thanks, Commissioner.

I wish I could give you off the top of my head the numbers, but we can actually provide them in terms of the size of the pharmaceutical markets and what's represented by the patented products, but basically five percent of the Chinese market is represented by patented products. I think it's less than one percent in the case of India.

India has had for some time a strong generics industry, and when it came time to implement its WTO obligations with TRIPS, the generics industry was very influential in the final drafting of the legislation that was passed in 2005, and it includes a series of provisions that undercut those commitments.

We've seen in the case of India over the past two years either the disallowance or the attack in one form or another on the patents on some 15 products; there are only around 45 patented products in the market. So essentially a third of the patented products in the market in India.

So there's been a pretty consistent industrial policy of promoting generics, and so that's quite different from the Chinese context where first off the legislation is pretty consistent with international practice. There are some enforcement problems. But, at least with engagement with the government, this seems to be heading in a positive trend. Question on data protection.

More broadly, on the healthcare system, China is much further

along in building a healthcare system. People have talked today about the challenges to the Chinese system, but if you were just to turn a little bit farther to the West, you'd find a country of a similar size that is vastly worse off. The Indian government spends something on the order of 1.5 percent of GDP per year on healthcare, which puts it at a level right up there with Niger and below Haiti in terms of spending per capita.

China's spending on healthcare all told is over five percent of GDP. That's both a private and public number.

The healthcare delivery systems in India are woefully inadequate. Almost--I don't remember the numbers, but it's something astonishing like 70 percent of healthcare spending or more is out of pocket. There's very little private insurance. What private insurance there is only inpatient care. And, if you're not in an urban area like Mumbai, then your chances of getting any adequate healthcare is pretty unlikely.

So I think that in terms of the overall healthcare reform, China is decades ahead, or at least a decade if not much more. In terms of the impact of industrial policy, India is more problematic. And also in India, the generic industry there is substantially an export industry, where something like 40 percent of U.S. pharmaceuticals are generics from India.

While a similar scale, you would think similar challenges, but there is quite a different context.

VICE CHAIRMAN REINSCH: Thank you.

One other small point, it's sort of a digression. You alluded in your testimony to the--I think it was your testimony--to the relationships that PhRMA companies have among others with NIH and others that are part of the institutional infrastructure in the United States that contributes to innovation.

Has your organization ever attempted to calculate, and if so, what's the answer, the percentage of pharmaceuticals or recently designed products that can be directly attributed to federal R&D?

MR. HUNTER: I'll have to track that down. I'm sure that there's some analysis, maybe not specifically framed in the way you framed it, but in that space. The NIH does absolutely critical work in doing fundamental research, which then leads to a lot of the further research and development, important development work that the pharmaceutical companies do.

And NIH is essentially unique in the world in its importance and how much it does this, but we'll try to track down some information responsive to the question.

VICE CHAIRMAN REINSCH: That would be helpful. This is part of my 30-year crusade against those who believe there is no connection, and every time I can find one I think it's worth pointing out.

CHAIRMAN SHEA: Keep crusading. There is only one question separating us from lunch, and that's from Commissioner Slane.

COMMISSIONER SLANE: Real quickly, I'm just interested in the trends here. A couple of decades ago, most of the pharmaceutical products in China were what I call Eastern medicine, and I'm just wondering

what percentage of the market our Western medicine has dominated, and will we start to see Rite Aids and CVSs on every corner in China?

MR. SHOBERT: The government has been regulating foreign distributors and retail pharmacies although that part of the FDI catalog was recently revised so I think you should expect to see, I don't know if CVS will be the first foreign entrant, but there is a UK company that's early into their expansion doing actual point of sale like we would recognize.

And in terms of actual percentage of TCM, I don't know. I can get you that. I don't know off the top of my head.

COMMISSIONER SLANE: But it's becoming more and more accepted by the--

MR. SHOBERT: Very much so. And I think it's going to become more important as the hospitals and doctors get away from being the point of sale for a pharmaceutical, and you start to see some sort of independent retail outlet separate from the hospital, separate from the doctor.

COMMISSIONER SLANE: Thank you.

COMMISSIONER WESSEL: Can I just ask a question in follow-up?

CHAIRMAN SHEA: Sure.

COMMISSIONER WESSEL: In that situation, would you expect to have dramatically different pricing between the hospitals and the retail?

MR. SHOBERT: I would expect you would have Western medicines and you'd have a brand of Western medicines that would be at these retail outlets largely, and you would see this being where the middle class goes to find independent high quality source of therapeutics.

CHAIRMAN SHEA: Well, thank you to all three of you for your time and insights. We very much appreciate it, and this part of the hearing is adjourned. We will reconvene at two o'clock.

Thank you.

[Whereupon, at 12:45 p.m., the hearing recessed, to reconvene at 1:55 p.m., this same day.]

PANEL III INTRODUCTION BY VICE CHAIRMAN WILLIAM REINSCH

VICE CHAIRMAN REINSCH: We will reconvene. Thank you for your patience, everyone.

Our final panel today will revisit the issue of drug safety in China, which we addressed in our first panel this morning with Dr. Hickey. Our first witness is Allan Coukell, the Senior Director of Drugs and Medical Devices at the Pew Charitable Trusts.

Pew is a nonprofit global research and public policy NGO. Mr. Coukell oversees initiatives related to drug and medical device innovation and safety, the pharmaceutical supply chain, FDA and specialty drugs, as well as other efforts related to health costs and care delivery. He contributed to Pew's landmark report, "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs," released in 2011.

Prior to joining Pew, he practiced as a clinical pharmacist in oncology and served as a senior medical writer and editor with Adis International. He is Vice Chair of the Medical Device Innovation Consortium and a board member of the Reagan Udall Foundation for the FDA.

Our second witness is Charles Bell, Programs Director for Consumers Union, a nonprofit consumer protection organization and the publisher of Consumer Reports magazine.

Mr. Bell works on a wide range of consumer policy issues, including the Internet, the environment, financial services, and international trade. Over his 24 years at Consumers Union, Mr. Bell has done extensive work on healthcare. He also helped to initiate grant-funded projects to provide consumer and policy information on nursing home quality, preventive health services, dietary supplements and Medicare HMOs.

Our final witness today is Dr. Ginger Zhe Jin, a Professor of Empirical Industrial Organization and Applied Econometrics at the University of Maryland. Her primary fields of research are industrial organization, health economics, and the economics of family.

She is a Research Associate of the National Bureau of Economic Research and a co-editor of the Journal of Economics and Management Strategy. She recently coauthored reports on comparative drug quality and pricing across countries. She received her Ph.D. from the University of California in Los Angeles in 2000.

As we've said to the previous witnesses-- and I think probably you weren't all here for that-- your written statement will automatically be entered in the record. If you can confine your oral statement to seven minutes, that would be a good thing because then we'll have plenty of time for questions. And we'll proceed in the order in which I introduced you.

OPENING STATEMENT OF ALLAN COUKELL
SENIOR DIRECTOR, DRUGS AND MEDICAL DEVICES, THE PEW CHARITABLE TRUSTS

MR. COUKELL: Mr. Chairman and members of the Commission, my name is Allan Coukell, and I oversee drug and device work at The Pew Charitable Trusts. Pew is an independent, nonprofit, nonpartisan research and public policy organization, and we have a longstanding focus on issues related to the safety and security of the drug supply chain. Thanks for the opportunity to provide testimony today.

Drug manufacturing for the U.S. market is far different than it used to be. About 40 percent of our finished drugs now made outside the country, and an even higher share, about 80 percent, of the active ingredients are made abroad with close to half coming from India and China.

The U.S. imported over 100 million kilograms of pharmaceutical goods from China in 2013. That's close to a 200 percent increase over the past decade, and most drug companies have key suppliers in that country.

So what does this mean for safety and security? Globalization creates challenges for the U.S. Food and Drug Administration and for manufacturers that outsource production to contractors overseas or purchase ingredients from foreign suppliers. Historically, the FDA has inspected foreign plants much less often than those in the United States--about every nine years on average compared with every two to three years domestically.

China is home to the highest number of sites subject to FDA inspection outside the U.S., but it receives the lowest levels of oversight. For example, in 2009, FDA inspected under six percent of Chinese sites. In contrast, FDA inspects plants in Europe much more frequently even though those facilities are subject to European regulation and oversight, which is broadly similar to our own.

I will note that thanks to additional funds and legislation passed in 2012, FDA's oversight overseas is on the increase although the absolute rate of inspections remains relatively low.

Inspections do identify quality problems. Just last month, the FDA put two Chinese facilities on import alert to prevent them from exporting drugs to the U.S. There are currently 33 pharmaceutical plants in China on import alert, several dating as far back as 2009.

The Chinese Food and Drug Administration, the CFDA, regulates all drugs used domestically in China as well as some drugs made for export. In 2007, China and the U.S. signed a memorandum of understanding to place certain drugs designated for export under greater oversight by the CFDA.

In 2012, China provided the FDA with a list of Chinese pharmaceutical firms where the CFDA had found Good Manufacturing Practice violations, and 61 of these firms had shipped products to the U.S. The FDA subsequently targeted those firms as priorities for inspection.

Older studies have found concerning rates of quality problems in the Chinese domestic market. A 1998 study found that 13 percent of 20,000 batches of medicine tested were substandard or counterfeit. Let's

acknowledge that a lot has changed in China since 1998.

China has taken steps in recent years to strengthen its oversight. When GMP standards were first made mandatory in 2004, up to a third of Chinese factories were unable to meet the regulations. China has continued to update its GMP requirements, most recently in 2011, but there are still wide variations. Let me touch just briefly on the adulteration of the blood thinner heparin in 2007 and 2008, which was the incident that in a lot of ways focused congressional attention, FDA's attention, and manufacturer attention on these risks.

In that case, a U.S. company was manufacturing in China, and it relied upon a long and complex supply chain for the blood thinner’s active ingredient. Somewhere in that upstream supply chain, someone deliberately substituted a counterfeit and toxic ingredient for crude heparin, presumably for economic reasons.

This was detected only when U.S. patients began to experience adverse events. This incident exposed a number of significant supply chain risks. There was inadequate FDA oversight; there was also failure of the manufacturer to audit its own suppliers.

Subsequent investigations identified so-called "show and shadow factories," where the factory of record was not the actual origin of active ingredient, and there were outdated tests and procedures in use that were easy to fool. And it was a sophisticated crime. The people who did it knew how to fool those tests.

When an ingredient comes from an unknown source and is made under unknown conditions, production quality and by extension safety cannot be assured.

Even after these safety problems came to light, FDA was unable to access some of those key suppliers. Outsourcing allows pharmaceutical companies to cut costs and reduce manufacturing time but can also result in diminished control and transparency.

According to a 2010 survey, 94 percent of pharmaceutical executives surveyed thought that raw materials coming from foreign suppliers were a serious or moderate risk.

In the past, FDA officials have expressed serious similar concerns. It's worth noting that current Good Manufacturing Practices do not explicitly require manufacturers to evaluate their suppliers prior to contracting nor to conduct on-site audits of suppliers' plants.

The Food and Drug Administration Safety and Innovation Act, FDASIA, passed two years ago, made explicit that GMPs require managing those upstream risks.

Private sector efforts are also important. I'd like to mention one. Rx360 is an industry consortium that has created a shared audit program and disseminates risk information and risk signals to its members.

In addition to the quality problems I've been talking about, counterfeits are a related but distinct risk. For example, in 2013, a pharmacist in Chicago was indicted for purchasing counterfeit drugs from

China and selling them from his U.S. pharmacy.

In 2009, a Chinese national was sentenced to prison for distributing counterfeit and misbranded pharmaceuticals in the United States. His counterfeits contained low levels of active ingredient and had many impurities.

My written testimony goes into two recent pieces of legislation--the FDA Safety and Innovation Act, which I mentioned, and the Drug Quality and Security Act, passed last year, which creates a national system to serialize and trace drugs in the U.S., to harden the system against counterfeits. I'd be happy to talk more about those during the question and answer period.

As we look to the risks in our drug supply, though, let me conclude by saying that stepped-up FDA enforcement is important, but ultimately we'll need each country to provide sufficiently robust oversight of its own manufacturing sector.

And to get there, some of the activities that we see happening now, cooperative agreements, capacity building, and more boots on the ground are very important steps forward.

So I thank you and welcome your questions.

VICE CHAIRMAN REINSCH: Thank you.

Mr. Bell.

PREPARED STATEMENT OF ALLAN COUKELL
SENIOR DIRECTOR, DRUGS AND MEDICAL DEVICES, THE PEW CHARITABLE TRUSTS

Testimony before the United States China Economic and Security Review Commission

Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products

April 3, 2014

Allan Coukell, Senior Director of Drugs and Medical Devices The Pew Charitable Trusts

Chairman Shea, Vice-Chairman Reinsch, and members of the Commission, thank you for the opportunity to provide testimony. My name is Allan Coukell. I direct drug and medical device work at the Pew Charitable Trusts. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the public.

Supply chain globalization & increased complexity

The geography and complexity of drug manufacturing for products intended for sale in the United States have changed dramatically in recent decades. The number of drug products made at non-U.S. sites for the U.S. market doubled between 2001 and 2008.[67] An estimated 40 percent of finished drugs used in the United States are made outside of the country.[68] An estimated 80 percent of the active ingredients and bulk chemicals in U.S. drugs are also made abroad,[69] and close to half of these are purchased from plants in India and China.[70] In a 2010 study of pharmaceutical

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[67] Autor, Deborah M. Exq. Director, CDER Office of Compliance. U.S. Food and Drug Administration. "Globalization: Challenges and Recent Case Studies." Presentation at DCAT Week, March 18, 2009. http://www.dcat.org/pages/internal_DCATWeekRecap.aspx. Accessed May 4, 2011

[68] Hamburg, Margaret. Commissioner, United States Food and Drug Administration. Testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. April 13, 2011. http://republicans.energycommerce.house.gov/Media/file/Hearings/Oversight/041311/Hamburg.pdf. Accessed April 27, 2011

[69] U.S. Government Accountability Office. (1998, March). "Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program." (Publication No. GAO/HEHS-98-21)

[70] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010.

executives conducted by the consulting firm Axendia, China was reported as the top source country for pharmaceutical ingredients: seventy percent of the executives surveyed reported having key suppliers in China.[71]

With globalization comes increased complexity. Prescription and over-the-counter (OTC) medications originate in factories all over the world, moving into the American marketplace through supply chains that can involve numerous processing plants, manufacturers, suppliers, brokers, packagers and distributors. This presents serious oversight challenges for both the Food and Drug Administration (FDA) and for manufacturers that outsource production to contractors overseas or purchase ingredients from foreign suppliers.

One of FDA's most important tools for ensuring the safety of drugs sold in the United States – whether they are made domestically or abroad – is the inspection of factories to verify compliance with good manufacturing practice (GMP) standards. The volume of drugs destined for the U.S. market makes it impossible to test samples of all products before they reach patients. Checking manufacturing quality is a critical preventive measure to protect the public from unsafe pharmaceuticals.

Despite our increasing reliance on overseas production plants, the FDA has historically inspected foreign plants much less frequently than those in the United States – about every 9 years on average, compared with every 2 to 3 years domestically. China is home to the highest number of sites subject to FDA inspection outside of the United States (920 in fiscal year 2009), but in the past has received the lowest levels of oversight compared with other countries. FDA inspected only 5.6 percent of Chinese sites in fiscal year 2009 (with 52 inspections that year, up from 19 in 2007).[72] Over an eight-year period (2002–2009), FDA conducted 182 inspections in China (out of 920 total facilities) compared to nearly a combined 900 inspections in Germany, Italy, the United Kingdom, Switzerland, France and Ireland (out of 938 total facilities).[73,74] The emphasis on European inspections is surprising considering that regulatory oversight and standards for E.U. manufacturers are generally on par with those in the United States, and thus E.U. sites are arguably at lower risk for quality and safety issues. The European Federation of Pharmaceutical Industries and Associations (EFPIA), which regularly surveys its member pharmaceutical companies on the number of regulatory inspections that occur at their sites, has also pointed out inspectional overlap between E.U. and the United States. In 2009, members reported 47 inspections of

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[71] Axendia Report. Achieving Global Supply Chain Visibility, Control & Collaboration in Life Sciences: 'Regulatory Necessity; Business Imperative". October 2010

[72] United States. Government Accountability Office. (2010, September). Drug Safety: FDA Has Conduced More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress is Needed. (Publication No. GAO-10-961)

[73] United States. Government Accountability Office. (2010, September). Drug Safety: FDA Has Conduced More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress is Needed. (Publication No. GAO-10-961)

[74] U.S. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers*. (Publication No. GAO-08-224T

plants in the U.S. by E.U. regulators, and 102 inspections of E.U. plants by the FDA.[75]

The FDA's inspection program is beginning to change as a result of 2012 legislation, which placed all manufacturing plants, whether foreign or domestic, on a single risk-based inspection schedule, and provided FDA with additional funds to inspect foreign generic drug facilities. The agency is working to implement this new law, but fiscal year 2013 has already shown a marked increase in inspections overseas. The FDA conducted 813 drug inspections in FY 2013,[76] which equates to 23% of the 3,493 foreign drug establishments registered with FDA that year.[77] By comparison, in FY 2009 the FDA inspected 424 foreign drug manufacturing sites,[78] which is 11 percent of the 3,765 that were registered that year.[79]

In the absence of sufficient expectation of oversight, some manufacturers may not rigorously observe quality measures. The FDA has over the years identified a number of quality problems at overseas plants. In China, 33 pharmaceutical plants have been placed on import alert – preventing them from exporting certain products to the U.S. – two in March of 2014.[80]

It is important to note that there is a range of manufacturing quality in all countries. There are well-run plants in China doing high quality manufacturing. There are also U.S. facilities with significant quality problems. For example, many of the drug shortages the U.S. is grappling with today have been linked with sterile production failures at domestic plants. Ultimately, the FDA must ensure plants, wherever they are, meet a baseline set of quality standards if they wish to supply the U.S. market.

Focus: China

The United States is the number one destination for Chinese pharmaceutical raw material exports—a multi-billion business each year ($2.2 billion in 2008).[81] The U.S. imported

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[75] Rönninger, F., Stephan. Hoffmann-La Roche Ltd. EFPIA 2009 Regulatory GMP Inspection Survey. April 2010

[76] Food and Drug Administration. "FDA-TRACK ORA Dashboard". http://www.fda.gov/AboutFDA/Transparency/track/ucm204013.htm. Accessed March 26, 2014

[77] Food and Drug Administration. "2014 Annual Report on Inspections of Establishments". http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM384063.pdf

[78] United States. Government Accountability Office. (2010, September). Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress is Needed. (Publication No. GAO-10-961)

[79] U.S. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers*. (Publication No. GAO-08-224T)

[80] Food and Drug Administration. "Import Alert 66-40" http://www.accessdata.fda.gov/cms_ia/importalert_189.html

[81] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010. http://www.uscc.gov/researchpapers/2010/NSD_BIO_Pharma_Report--Revised_FINAL_for_PDF--14_%20April_2010.pdf accessed 4/14/2010.

over one hundred million kilograms of pharmaceutical goods from China in 2013, 26 percent of all such imports.[82] In the decade between 2003 and 2013, pharmaceutical imports from China increased 192 percent.[83] In particular, China is a major source for older and off-patent pharmaceutical ingredients in medicines sold in the United States.[84, 85] U.S. Census Bureau data from 2009 indicate that the United States imported large quantities of three major over-the-counter (OTC) pain relievers: ibuprofen, acetaminophen and aspirin (3 million, 3.5 million and 4 million kilograms, respectively).[86] For all three products, the largest portion of imports came from China. China is also a major source of a number of older antibiotics. Ninety-four percent of imported tetracycline salts, an important class of antibiotics, originated in China from 2006 to 2008, as did three-quarters of imported streptomycin derivatives and salts used in injectable antibiotics and eye drops.[87]

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[82] Source of original data: United States Census Bureau, Foreign Trade Division

[83] Source of original data: United States Census Bureau, Foreign Trade Division

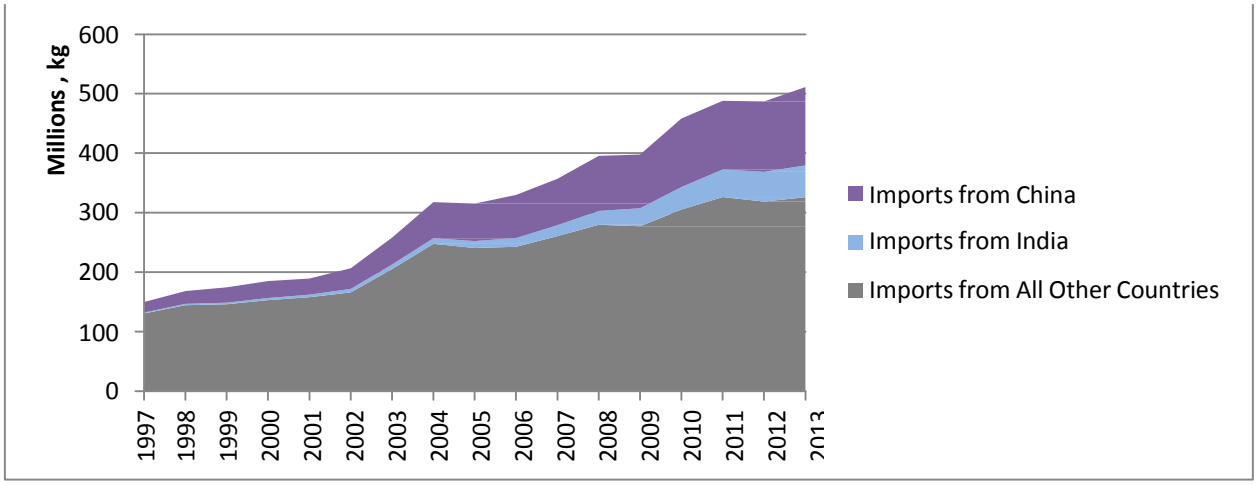
[84] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States-China Economic and Security Review Commission by NSD Bio Group. April 2010.

[85] Kennedy, Robert, Manager, Industry Research, Thomson Reuters API Intelligence. "Can China retain its API sourcing appeal?" *Scrip100*. December 9th, 2009

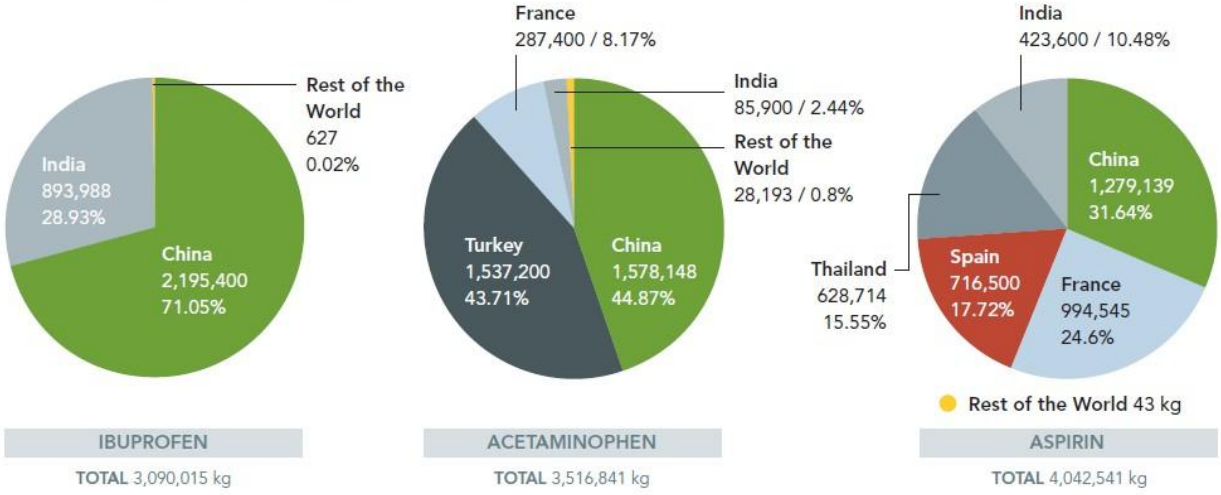
[86] Source of original data: United States Census Bureau, Foreign Trade Division

[87] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States-China Economic and Security Review Commission by NSD Bio Group. April 2010.

U.S. imports of pharmaceuticals by weight (kg), 1997 – 2013 [88]



Top source countries for U.S. imports of ibuprofen, acetaminophen and aspirin by weight (kg)in 2009



Source: U.S. Census Bureau, Foreign Trade Division.

The Chinese bulk pharmaceutical market has been growing by about 20 percent in production value each year,[89] and China is home to thousands of drug manufacturing facilities.[90] The FDA has estimated that as many as 920 manufacturing plants in China may manufacture

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[88] Source of original data: United States Census Bureau, Foreign Trade Division

[89] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States-China Economic and Security Review Commission by NSD Bio Group. April 2010.

[90] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States-China Economic and Security Review Commission by NSD Bio Group. April 2010. http://www.uscc.gov/researchpapers/2010/NSD_BIO_Pharma_Report--Revised_FINAL_for_PDF--14_%20April_2010.pdf accessed 4/14/2010.

drugs and drug ingredients intended for the U.S. market, and therefore may be subject to inspection by FDA,[91] a striking increase from just eleven such sites in 2002.[92]

The Chinese Food and Drug Administration (CFDA) regulates all drugs used domestically in China, as well as some drugs made for export.[93] Although China requires that exported medical products meet the regulatory standards of the destination country; it has in the past placed full responsibility with the receiving party for ensuring that products meet those quality standards.[94] In 2007, China and the U.S. signed a memorandum of understanding to place certain drugs designated for export under greater oversight by the CFDA, including a number of antibiotics.[95] In 2012, China provided the FDA with a list of Chinese pharmaceutical firms where CFDA had found GMP failures. Sixty one of these firms had shipped products to the United States, and the FDA then targeted these firms as priorities for inspection.[96]

Older measurements of drug quality have indicated that substandard and counterfeit products have been an issue in the Chinese domestic market. A survey of medicine quality by China's State Food and Drug Administration in 1998 found 13.1 percent of 20,000 batches tested to be substandard or counterfeit.[97] China has taken steps over the years to strengthen domestic oversight of pharmaceutical manufacturing and modernize GMP regimes. When GMP

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[91] U.S. Government Accountability Office. (2010, September). Drug Safety: FDA Has Conduced More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress is Needed. (Publication No. GAO-10-961)

[92] United States. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers*. (Publication No. GAO-08- 224T)

[93] Solomon, Steven M. D.V.M., M.P.H. Food and Drug Administration. "FDA's Activities Related to China". Testimony before the Congressional-Executive Commission on China. May 22, 2013.

[94] Article 3, Regulations on Pharmaceutical Processing for Export (trial version). State Food and Drug Administration. China. released July 29, 2003. Cited in: *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010. http://www.uscc.gov/researchpapers/2010/NSD_BIO_Pharma_Report--Revised_FINAL_for_PDF--14_%20April_2010.pdf Accessed 4/14/2010.

[95] Article 3, Regulations on Pharmaceutical Processing for Export (trial version). State Food and Drug Administration. China. released July 29, 2003. Cited in: *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010. http://www.uscc.gov/researchpapers/2010/NSD_BIO_Pharma_Report--Revised_FINAL_for_PDF--14_%20April_2010.pdf Accessed 4/14/2010.

[96] Solomon, Steven M. D.V.M., M.P.H. Food and Drug Administration. "FDA's Activities Related to China". Testimony before the Congressional-Executive Commission on China. May 22, 2013. http://www.fda.gov/newsevents/testimony/ucm353577.htm. Accessed March 27, 2014

[97] Tomlinson R. China cracks down on counterfeit medicines. Br Med J; Vol. 318: 624. March 1999

standards in China were made mandatory in 2004,[98] up to one-third of Chinese factories were unable to meet the regulations, according to one estimate.[99] China has continued to update its GMP requirements – most recently in 2011[100] – but there are still wide variations in production and GMP capacity among plants producing pharmaceutical products in China.[101,102]

Heparin

Quality problems in China came to the fore in 2008, after dozens of adverse events including some deaths, were linked to the adulteration of heparin, a widely used blood thinner. The drug was manufactured by Baxter Healthcare, a U.S. company that was sourcing active ingredient and precursor ingredients from a complex upstream supply chain in China.[103] Investigations revealed that somewhere in that supply chain, the correct active ingredient was replaced by a substance known as over-sulfated chondroitin sulfate (OSCS), which standard tests then in use were unable to detect.[104] The exact source of the contamination has never been determined, but OSCS is a synthetic product, and its introduction is generally believed to have been intentional, for economic gain.

Adulterated heparin exposed a number of significant supply-chain management problems on the part of the manufacturer and the FDA. Baxter began receiving heparin from a new Chinese plant in 2004, but did not conduct its own audit of that plant until 2007, relying instead on an earlier assessment by a different company.[105] FDA approved the plant as a supplier for Baxter without conducting a pre-approval inspection,[106] in part because the

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[98] Chervenak, Matthew. China: moving towards innovation in pharma. *Drug Discovery Today*, Volume 10, Issue 17: 1127-1130, September 1, 2005,

[99] Chervenak, Matthew. China: moving towards innovation in pharma. *Drug Discovery Today*. Vol. 10, No. 1. September 2005.

[100] Jialing, Dai and Bowman Cox, China Releases New Drug GMPs; Domestic Consolidation Expected. *The Gold Sheet*. Vol. 45, No. 2. February 2011.

[101] Kennedy, Bob. Manager of Industry Research, Thomson Reuters. "For How Long Will the Chinese API Sourcing Market Retain Its Appeal?" Presentation at API Global Sourcing Strategies 2009. Berlin, Germany, June 29, 2009

[102] Kennedy, Bob. Manager of Industry Research, Thomson Reuters. "Can China retain its API sourcing appeal?" Scrip100, December 9, 2009.
http://thomsonreuters.com/content/science/pdf/ls/hub/can_China_retain_api_sourcing_appeal.pdf
Accessed January 19, 2011

[103] Blossom, David B., Kallen, Alexander J., et al. Outbreak of Adverse Reactions Associated with Contaminated Heparin. *N Engl JMed,* December 18, 2008 359:2674–84.

[104] Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International Before Subcommittee on
Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives; April 29, 2008.

[105] Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International Before Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. April 29, 2008

[106] The Heparin Disaster: Chinese Counterfeits and American Failures: Hearings before the Subcommittee on Oversight and Investigations, of the House Committee on Energy

agency confused the plant with another site in its database. When FDA finally inspected the plant after the adverse events occurred, its inspectors found a number of manufacturing quality issues,[107] including poor control of incoming raw materials.[108] When, in 2008, Baxter sent inspectors to retroactively evaluate its supply chain, they were denied access to upstream workshops and consolidators.[109] FDA was also denied access to two upstream consolidators of heparin.[110]

Since these events, Baxter reported a number of initiatives to secure its supply chain against future contamination and adulteration, including examining its global supply-chain practices to identify vulnerabilities, reviewing relationships with high-risk suppliers, reducing the number of suppliers, doing more concentrated audits and reviewing test methods.[111] The adulteration of heparin also resulted in an increased FDA focus on global production and in Congressional attention, which led to new authorities discussed below.

Ingredient falsification

Ingredient falsification (such as occurred in the heparin example) is a challenging issue to address when supply chains are long and complex. When an ingredient comes from an unknown source, and is made under unknown conditions, production quality, and by extension product quality and safety, cannot be assured.

Observers of the pharmaceutical manufacturing sector in China describe substandard unknown or unapproved sites. In some cases these deceptions have lasted years. Shanghai No. 1, a Chinese supplier to
U.S. manufacturer International Medication Systems, Limited (IMS), claimed to be a manufacturer of heparin but in reality was a "show" factory. Shanghai No. 1 was registered with FDA as an exporter of heparin active ingredient to the United States and had an authorized U.S. agent, Amphastar Pharmaceuticals Inc., which in 2004 declared to FDA that Shanghai No. 1 produced heparin under GMP conditions.[112] In fact, Shanghai No. 1 had been

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and Commerce, 110th Cong., 2d Sess. (2008) (Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International).

[107] Warning Letter WL 320-08-01, April 21, 2008. To: Dr. Yan Wang, Ph.D., General Manager, Changzhou SPL Company, Ltd (a/ k/ a "Kaipu"). From: Food and Drug Administration, Division of Manufacturing and Product Quality Office of Compliance Center for Drug Evaluation and Research.

[108] Warning Letter WL 320-08-01, April 21, 2008. To: Dr. Yan Wang, Ph.D., General Manager, Changzhou SPL Company, Ltd (a/ k/ a "Kaipu"). From: Food and Drug Administration, Division of Manufacturing and Product Quality Office of Compliance Center for Drug Evaluation and Research.

[109] Gardner, Erin. Director, Corporate Communications, Baxter International Inc. Email correspondence, February 25, 2011

[110] U.S. Government Accountability Office (October 2010). Food and Drug Administration: Response to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working With External Entities Were Recently Added. (Publication No. GAO-11-95).

[111] Gardner, Erin. Director, Corporate Communications, Baxter International Inc. Telephone Interview, 2/ 19/ 10.

[112] Warning Letter WL 320-09-01, April 14, 2009,. To: Dr. Mao Jian Yi, General Manager, Shanghai No. 1 Biochemical & Pharmaceutical Co. Ltd. From: Inspections, Compliance,

shipping heparin to the United States that was labeled as having been produced at their facility, but was actually made at two external plants.[113] IMS had been importing this falsely labeled heparin as early as 2001, but the fraudulent activity was only discovered seven years later. FDA investigated one of the external plants, and in addition to finding GMP violations, found that the plant had made 19 lots of heparin that were contaminated with Over-Sulfated Chondroitin Sulfate, the same substance associated with adverse events in the U.S., though these lots did not ultimately reach U.S. patients.*,[114]

Pharmaceutical brokers and traders have also been responsible for concealing the source of drug ingredients. For instance, diethylene glycol (an industrial solvent) has been labeled as glycerin (a common inactive ingredient for cold and cough syrups) and sold into distribution numerous times, causing hundreds of deaths.[115,116,117,118] In one of these cases, the Panamanian government prepared cough medicine with diethylene glycol labeled as glycerin that had originated in China.[119, 120] The official number of deaths was 78,[121] but unofficial

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Enforcement, and Criminal Investigations, Food and Drug Administration, Division of Manufacturing and Product Quality, International Compliance Team

[113] Warning Letter WL 320-09-01, April 14, 2009,. To: Dr. Mao Jian Yi, General Manager, Shanghai No. 1 Biochemical & Pharmaceutical Co. Ltd. From: Inspections, Compliance, Enforcement, and Criminal Investigations, Food and Drug Administration, Division of Manufacturing and Product Quality, International Compliance Team

[114] Warning Letter WL 320-09-02, April 14, 2009,. To: Ms. Wang Weiru, President, Qingdao Jiulong Biopharmaceuticals Co. Ltd. From: Inspections, Compliance, Enforcement, and Criminal Investigations, Food and Drug Administration, Division of Manufacturing and Product Quality, International Compliance Team

[115] Rentz ED, Lewis L, Mujica OJ, Barr DB, Schier JG, Weerasekera G, Kuklenyik P, McGeehin M, Osterloh J, Wamsley J, Lum W, Alleyne C, Sosa N, Motta J, Rubin C. Outbreak of acute renal failure in Panama in 2006: a case-control study. *Bull World Health Organ* 2008; 86:749–756.

[116] Rivera-Martinez, Edwin. Chief, Manufacturing Assessment and Preapproval Compliance Branch, Division of Manufacturing & Product Quality, Office of Compliance, Center for Drug Evaluation & Research, United States Food and Drug Administration. "Ensuring the Integrity of the Pharmaceutical Ingredient Supply Chain." Presentation at the 2008 PDA/ FDA Pharmaceutical Ingredient Supply Chain Conference, San Diego, CA. December 1, 2008.

[117] Schier JG, Rubin CS, Miller D, Barr D, McGeehin MA. Medication-associated diethylene glycol mass poisoning: A review and discussion on the origin of contamination. *Journal of Public Health Policy*. 2009. Vol. 30, No. 2.

[118] Schep LJ, Slaughter RJ, Temple WA, and Beasly DMG. Diethylene glycol poisoning. *Clinical Toxicology*. 2009. Vol. 47 No. 6

[119] Rentz ED, Lewis L, Mujica OJ, Barr DB, Schier JG, Weerasekera G, Kuklenyik P, McGeehin M, Osterloh J, Wamsley J, Lum W, Alleyne C, Sosa N, Motta J, Rubin C. Outbreak of acute renal failure in Panama in 2006: a case-control study. *Bull World Health Organ* 2008; 86:749–756.

[120] Rivera-Martinez, Edwin. Chief, Manufacturing Assessment and Preapproval Compliance Branch, Division of Manufacturing & Product Quality, Office of Compliance, Center for Drug Evaluation & Research, United States Food and Drug Administration. "Ensuring the Integrity of the Pharmaceutical Ingredient Supply Chain." Presentation at the 2008 PDA/ FDA Pharmaceutical Ingredient Supply Chain

reports suggest the possibility of a much larger toll.[122]

European inspectors in Zhejiang, China, found empty drums blocking access to part of a certified pharmaceutical plant exporting to Europe and the United States. Further investigation revealed a vast warehouse of substandard or falsely certified drug active ingredients. Image courtesy of Philippe André, Associate Professor at the School of Pharmaceutical Science and Technology at Tianjin University, China (2008).[123]

[*] Shanghai No. 1 was not part of Baxter Inc.'s heparin supply chain.

Industry responsibility

Outsourcing allows pharmaceutical companies to cut costs and reduce manufacturing time,[124] but can also result in diminished control and transparency, particularly when contractors and

Conference, San Diego, CA. December 1, 2008.

[121] Rentz ED, Lewis L, Mujica OJ, Barr DB, Schier JG, Weerasekera G, Kuklenyik P, McGeehin M, Osterloh J, Wamsley J, Lum W, Alleyne C, Sosa N, Motta J, Rubin C. Outbreak of acute renal failure in Panama in 2006: a case-control study. *Bull World Health Organ* 2008; 86:749–756.

[122] Schep LJ, Slaughter RJ, Temple WA, and Beasly DMG. Diethylene glycol poisoning. *Clinical Toxicology*. 2009. Vol. 47 No.

[123] André, Philippe, Associate Professor at Tianjin University, China. "API Manufacturing Situation in China." Presentation to European Fine Chemicals Group, 5/13/09

[124] Shahani, Shalini. "Contract Pharmaceutical Manufacturing, Research and Packaging". BCC Research, Wellsley, MA. October 2009.

suppliers are in distant geographic locations. According to a 2010 survey by the Axendia consulting firm, 94 percent of pharmaceutical executives think that raw material sourcing from foreign suppliers is a serious or moderate risk.[125]

Both members of industry and FDA experts recognize the need for strong contractor and supplier management.[126, 127, 128] In the past, FDA officials have expressed concerns about industry supply-chain vulnerabilities, including insufficient knowledge of contract manufacturing sites, too little on-site auditing of suppliers and over-reliance on supplier-provided documentation[129] of[130] testing[131].[63,64,65]

Current GMPs require manufacturers to control the quality of incoming drug components through testing. However, they do not explicitly require manufacturers to evaluate component suppliers prior to contracting with them, nor to engage in quality agreements with those suppliers, nor to conduct on-site audits of suppliers' plants.[132] The Food and Drug Administration Safety and Innovation Act (FDASIA), enacted in 2012, made explicit that GMPs require managing the risks of and establishing the safety of ingredients and raw materials. The FDA has indicated it may issue a proposed rule to update regulations by July 2015, and a final rule by October 2016, but FDASIA's new quality requirements are enforceable even without new regulations.

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[125] Axendia Report. Achieving Global Supply Chain Visibility, Control & Collaboration in Life Sciences: 'Regulatory Necessity; Business Imperative". October 2010

[126] Trautman, Kimberly, Medical Device Quality Systems Expert, Office of Compliance, Center for Devices
and Radiological Health [ok? per text], Food and Drug Administration. "Inside the Development of GHTF SG3 — Managing Internal and External Suppliers" Presentation at FDANews Supplier Quality Management Congress. Arlington, VA. August 19-21, 2009

[127] Cynthia Ely, Supplier Quality Management Specialist, Amgen. Presentation at FDA News Supplier Management Congress. Arlington, VA. August 19-21, 2009

[128] Niedelman, Steven. Senior Consultant, Crowell & Moring. (and former director of ORA, FDA) Interview 11/16/09

[129] Rosa, Carmelo, M.S., Psy.D. Acting Chief, International Compliance Branch, Division of Manufacturing & Product Quality
Office of Compliance, Center for Drug Evaluation & Research, Food and Drug Administration "Catching Up to 21st-Century
Challenges: FDA's Supplier Quality and Compliance Outlook" presentation at FDA News 2nd Annual Supplier Quality Management Congress. Bethesda, MD, August 18 -20, 2010. http://www.fdanews.com/ext/files/Conference/SQMS10presentations/Rosa-%20August%202010%202nd%20Supply%20Chain%20Congresss%20Compliance%20Update%20Bethesda%20M_D.pdf. Accessed May 2, 2011.

[130] Rothman, Barry. Division of Manufacturing & Product Quality, Office of Compliance, Center for Drug Evaluation & Research, Food and Drug Administration "Pharmaceutical Ingredient Supply Chains". Presentation at FDA News Supplier Management Congress. Arlington, VA. August 19-21, 2009

[131] Rivera-Martinez, Edwin. Chief, Manufacturing Assessment and Preapproval Compliance Branch, Division of Manufacturing & Product Quality, Office of Compliance, Center for Drug Evaluation & Research, United States Food and Drug Administration. "Ensuring the Integrity of the Pharmaceutical Ingredient Supply Chain." Presentation at the 2008 PDA/FDA Pharmaceutical Ingredient Supply Chain Conference, San Diego, CA. December 1, 2008.

[132] 21 CFR 211.84 (d)(2)

In addition, a number of companies have taken a private sector collaborative approach to address concerns about supply chain quality control through information sharing and leveraging one another's supplier audit results. Rx360, an industry consortium, has created such a shared audit program and also disseminates information on risk signals to its members.[133]

Counterfeits

In addition to legitimate drugs that are of poor quality, counterfeit drugs – fakes that imitate the product or packaging of a licensed manufacturer – have also entered the U.S. drug supply numerous times over the past few decades. For example, counterfeit cancer medication has been found in the U.S. at least three times since 2012.[134, 135,136] The origin of the counterfeits is not known. In 2013, a pharmacist in Chicago was indicted for allegedly purchasing Chinese counterfeits and selling them from his U.S. pharmacy store.[137] And in 2009, a Chinese national was sentenced to prison for distributing counterfeit and misbranded pharmaceuticals in the United States. His counterfeits contained low levels of active ingredient, and many had impurities.[138]

Counterfeits may also be real medicines that are illicitly diluted or otherwise adulterated. In 2002, counterfeit high-dose Epogen® was actual low-dose Epogen® that had been relabeled as a higher strength, and was successfully sold to legitimate distributors and pharmacies.

The public health risks of poor quality and counterfeit drugs are the same: counterfeits may have little or no active ingredient, or may even contain harmful chemicals. However, while the risks of counterfeit and substandard drugs are analogous, the solutions and players are different. Poor quality drugs enter from within the legitimate supply chain, and the FDA and the regulated industry are responsible for conducting sufficient oversight to prevent quality failures. Counterfeit drugs, conversely, normally enter from outside the legitimate supply

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133 www .rx-360.com

134 U.S. Food and Drug Administration. "Avastin (bevacizumab): Counterfeit Product - FDA Issues Letters to 19 Medical Practices" http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm291968.htm. Accessed February 24, 2014

135 U.S. Food and Drug Administration. "Another counterfeit cancer medicine found in U.S. - Illegal practice puts patients at risk". http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm298047.htm. Accessed February 24, 2014

136 U.S. Food and Drug Administration. "Health Care Provider Alert: Another Counterfeit Cancer Medicine Found in United States". http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm33 8283.htm. Accessed February 24, 2014

137 U.S. Food and Drug Administration, Office of Criminal Investigations. " April 18, 2013: Suspended North Side Pharmacist Indicted for Allegedly Smuggling and Trafficking Counterfeit Viagra" . U.S. Department of Justice Press Release, April 18, 2013.

138 Press Release. " Distributor of Counterfeit Pharmaceutical Drugs Sentenced." Department of Justice, U.S. Attorney's Office, Southern District of Texas. January 15, 2009. http:/ / www.justice.gov/ criminal/ cybercrime/ XuSent.pdf. Accessed May 5, 2011

chain. Law enforcement works to catch both suppliers of counterfeits as well as persons knowingly bringing them into the U.S. for further sale. Important new tools were established in the 2013 Drug Quality and Security Act (which is discussed below) to help protect the drug supply from counterfeits.

Recently enacted legislation

Two major laws to safeguard the drug supply were passed in 2012 and 2013: Title VII of the FDA Safety and Innovation Act (FDASIA) focused on "upstream" manufacturing supply chain security, and Title II of the Drug Quality and Security Act (DQSA) laid the groundwork for improving safety of the "downstream" drug distribution system.

FDASIA

Title VII of FDASIA enhances overseas inspections by creating a single risk-based inspection framework for both foreign and domestic plants. While there is no minimum frequency for inspections, one risk criteria that must be considered is whether a plant was inspected in the previous four years. The law also requires manufacturing establishments to register annually with FDA and submit a unique facility identification number, which will help FDA accurately identify plants in its internal databases.

FDASIA also requires drug importers to register with FDA, and adhere to Good Importer Practices (GIP) which will be developed by the Secretary; FDA has indicated that it expects to propose a GIP rule by April 2015, and finalize it by January 2017.

Title VII also gave the FDA some important new authorities, including the ability to require importers to provide compliance information as a condition of entry for an imported drug, and the power to block importation of a drug product if the plant making it delays, limits, or refuses inspection. The agency issued at least two warning letters for this reason in 2013.

FDA may also now request documents outside of an inspection. And the agency was given the authority to administratively detain drugs, meaning the FDA can halt the movement of potentially violative drugs while investigating and determining the appropriate response.

FDASIA Title VII also recognized the need for international collaboration to ensure the safety of the global drug supply. It gives the agency explicit extraterritorial jurisdiction, and creates a limited framework for the sharing of confidential information with other foreign regulators. The FDA may also enter into agreements to recognize inspections by foreign regulators that are capable of conducting inspections that meet U.S. standards, and the results of these foreign inspections may be used as evidence of compliance with U.S. law.

Finally Title VII recognizes the responsibilities of the pharmaceutical industry to ensure drug quality. It clarifies that current good manufacturing practices include company control of drug ingredient quality – an important step to ensure industry takes responsibility for managing their suppliers and ensuring the safety of drug ingredients. It allows the FDA to require industry to notify the agency about identified drug theft and counterfeiting.

In addition to Title VII, FDASIA Title III – the Generic Drug User Fee Amendments of 2012 (GDUFA) – also contains provisions relevant to the drug supply chain. Specifically, under GDUFA, the generic drug industry will pay fees that will fund FDA inspections of generic drug plants both here and overseas, with a goal of inspection parity between foreign and domestic sites by 2017. These are critical new resources for the FDA, though they are targeted just for generic drugs, and not for branded products.

One final Title of FDASIA worth noting is Title X, which seeks to help address drug shortages by requiring manufacturers to provide advance notification of an impending shortage to FDA when possible. The FDA has reported that this notification requirement has allowed them to more quickly take steps to prevent and resolve drug shortages.[139]

DQSA

Title II of the Drug Quality and Security Act, passed in late 2013, establishes a national serialization and traceability system for medicines sold in the United States. This will fundamentally change the distribution system for drugs in this country.

Beginning in late 2017, each package of prescription drugs will be given a unique serial number enabling it to be verified, and, eventually, allowing for its distribution history to be traced. This serialization system will be an important new tool for ensuring the legitimacy of pharmaceutical products, and it should also allow for quicker location of product within the supply chain in the event of drug recalls. It will also aid investigators seeking to trace back the source of problems within the drug distribution chain.

Next steps

As drug manufacturing becomes increasingly global, collaboration between regulators and harmonization of quality standards is essential. Collaboration and capacity development activities are important, such as the FDA's recent cooperative agreement with Indian pharmaceutical regulators.[140] Ideally, each country will eventually provide sufficiently robust oversight of its production facilities to ensure the quality of drug products, whether used domestically or shipped abroad.

Until such harmonization is possible, the FDA must continue to develop its ability to monitor drug production overseas. The FDA has increased drug plant inspections in India, and is also seeking to increase its on-ground inspectorate in China. In-country inspectors can help ensure timely access to plants: while many domestic inspections are surprise visits, foreign inspections are often pre-announced by FDA to ensure that necessary personnel are present.[141]

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[139] Government Accountability Office. "Drug Shortages. Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability". February 2014.

[140] Hamburg, Margaret. Food and Drug Administration. "Visiting India: Sharing a Vision for Strengthening Food and Medical Product Safety" February 11, 2014.

[141] U.S. Government Accountability Office. (2007, November). *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers*. (Publication No. GAO-08-224T)

Congress should conduct ongoing oversight of FDASIA title VII implementation to ensure FDA is using its new authorities to protect the U.S. drug supply. Congress should also make sure the tools the agency has been given are sufficient. For example, the authority provided FDA to share information with foreign regulators is limited by a fairly onerous process wherein the commissioner herself must certify a foreign regulator has the ability to protect trade secrets.

Congress should also monitor implementation of DQSA Title II to make sure the new drug serialization and traceability system is implemented in a robust manner that provides maximum patient protection. In particular, as the system is phased-in over the years, Congress, FDA, and stakeholders should explore use of the drug serial number as a routine, proactive check to ensure patients are getting legitimate products.

The DQSA contains some requirements for companies in the supply chain to make use of serial numbers, but in most cases only when there is an existing belief that a product is suspect. An even more powerful use of serial numbers would be to use them as a proactive check to identify counterfeit or illegitimate product that otherwise might pass unnoticed into the drug supply chain. Italy and Turkey already require pharmacy authentication of serialized medicines in order to protect their citizens and prevent fraud, and additional countries such as China and Brazil are advancing similar requirements.[142, 143] According to one summary, the Chinese system will require serialized drugs to be tracked in a Drug Electronic Supervision Network. Every member of the supply chain must report serial number transaction information to the database, including the retail sector.[144]

Even without a federal requirement, verification should become routine in pharmacies. To achieve this, the system must be designed to ensure that verification is practical and efficient. Waivers of DQSA's requirements should be rare, lest we exempt businesses like the pharmacist in Chicago who was indicted last year for substituting Chinese counterfeits for legitimate products.[145]

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[142] Basta, Nicholas. "Serialization systems are going into operation around the world, but cross-industry collaboration awaits new legislation," Product Security Report, August 27, 2012 http://www.pharmaceuticalcommerce.com/index.php?pg=special_report&articleid=26610&keyword=2012%20product%20report-serialization-RxTEC.

[143] Turkish Ministry of Health. "G.D. of Pharmaceuticals and Pharmacies Guidance on Implementation of Identification and Barcoding of Medicinal Products for Human Use, Version 1.2" Ankara, 2009. http://www.clinicaltrial-storage.com/index.php/regulations-in-turkey-menu/89-turkish-drugs-barcode-guidance-v1-2

[144] Optel Vision. "China Track & Trace Regulations" http://www.optelvision.com/system/files/China%20T%26T%20Regulation%20by%20Optel%20Vision.pdf. Accessed March 26, 2014

[145] U.S. Food and Drug Administration, Office of Criminal Investigations. "April 18, 2013: Suspended North Side Pharmacist Indicted for Allegedly Smuggling and Trafficking Counterfeit Viagra". U.S. Department of Justice Press Release, April 18, 2013. http://www.fda.gov/ICECI/CriminalInvestigations/ucm349021.htm. Accessed February 24, 2014.

OPENING STATEMENT OF CHARLES BELL
PROGRAMS DIRECTOR, CONSUMERS UNION

MR. BELL: Good afternoon, Mr. Chairman and members of the Commission. Thanks very much for providing me the opportunity to come before you.

I'm Charles Bell. I'm the Programs Director for Consumers Union. And today I would like to speak to you about some issues relating to dietary supplement safety. We are quite concerned about issues relating to the international supply chains for prescription drugs and for medical devices, but I thought I could probably add the most value by addressing this topic, which I think gets somewhat less attention.

So consumers use dietary supplements because they think these products will be beneficial for restoring, improving and maintaining health, and, you know, many of these products are generally safe, and I don't want to be overly alarmist about them, but we are seeing some significant problems in the marketplace that pose unreasonable hazards to consumers, in our estimation.

Americans spend an estimated $32 billion a year on dietary supplements, purchasing more than 85,000 products, including vitamins, minerals, botanicals, amino acids, probiotics and other supplement ingredients, and six in ten Americans reportedly take dietary supplements on a regular basis with, for example, 46 percent taking multiple vitamins on a daily basis.

So what we find is that consumers generally tend to think if a product was not safe, the federal government would not allow it to be sold on shelves of retail pharmacies and grocery stores. What we find is there's quite a big disparity in the safety requirements for dietary supplements as opposed to prescription drugs.

There is no mandatory pre-market safety testing for dietary supplements. And they also don't have to demonstrate efficacy. So what that means is that a lot of products can be introduced with relatively minimal pre-market testing.

If it has a new dietary ingredient, there are now requirements that FDA has to be notified in advance, but generally speaking a lot of products do come into the market. These are presumed generally to just contain dietary ingredients so people think these are food products, and they would therefore be safe.

Now, over the last decade or so, a lot of the sourcing of dietary supplements and vitamin ingredients has shifted to China, following the pattern set by the drug industry, and this is raising certain concerns, and just the global sourcing of dietary supplement ingredients is raising certain concerns.

One concern is the potential contamination of imported supplement ingredients with toxic plants and heavy metals. And according to a 2009 article by Dr. Peter Cohen in the New England Journal of

Medicine, a wide range of dietary supplements have been found to be contaminated with toxic plant material, heavy metals or bacteria.

As one example of this, in 2007, the FDA announced a recall of Chinese herbal medicines contaminated with aristolochic acid, a powerful nephrotoxin that can cause kidney failure, and also contaminated with ephedra, an illegal supplement ingredient banned in the U.S. since 2004.

There was, in 2010, a GAO investigation that found trace amounts of lead and other contaminants in many supplements that were tested, and they also found pesticide residues that appeared to exceed legal limits.

And one of our concerns at Consumers Union about this practice is the heavy metal uptake in consumers is cumulative, and there's essentially no beneficial dose of lead or cadmium. Many people take multiple supplements, and we have relatively limited information about the assurance of quality for these imported or domestic ingredients for that matter. So this is a concern that we have.

A second very serious concern is the contamination and adulteration of dietary supplements with prescription drugs. More than 500 supplements in the U.S. have already been found to be adulterated with pharmaceuticals or pharmaceutical analogues.

And recent recalls from--Class I drug recalls from January 1, 2004 through December 2012, we had in this country 465 drugs and supplements that were recalled. Just over half of these were classified as dietary supplements rather than pharmaceutical products, and most of them were products marketed for body building, sexual enhancements or weight loss that were spiked with illegal prescription drugs.

And so in my testimony, I give a number of description of incidents relating to the contamination of those products. Often in the sexual enhancement case with Viagra-like drugs, that can be very harmful to people's health, can pose risks of adverse drug reactions or heart trouble with underlying cardiac symptoms.

Another case, weight loss products. We've seen many products in the market that have been contaminated with the drug Sibutramine, which was used in the drug, the brand name drug Meridia, that was withdrawn from our marketplace in 2010, and this is a weight loss drug, and it's just appeared in product after product. If you go on the FDA Web site and look at tainted supplements, you'd tend to see it there.

I myself bought this product in 2010 about month after it had been recalled by FDA. It's called Reduce Weight Fruta Planta, and it was recalled at that time for having been contaminated with Sibutramine, and, interestingly enough, I went on the FDA site, and there's another version of this in 2014 that was just recalled in February for being contaminated with another drug, a potential laxative that's been classified as a carcinogen.

So the point is that these products seem to have a lot of durability in staying in the market even after an FDA recall, and many consumers are using them.

In another case, they found in Massachusetts over 500 women using a Chinese herbal supplement spiked with Sibutramine 61 percent after it had been recalled by FDA.

So I hope my testimony will be useful in sort of explicating some of the problems that we're seeing. In other cases, we're also seeing steroids spiked with steroids. And there's evidence from some articles that I found that a lot of the materials are coming from China.

So, granted, these are illegal activities, and they're activities where U.S. companies are also involved to some considerable extent so we share responsibility for addressing them, but we think it's very important for consumer protection that we develop stronger standards for what kind of products are going to be allowed to enter our marketplace.

And I have to say given all the other responsibilities that FDA has to assure the safety of the drug supply, there is a risk that this issue will not get that much attention, and I think that would be too bad because the conditions that will allow for the illegal adulteration of dietary supplements are probably only expanding.

There's a lot of scientists and chemists and entrepreneurs that would love to have the extra income by selling into this very lucrative market, and so actually we may be in the very early days of this growing healthcare scandal.

Thank you. I'm sorry I've gone over time. I'd like to give the floor to my colleague.

VICE CHAIRMAN REINSCH: Your overtime is minuscule compared to most everybody else.

Dr. Jin, go ahead.

PREPARED STATEMENT OF CHARLES BELL
PROGRAMS DIRECTOR, CONSUMERS UNION

Testimony of Charles Bell, Programs Director Consumers Union before the U.S.-China Economic and Security Review Commission Hearing on China's Healthcare Sector, Drug Safety and the U.S.-China Trade in Medical Products April 3, 2014

101 Truman Avenue, Yonkers, NY 10703-1057 • (914) 378-2000

Good afternoon, Chairman Shea and members of the Commission. Thank you very much for providing me the opportunity to come before you today. I am Charles Bell, Programs Director for Consumers Union.

Consumers Union is the nonprofit publisher of *Consumer Reports* magazine. Since 1936, our mission at Consumers Union has been to test products, inform the public, and protect consumers. Today I offer this testimony on drug, supplement and medical product safety as part of our consumer protection function.

INTRODUCTION

Consumers use drugs, dietary supplements and medical devices because they think these products will be beneficial for restoring, improving and/or maintaining health. They also generally assume that such products are safe for their intended use, and would not be permitted to be sold by the federal government if they were unsafe and pose unreasonable risks to consumers.

Unfortunately, in our research and reporting, we have found some very profound and troubling gaps in the system we have today to assure drug, supplement and medical device safety. Today, I would like to highlight several concerns about the international supply chain for dietary supplements.

DIETARY SUPPLEMENT SAFETY

Americans spend an estimated $32 billion on dietary supplements annually, purchasing more than 85,000 products, including vitamins, minerals, botanicals, amino acids, pro-biotics and

other supplement ingredients.[146] Six in 10 Americans reportedly take dietary supplements on a regular basis, with 46 percent taking multiple vita-min/mineral products on a daily basis and 35 percent taking single vitamins, such as vitamin C. About 1 in 4 people (23%) use herbal and speciality supplements.[147]

Because dietary supplement products are sold in the same stream of commerce as approved over-the-counter products, and consumers often assume that if they were not safe, the government would not permit them to be sold.

For example, in an October 2002 nationwide Harris Poll of 1,010 adults, 59 percent of respondents said they believed that supplements must be approved by a government agency before they can be sold to the public. Sixty-eight percent said the government requires warning labels on supplements' potential side effects or dangers. Fifty-five percent said supplement manufacturers can't make safety claims without solid scientific support.

Unfortunately, the respondents in this poll are incorrect. None of those widely expected protections exist for dietary supplements—they exist only for prescription and over-the-counter medicines. With respect to testing for hazards, before approval, drugs must be proved effective, with an acceptable safety profile, by means of lab research and rigorous human clinical trials involving a minimum of several thousand people, and several years. In contrast, supplement manufacturers can introduce new products without any testing for safety and efficacy. The maker's only current obligation is to send the FDA a copy of the language on the label.

Because dietary supplements, by definition, are expected to contain only dietary ingredients; the federal law on supplements does not require premarket approval. There are new requirements that manufacturers should provide advance notification to FDA if they are including a "New Dietary Ingredient" or NDI, but the agency has expressed concern that many companies have not provided such notification.

The lower bar for introducing supplement products means that supplement manufacturers can much more easily introduce products with substandard, contaminated or adulterated ingredients into the U.S. retail and online markets. What we have been seeing over the last several years is that this is a key vulnerability that is very difficult, time-consuming and expensive to address.

QUALITY AND SAFETY OF IMPORTED SUPPLEMENT INGREDIENTS

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As noted in the 2010 report issued by the U.S.-China Economic and Security Review Commission. NSD Bio Group LLC, a research group under contract to the Commission, in recent years the U.S. has greatly expanded sourcing of pharmaceutical and dietary supplement products and ingredients from China.[148]

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[146] Cohen, P. "Hazards of Hindsight: Monitoring the Safety of Nutrional Supplements," N Engl J Med, 370:14, 4/13/14, p. 1277.
[147] Rouse, C. "Buyer beware when purchasing supplements," Time Reporter, New Philadelphia, OH, 12/16/13.
[148] NSD Bio Group LLC, "Potential Health and Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced

As the report noted, China is now the largest bulk drug manufacturing and exporter in the world, and has emerged as America's number one pharmaceutical trade partner. China is also the number one producer of Acetominophen and many other commonly used over-the-counter cold and allergy medications.

The report described the huge and growing size of the US market for dietary and nutritional supplements, and pointed out that many US nutrition supply companies are either based in China or do extensive sourcing there.

"China has come to dominate the vitamin raw material market over the last decade, controlling approximately one third of the world's vitamin production," according to the report. For example, China now supplies 92% of the vitamin C, 65% of vitamin B, and 40% of vitamin E raw materials imported into the U.S.

While the FDA has recently launched new initiatives to expand its Foreign Drug Inspection Program and has stationed an increased number of inspectors in China, Consumers Union is concerned that current oversight capacity and process is inadequate for the task of policing such a diverse array and large volume of imported products and ingredients.

Our concerns fall into several different categories.

1) POTENTIAL CONTAMINATION OF IMPORTED SUPPLEMENT INGREDIENTS WITH TOXIC PLANTS AND HEAVY METALS

Acute lead poisoning symptoms can include abdominal pain, muscle weakness, nausea, vomiting, diarrhea, weight loss and bloody or decreased urinary output. Children are particularly vulnerable to lead poisoning. Also note that people with high levels of lead in their blood may show no symptoms, but the condition can still damage the nervous system and internal organs.

According to an 2009 article by Dr. Pieter Cohen in the New England Journal of Medicine, "a wide range of dietary supplements have been found to be contaminated with toxic plant material, heavy metals, or bacteria."[149]

As an example of supplements contaminated with toxic plant material, in 2007 the FDA announced a recall of Chinese herbal medicines contaminated with aristolochic acid, a powerful nephrotoxin that can cause kidney failure, and ephedra, an illegal supplement ingredient banned in the U.S. since 2004.[150]

Ingredients," prepared for the US China Economic and Security Review Commission, April 2010.

[149] Cohen P. American Roulette: Contaminated Dietary Supplements, NEJM, 10/7/09, NEJM.org.

[150] U.S. FDA, "Herbal Science International, Inc. Recalls Twelve Dietary Herbal Supplements Nationwide Because of Possible Health Risk Associated with Ephedra, Aristolochic Acid and Human Placenta," Firm Press Release, available at:

In October 2013, Health Canada warned consumers that Compound Danshen Dripping Pills manufactured in China, had been associated with a Canadian case of methemglobinemia, a rare but serious condition that can result in coma or death.[151] These products are available for sale to consumers in the U.S. on Ebay as of April 2, 2014, one from a seller in New York and one from a seller in China.[152]

Over half of herbal dietary supplements tested in a Congressional investigation contained trace amounts of lead and other contaminants.[153] While the levels of heavy metals did not exceed levels that the investigators thought were dangerous, in 16 of 40 samples, the pesticide residues appeared to exceed legal limits.

In 2010, Dr. Tod Cooperman of ConsumerLab.com of White Plains New York testified that 40% of St. John's wort supplements and 14% of valerian supplements tested by his lab exceed World Health Organization guidelines for cadmium contamination. The FDA has not established limits for cadmium in dietary supplements. ConsumerLab.com also testified that a significant number supplements failed California's Proposition 65 limits for lead and cadmium.

As Dr. Cooperman pointed out to the Senate Aging Committee, "While individual products with elevated levels of lead and cadmium are generally not toxic in themselves, they unnecessarily expose Americans to toxins, and the effects are cumulative." As Dr. Cooperman pointed out, some consumers may take as several or many dietary supplements each day, so elevated levels of lead or cadmium in these products could pose health concerns.[154]

A 2009 study published in the Journal of General Internal Medicine found that women who use herbal dietary supplements have elevated levels of lead in their blood, that were 10% higher than women who did not use herbal supplements.[155] The researchers state that "…excess lead found

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http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2008/ucm112427.htm

[151] Health Canada, Foreign Product Alert. The alert states that: "This product is not authorized for sale in Canada and has not been found in the Canadian marketplace, but it is possible it may have been brought into the country by travellers or purchased over the Internet." Available at: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/36157a-eng.php

[152]

[153] Harris, G. "Study Finds Supplements Contain Contaminants," The New York Times, May 25, 2010; and U.S. Government Accountability Office, "Herbal Dietary Supplements: Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice," Testimony before Senate Committee on Aging, 5/26/10, GAO-10-662T

[154] Testimony of Tod Cooperman, MD, President, ConsumerLab.com to Senate Special Committee on Aging, 5-26-2010.

[155] Buettner, C. et al. "Herbal Supplement Use and Blood Lead Levels of United States Adults ," J Gen Intern Med. Nov 2009; 24(11): 1175-1182. Published online Jul 3, 2009, available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2771230/

in some herbs may, in part, be due to herbs grown in less-regulated countries, such as China and India, which are major exporters of raw plant products for the supplement industry. Alternatively, uncontaminated herbs could acquire lead during manufacturing due to contaminated water, equipment, pipes, or storage."[156]

Because resources for testing and surveillance are very limited, such reports probably represent only the fraction of the contaminated supplements that are present in the marketplace. Consumers Union is concerned that FDA is not providing adequate oversight of supplement contamination problems. We need to assure consumers that dietary supplements are consistently low in heavy metals and other forms of chemical or mineral contamination. At a minimum, we believe that products should not exceed U.S. Pharmacopeia limits for lead and other heavy metals. Because consumers do not expect to encounter heavy metal contamination in supplements, and many consumers may take multiple supplements or multiple doses of supplements, additional oversight may be needed to reduce hazards and warn consumers about unexpected health risks.

2) CONTAMINATION AND ADULTERATION OF DIETARY SUPPLEMENTS WITH PRESCRIPTION DRUGS

Over the last several years, there has been an increasing number of FDA recalls of dietary supplements relating to adulteration with prescription drugs. According to an article by Dr. Pieter Cohen in the New England Journal of Medicine, "More than 500 supplements have already been found to be adulterated with pharmaceuticals or pharmaceutical analogues, including new stimulants, novel anabolic steroids, unapproved anti-depressants, banned weight-loss medications, and untested sildenafil (erectile dysfunction drug) analogues."[157] The FDA maintains an ongoing list of these tainted supplements.

From January 1, 2004 through December 19, 2012, 465 drugs and supplements were subject to a Class I recall in the U.S. Just over one-half of these (237, or 51% of the total) were classified as dietary supplements rather than pharmaceutical products. Dietary supplements promoted as sexual enhancement products were the most commonly recalled product, followed by body-building and weight-loss products. While one-quarter of the recalled products were manufactured in other countries, three-quarters of them were actually manufactured in the U.S.[158] However, news accounts suggest the U.S. products are often manufactured with ingredients sourced and imported from other countries, including China, as outlined below.

When supplements are adulterated, dosages of the unregulated pharmaceutical ingredients may vary widely, posing hidden risks of drug interactions and adverse events.

A) SEXUAL ENHANCEMENT SUPPLEMENTS

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[156] Ibid.

[157] Cohen, P. "Hazards of Hindsight: Monitoring the Safety of Nutritional Supplements," N Engl J Med, 4/3/14, p. 1277.

[158] Harel, Z. et al. "The Frequency and Characteristics of Dietary Supplement Recalls in the U.S.," Research Letter., JAMA Internal Med, 4/15/13, p. E1-E3.

- In April 2008, U.S. Marshals seized more than 14,000 dosages of sexual enhancement supplements spiked with prescription drugs at FDA's request. The products were Shangai Regular, Shangai Ultra, Super Shangai, Naturalë Super Plus, and Lady Shangai. The seized products, valued at more than $100,000, originated in China and were packaged and distributed by Shangai Distributors Inc. of Coamo, Puerto Rico.[159]

- In 2011, Kelly Harvey of NovaCare, a dietary supplement company in Utah, was indicted in a 31 count felony for manufacturing and distributing adulterated sexual enhancement supplements. "The U.S. Attorney's Office argues that Harvey knowingly imported vast quantities of a spiked compound from China that he turned into more than one million capsules a month. NovaCare allegedly sold the pills to distributors, making made more than $2 million on the products from August 2007 to June 2010."[160]|

- In August 2013, the Associated Press reported that "ingredients used to alter herbal [sexual enhancement] pills come from Asia, particularly China, where the sexual enhancers are cooked up in labs at the beginning of a winding supply chain. The FDA has placed pills by two manufacturers in China and one from Malaysia on an import watch list."[161] The risks of using such products with unregulated ingredients are considerable, the article said, because "For men on common heart and blood-pressure drugs, popping one could lead to a stroke, or even death."[162]

In the U.S., herbal sexual enhancement products are sold as dietary supplements and are legally permitted to make claims such as 'enhances sexual performance' without any evidence of efficacy or safety." As Dr. Pieter Cohen points out, some men may elect to use these products to avoid the embarrassment and cost of visiting a physician, and/or perceive them to be a safer alternative to using a prescription drug. However, they may not realize that products they select actually contain higher dosages of a prescription drug such as sildenafil citrate (the active ingredient in Viagra), or multiple, unexpected pharmaceutical ingredients.[163] To put the problem in further context, U.S. sales constitute only a fraction of the global market for adulterated pills. One study found that 77% of natural sexual enhancement supplement in Singapore were spiked

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[159] U.S. Food and Drug Administration, "Hidden Risks of Erectile Dysfunction 'Treatments' Sold Online," FDA Consumer Health Information, 2/21/09 accessed at: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048386.htm

[160] Canham, M. "Feds plow new ground in spiked supplement case," Salt Lake City Tribune, 10/1/11, available from: http://www.sltrib.com/sltrib/news/52657684-78/harvey-company-products-case.html.csp

[161] Associated Press. "All natural sex-pills pose hidden dangers," 8/8/13, accessed at: http://www.nbcnews.com/id/21758130/ns/health-mens_health/t/all-natural-sex-pills-pose-hidden-dangers/#.Uz0sJ6Ivm8g

[162] Ibid.

[163] Cohen, P. "Adulterated Sexual Enhancement Supplements: More than Mojo," JAMA Intern Med, published online 5/13/13.

with prescription drugs.[164]

B) WEIGHT LOSS PRODUCTS

Over the last decade, the FDA has also identified and recalled numerous weight loss products that are spiked with illegal prescription drugs. A very common drug found in these products is sibutramine, and the dosages found can be as much 3 times the recommended dose. Sibutramine was originally developed and marketed as drug for treating obesity, under the brand name Meridia. Meridia was voluntarily withdrawn from the marketplace by its manufacturer in 2010, because of clinical trial data indicating an increased risk of heart attack and stroke.

Dietary supplements spiked with sibutramine can put consumers without any history of health problems at risk for adverse events such as increased blood pressure, tachycardia, palpitations, and seizure. For consumers who have health problems or are taking other prescription drugs or supplements, the consequences could be equally or more serious. Other unregulated prescription drugs found in dietary supplements offered for sale in the U.S. over the last few years have included fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein.[165]

- In 2009, the FDA recalled Pai You Guo, a supposedly natural weight-loss supplement from China, that contained sibutramine and phenolphthalein, an ingredient removed from over-the-counter laxatives after it was identified as a potential carcinogen. A study of 500 Brazilian women in Boston found that one in 5 used Pai You Guo. 85% reported at least one side effect commonly associated with sibutramine, including dry mouth, anxiety and insomnia. 61% of the users reported using the product after the FDA recall.[166]

- Also in 2009, U.S. Border and Customs Agents intercepted Super Slim and Meizitang diet pills spiked with sibutramine that were shipped from China to Colorado, by a company based in Southwest China. In 2010, federal agents arranged to meet the owner of the Chinese company, Shengyang Zhou, in Bangkok and negotiated the purchase of 2 Day Diet and Super Slim supplement pills adulterated with sibutramine, and also a counterfeit version of the diet drug Alli that contained sibutramine rather than its usual drug, orlistat.. Mr. Zhou later pleaded guilty to trafficking and attempted trafficking in counterfeit goods, and served time in federal prison. The owner said that "…he had a factory that could make thousands of boxes of 30 types of weight-loss products per day…. He told the agents he had 20 employees, each making $300 a month, and that he sold his product through at least two websites. Zhou said he bought his bottles from one

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[164] Ibid.

[165] Questions and Answers About FDA's Program Against Contaminated Weight Loss Products, updated 9/3/13, accessed at: http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm136187.htm

[166] Hobson, K. "Women Still Using Pai You Guo Supplement Despite Ban," The Wall Street Journal, August 16, 2011, accessed at: http://blogs.wsj.com/health/2011/08/16/women-still-using-pai-you-guo-supplement-despite-ban/

company, empty capsules from another and the sibutramine from yet another."[167] During Zhou's sentencing, he was ordered by the judge to pay $87,000 in lost wages to a California emergency room doctor, who had experienced a stroke after purchasing and using the counterfeit Alli pills on Ebay.[168]

- In 2010, a Chinese herbal supplement called Reduce Weight Fruta Planta, distributed by PRock Marketing LLC of Florida was recalled by the FDA. FDA testing confirmed that Fruta Planta contains sibutramine. FDA also stated it had received received multiple reports of adverse events associated with the use of Fruta Planta and Reduce Weight Fruta Planta, including several cardiac events and one death.[169] I (Charles Bell of Consumers Union) purchased a box of Fruta Planta from a New York based web site several months after the recall, and also found it being sold in a grocery store in Ossining, NY. The manufacturer listed on the box is "Hainan Resurgence Natural Healthy Food Co." in Guangzhou City, China. In February 2014, MyNicKnaxs, LLC, a different manufacturer, announced a recall of Reduce Weight Fruta Planta, indicating that FDA lab analysis had confirmed the product contains Phenolphthalein, a potential carcinogen once used in over-the-counter laxatives.[170]

- In 2012, Thuy Thi Kim Nguyen, a Louisiana nail salon owner was sentenced to three years probation and ordered to pay $365,000 in restitution, for selling Extreme Body Reshape and Figure Reshape dietary supplements spiked with sibutramine, which she had arranged to have manufactured for her in China.[171]

- A supplement marketed as a Chinese herbal supplement in Kansas in 2010 was found to be contaminated with sibutramine, fenfluramine, propranolol, and ephedrine. The product Que She, was advertised as "Slimming Factor Capsule" and as "an all-natural blend of Chinese herbs.[172]

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[167] Tsouderos, T. "Unsafe drugs put in the mix; some products called health aids prove anything but," Chicago Tribune, August 10, 2012, Zone C Page 1.

[168] Ibid.

[169] U.S. FDA, Press Release, FDA warns consumers not to use Fruta Planta weight loss products; *All Fruta* Planta products being recalled by maker because it contains sibutramine" December 31, 2010, accessed at: http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm238491.htm

[170] U.S. FDA, "Reduce Weight Fruta Planta: Recall – Undeclared Drug Ingredient," updated 2/15/14, accessed at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm385999.htm

[171] Burgess, R. "Woman gets probation for supplement drugs," The Advocate (Baton Rouge, Louisiana), November 3, 2012

[172] US Food and Drug Administration, "Que She Herbal Supplement: Undeclared Drug Ingredients," July 8, 2010, http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm218439.htm

- A regulatory crackdown in China in 2012 netted 1,900 arrests and $180 million in counterfeit products, including some products containing sibutramine. [173]

- A case of renal failure in a 33-year old woman was reported last month in North Carolina, by a doctor who said the patient had used Zi Xiu Tang Bee Pollen, a Chinese herbal supplement is marketed as weight loss and body reshaping supplement.[174] Some lots of this product had been voluntarily recalled by its manufacturer, Zi Xiu Tang Success, LLC of Kutztown, PA in 2012.[175] In 2013, the FDA sent a warning letter to the product's manufacturer, stating that lab analysis had confirmed that some lots of the product contained undeclared sibutramine.[176] Some Zi Xiu Tang Bee Pollen products appear to be manufactured in China, while others are alleged to be counterfeit.

C) BODY-BUILDING PRODUCTS

Significant involvement of Chinese manufacturers in providing ingredients for adulterated body-building supplements is suggested by the following reports:

- A 2013 article in the Newark Star-Ledger reports that products originating from China now account for more seizures of illicit steroids than anywhere else in the world, according to US Customs and Border Patrol statistics. "…Last year, more than 400 pounds of steroids and other performance enhancing drugs shipped from China and Hong Kong were seized at U.S. entry ports — ten times as much as any other country."[177]

- "We get 700,000 international parcels a day that we're screening. Finding this is really like looking for a needle in a haystack," said Wilfred Rivera, U.S. Customs and Border Protection branch chief at the International Mail Facility at John F. Kennedy International Airport, who was quoted in the article.

- Production of illegal steroids has shifted to China after many illegal labs in Mexico were shut down. In 2007, the Drug Enforcement Administration targeted 56 labs in the U.S.

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[173] "China Crackdown on Counterfeit Drugs Nets $180 Million in Fakes, 1,900 Arrests",
International Pharmaceutical Regulatory Monitor, August 10, 2012

[174] Joshi, H.J. and Obi, R. "A case report of chronic interstitial nephritis associated with
Chinese herbal supplement Zi Xiu Tang Bee Pollen," Department of Nephrology and Hypertension, East Carolina University College of Medicine, Greenville, NC, USA. Case Report in Internal Medicine, 2014, Vol. 1, No. 2, 3/28/14, accessed at: http://dx.doi.org/10.5430/crim.v1n2p65

[175] U.S. FDA, "Zi Xiu Tang Success, LLC Issues Voluntary Nationwide Recall Of Classic Zi Xiu Tang Bee Pollen Capsules And Ultimate Formula Capsules Due To Undeclared Sibutramine," accessed at:
http://www.fda.gov/Safety/Recalls/ucm326267.htm

[176] Letter to Zi Xiu Tang Success, LLC 5/14/13, accessed at:
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm354241.htm

[177] Sherman, T. "Black market steroids pipeline leads from N.J. to China, feds say," Newark Star-Ledger, June 18, 2013

that were manufacturing anabolic steroids and Human Growth Hormone supplements. Investigators found the labs were using raw powders that had originated in China. More than 120 people were arrested as part of the international investigation, known as Operation Raw Deal.

- "Despite the big bust, however, China remains a steroids drug store for both 'designer' compounds and knock-offs of brand name pharmaceutical products only available here by prescription, all accessible to anyone with an internet connection," according to officials quoted in the article.[178]

- In November, a federal grand jury in Portland, Oregon indicted 16 people accused of conspiring to import illegal anabolic steroids, mostly from China, and using a local business, SJ Motors, as a front for drug trafficking and money laundering. According to the Portland Oregonian, "…Investigators tracked at least 68 shipments of illegal steroids from China to the defendants between 2008 and this past August, the indictment said. They also identified nearly 50 Western Union wire transfers of money to Chinese chemical companies to buy anabolic steroids."[179]

POSSIBLE VITAMIN ADULTERATION

In May, 2012, Minneapolis-based MOM Brands brought a lawsuit against a DMH Ingredients in Chicago, alleging that alleging that antifreeze-tainted vitamin C (sodium ascorbate) originating in China ended up in thousands of boxes of its Malt-O-Meal branded cereral. The Minneapolis Star-Tribune reported that an independent lab had found that the sodium ascorbate was tainted with chemicals including ethylene glycol, which is widely used as antifreeze. The company said in its court papers that it believed the tainted vitamin C originated from a plant in Shenyang, China. The case was later settled by the parties to their mutual satisfaction, and the terms of the settlement were not disclosed to the public.[180].

ECONOMIC ADULTERATION OF DIETARY SUPPLEMENTS

Despite the FDA's best efforts, problem of spiked dietary supplements seems particularly resistant to detection, enforcement, and eradication. Over the past six or seven years, the FDA has issued hundreds of recall notices and warnings to manufacturers and consumers. It has directed distributors to recall tainted supplements and seized millions of dollars worth of supplement products. It has expanded its surveillance programs and investigated some big-time offenders -- but still the problem continues.

As one 2011 New York Times article put it:

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[178] Ibid.

[179] Bernstein, M. "Portland business served as a front for illegal steroid drug trafficking ring, indictment says," The Oregonian, 11/14/13.

[180] Hughlett, M. "Malt-O-Meal maker sues over tainted ingredient," Minneapolis StarTribune, May 25, 2012. Hughlett, M., "MOM Brands Settles Tainted Ingredient Suit Against Supplier, Minneapolis StarTribune, February 20, 2013.

> "It's a remarkable tidal wave of products," Michael Levy, acting director of the F.D.A.'s office of drug security, integrity and recalls, says while sitting at a table laden with contraband in Silver Spring, Md. "We are removing only a fraction."
>
> The problem, he says, is that the F.D.A. lacks the resources to stem the influx of illegal raw ingredients and finished products — mainly from Asia — to the United States. Moreover, he says, the agency cannot easily prevent adulterated products disguised as supplements from reaching the market.
>
> That is because supplement makers in the United States can introduce new products much more easily than pharmaceutical companies. Drug makers are required to prove that their products are safe and effective, and they must obtain federal approval before going to market. But dietary supplements, by definition, contain only dietary ingredients; the federal law on supplements does not require premarket approval. That can make it easy for purveyors of spiked products to use the cover of supplements to ply their wares.
>
> Trying to get tainted products off the market is expensive and time-consuming. Before federal officials can take action, Mr. Levy says, they must first buy suspect items or catch them at the border, and then test them in an agency lab.[181]

CHEAP INGREDIENTS MAY COME AT A HIGH PRICE

For dietary supplements specifically, there is also a key problem that oftentimes, it is only the manufacturer that is calling the shots. Manufacturers decide what they will market, and can introduce products to the US market without any showing of safety or efficacy. And a lot of the quality assurance decisions are basically up to them.

My understanding is that the number of cGMP inspections of facilities producing dietary supplements in China has been quite limited. The US FDA cGMP compliance is not required by law for Chinese suppliers, although they can participate in voluntary certification programs. The FDA has some reach into these issues through its ability to hold US supplement manufacturers accountable their interactions with suppliers.

A recent article in Nutritional Outlook, subtitled "You Want Cheap, You'll Get Cheap," described pressures that price may place of the quality of supplied ingredients:

> If a manufacturer is shopping solely on price, it will most likely get what it pays for—poor quality and potentially unsafe materials. Pushing suppliers down on price opens the door to economic adulteration and gives unscrupulous suppliers an area of opportunity. This ethical business decision lies solely in the hands of the manufacturer.

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[181] Singer, N. "Ingredients of Shady Origin, Posing As Supplements,," The New York Times, 8/27/11, accessed at: http://www.nytimes.com/2011/08/28/business/supplement-drugs-may-contain-dangerous-ingredients.html?pagewanted=all

> One of the biggest complaints I receive from Chinese suppliers is that because there are manufacturers willing to shop based on price alone, it creates competition that a reputable supplier could never compete with.
>
> I recently spoke with Dasherb, a German-Chinese joint-venture botanical supplier in Shenyang, Lioaning Province, on the issue of shopping on price and not knowing your supplier. ***Mr. Shi, the company's general manager, told me that there are suppliers in China producing 100 kilos of herbal extract from 100 kilos of raw material. It's obviously impossible to create an extract that weighs the same as the material you started with. Thus, he added, some companies will add useless plant material to add bulk.*** In this case, while it may not be harmful to health, the manufacturer is still left with a poor-quality extract, which will yield a substandard finished product with little to no efficacy.[182]

Mr. Shi went on to say that his company would not do business like that. But this is a very interesting comment about what may be happening with financial pressure on ingredient prices. Cheap can come with a high price for the consumer. In the case of substandard ingredients, consumers may get products that do not provide the promised health or therapeutic benefits. We in the consumer movement tend to worry about safety issues first and foremost, but assuring the quality of supplement ingredients is also important for protecting the public against economic fraud.

RECOMMENDATIONS

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It is very important to ensure that dietary supplements are safe for their intended uses, and do not themselves create serious health problems. Consumers should be assured that dietary supplements they buy follow sound manufacturing practices, and are not adulterated or contaminated with heavy metals like lead, or prescription drugs. Throughout my testimony, I hope the point has also been made clear that many of the incidents and problems I am describing have come about as a result of actions by US manufacturers and distributors, working in partnership with Chinese suppliers or companies. So there is an issue of mutual responsibility which needs to be addressed, and always there is the issue of exercising due diligence and responsibility toward end users -- consumers.

In addition, concerns about the integrity of imported ingredients and the supply chain are not just limited to China. US health and safety officials must assure the safety of all imported products that are used in the U.S., particularly food, drugs and supplements, regardless of the country of origin. As foreign trading partners play a larger role in supplying nutritional supplements and materials for their production, there is an urgent need for greater public oversight to assure the quality of imported products and ingredients.

Further, as consumer advocates, we are concerned about the health and safety of consumers

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[182] Crowther, Jeff, "Dietary Supplements and China: Supply Chain Woes," Nutritional Outlook, March 25, 2011. Accessed at: http://www.nutritionaloutlook.com/article/dietary-supplements-and-china-supply-chain-woes

worldwide. Supply chain defects anywhere can be a threat to consumers everywhere. Reports indicate that many of the adulterated supplements entering the U.S. are also widely sold in other countries. Safety improvements are important for consumers especially in countries with weaker regulatory systems, who have less protection and information about these emerging hazards.

As pointed out by authors Virgina Wheatley and John Spink, in their paper "Defining the Public Health Threat of Dietary Supplement Fraud," our national challenge is not just to interdict illegal and adulterated supplements, but to disrupt those parts of the supply chain that allow those practices to incubate, regenerate, and flourish.

> **Focus on reducing the [dietary supplement] fraud opportunity**. Disrupting a fraudulent dietary supplement operation requires "outside the box thinking." The fraudsters are clandestine, stealthy, well informed, and very creative at circumventing detection or inspection hurdles. The persistence of the fraudster is why the concept is an "opportunity" rather than framed as a public health and economic threat. Prevention should focus on the motivation of the fraudster. Just because regulatory agencies remove fraudulent products from retail stores does not mean that the supply chain shuts down. Regulatory agencies should focus on prevention by conducting full traceback and traceforward activities to determine where the product has been bought and sold. A business should provide invoices with their supplier information to demonstrate legitimacy of a suspected product. If a product is fraudulent, regulatory authorities should follow up with an investigation of the supplier(s). Regulatory authorities should require the business to issue written notices to their customers that the implicated product(s) has been recalled, and that they should return it for a refund. The investigation should not stop at "how" the product was made and the system breached, but "why" did the fraudster perceive a fraud opportunity in the first place. Once fraudulent products are identified, regulatory authorities must work together with FDA or their counterparts in other states to identify and share information that will assist in cutting off or disrupting fraudulent supply chains. Customs authorities should be apprised and provided with written information on fraudulent suppliers and products so that they can take steps to stop importation at the border.[183]

In the U.S., Consumers Union has been a strong supporter of the Dietary Supplement Labeling Act (S. 1425), proposed by Senators Richard Durbin and Sen. Richard Blumenthal. The Durbin-Blumenthal would give consumers of dietary supplements a clearer understanding of what they are taking by:

> **1. Allowing FDA to track how many dietary supplements are on the market and what ingredients they contain.** Under The *Dietary Supplement Labeling Act*, manufacturers would be required to provide registration information for new products within 30 days after being marketed. They would also be required to provide a description of each product, its ingredients, and a copy of the label. If a product is

[183] Wheatley, C. and Spink, J. "Defining the Public Health Threat of Dietary Supplement Fraud," Comprehensive Reviews in Food Science and Food Safety, Vol 12, 2013. p. 599-613.

removed from the market, they would be required to inform the FDA. Currently it has been estimated that FDA lacks basic information for many supplement manufacturers and could have significant difficulty contacting them in the event of a recall.

2. Requiring more information on product labels including warnings associated with specific ingredients. The bill would require dietary supplements labels to display a warning if the product contains an ingredient that may cause serious adverse events, drug interactions, contraindications or risk for subpopulations such as children and pregnant women. If a proprietary blend contains such a dietary ingredient, the weight per serving of that ingredient must be disclosed on the label. Labels also would have to include the batch number, which would help the FDA identify and recall contaminated product.

3. Giving FDA the authority to require manufacturers to provide proof for any potential health benefit claims. Manufacturers of dietary supplements are allowed to use claims about the benefits of their product for marketing purposes. Manufacturers are also required to have substantiation supporting claims on product labels to ensure they are truthful and not misleading. The *Dietary Supplement Labeling Act* would give FDA the authority to require manufacturers, upon request, to submit substantiation supporting structure and function claims on labels.

4. Directing the FDA to clarify the distinction between dietary supplements and food and beverage products with additives. The vague distinction between a dietary supplement and a conventional food has created a murky and growing market space where industry is selling products like beverages with high levels of additives that act as stimulants and brownies with high levels of ingredients that lull the body into relaxation. The bill would direct the FDA to establish a definition for "conventional foods" in order to clarify for industry, for consumers and even for the agency itself what products are foods and should be regulated as foods and what products are meant to be health aids and should be regulated as dietary supplements.

These ambitious and significant provisions are fundamental for a reformed oversight system. But even the relatively modest requirements of this law have drawn political resistance from some quarters of the supplement industry.

Because our system for monitoring dietary supplement safety problems is almost exclusively a post-marketing system, Consumes Union also believes we need a more robust national database for dietary supplement adverse event reporting, that draws on a wider ray of reporting sources. In his April 2014 article in the New England Journal of Medicine, Dr. Pieter Cohen has proposed that integrating data from all key organizations that track supplement hazards into a common database, integrating adverse event and incident reports from poison control center, the Department of Defense, local departments of public health, and manufacturers. Researcher Ano Lobb, a public health consultant who has worked in the past on the Consumer Reports Health Letter, the only warning about Hydroxycut were growing case reports in the medical literature. (Hydroxycut was recalled by FDA in 2009, after FDA received six dozen reports of adverse events, including 23 cases of liver toxicity and at least one death.) Lobb also points out that the

nation's Poison Control Centers may be detecting 10 times more adverse events related to supplements. The FDA could potentially increase its postmarket surveillance capacity by incorporating the Poison Control Center data, and coordinating with independent researchers who could help provide earlier warning of supplement hazards.[184]

Dr. Pieter Cohen has also proposed creating a supplement response team make up of expert clinicians, toxicologists, pharmacologists and chemists, who could quickly take action and respond to emerging hazards. The changes Dr. Cohen has proposed would help ensure that the FDA has much better, accurate and timely information and reports on particular hazards, but also that clinicians would get expert advice to care for affected patients. [185]

Ulimately, as Dr. Cohen also points out, however, there is also no substitute for requiring mandatory, rigorous premarket safety testing for all dietary supplement products before they enter the marketplace. That would be a far more effective and efficient way to keep unsafe and ineffective products from reaching consumers. Without that basic safeguard, the U.S. is leaving the back door open to a huge number of questionable products that are likely to contain unsafe and illegal ingredients. We certainly appreciate the policy and political challenges inherent in achieving such a protection. But it is troubling to contemplate how continued pressures for economically-motivated adulteration of supplements in the global supply chain will play out for U.S. consumers, if we do not have it.

A final concern is the level of priority that is given to addressing dietary supplement safety concerns, relative to the many other needs and pressures on FDA. With so much on its plate for protecting the public on pharmaceutical issues – and a large multi-year backlog of Chinese drug facilities to inspect -- it is understandable the FDA would prioritize issues related to what it perceives on the biggest risks. I hope that what I've share with you today gives you some sense of what some of the safety issues are for another very important category of health products, which are used by hundreds of millions of Americans.

CONCLUSION

Mr. Chairman, Members of the Commission, thank you very much for the opportunity to testify here today about this critically important consumer protection issue. We thank you for your efforts to protect consumers in international trading arrangements, and look forward to working with you as you move forward in addressing these issues.

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[184] Lobb A. Enhancing FDA's Post-Market Surveillance of Dietary Supplements: Two Simple Steps to Build Capacity. Journal of Dietary Supplements, 9/21/09, Vol 6(3), 204-210.

[185] Cohen, P. "Hazards of Hindsight – Monitoring the Safety of Nutritional Supplements," New England Journal Of Medicine, April 3, 2014, p. 1277-1280.

OPENING STATEMENT OF DR. GINGER ZHE JIN
PROFESSOR OF ECONOMICS, UNIVERSITY OF MARYLAND

DR. JIN: Thank you for having me.

My name is Ginger Jin. I have devoted my research career to studying markets with asymmetric information, especially the markets where sellers have better information about product quality than their buyers, and medical products is a classical example in this category.

However, medical products is also a special case in the sense that many consumers, will remain in the dark even after they have consumed the products, and sometimes there will be adverse consequences that consumers do not expect, and those consequences not only apply to consumers who actually consume the products, but also to consumers who do not consume the products, through either drug resistance or contagion.

So in my oral testimony, I'm going to first describe a study that I have done about poor- quality drugs, and then I will offer my opinion about challenges facing the Chinese regulators in this area.

Research about poor-quality drugs has been frustrated by the lack of clear definition of counterfeit, fake, falsified or substandard drugs. According to the World Health Organization, counterfeit drugs refers to the drugs that infringe the intellectual property rights of other legal drugs in terms of trademarks, patents, copyrights and so forth. In other words, counterfeit emphasizes IP infringement and the intent to deceive other than the chemical contents.

However, the chemical contents are what lead to public health consequences, which arguably could be as large as, if not larger, than the consequence of IP infringement.

In the study that is forthcoming in the Journal of Economic and Management Strategy, we have focused on testing a special kind of drug, Ciprofloxacin. It's a special type of antibiotic. It's a very important antibiotic that fights many bacteria, including anthrax.

So we acquired about 1,437 samples from all over the world in 18 poor-to-mid-income countries. We tested their active ingredients, and classified them to be falsified if we couldn't find any correct active ingredient in the drug sample of Cipro.

We classified them as substandard if the active ingredient can be found in some extent but less than 80 percent of the required amount. So in our 1,437 samples we found about 59 samples to be falsified, and that accounts for about 4.1 percent of the whole sample. The other 83 turned out to be substandard and they accounted for about 5.8 percent. So total is 9.88 percent, and this percentage is much higher than what we would get from visual inspection. If we just look at a visual inspection, we'll spot about 11 samples to be a problem. And all those 11 samples turned out to fail our active ingredient test.

This estimate is just one study, and it tends to understate the problem because we only sample from pharmacies that have physical stores.

We also only test active ingredients while the problem of quality could go much beyond active ingredient into impurity or other degradation issues.

That being said, for a falsified drug that has no active ingredient of Cipro but claimed to be Cipro, it's almost for sure to be an intentional cheating. There was insufficient active ingredient in substandard drugs. That could be intentional or unintentional.

In our study, we also tried to tie the test outcomes to the regulatory environment. We look at whether the country has price regulations and what's the maximum penalty for counterfeiting. We also look at whether the product has been locally registered or that the product has been prequalified in WHO program, and whether the product has already been approved in the U.S. or by West Europe standards.

When we put all those regulatory variables in the analysis, we find that only product registration--this is local product registration--turns out to be important in predicting the passing feature of the drug sample. However, all the U.S. approved or WHO prequalified drugs, are also locally registered. Statistically, we show that products registered at the local government tend to have a better quality.

However, that does not necessarily suggest that product registration at the local government would solve the problem because we also find a very intriguing finding, and that is the falsified drugs are more likely to be registered products. They seem to try to target the well- known generic brands, and they actually price almost the same level as the authentic version.

In contrast, substandard drugs, typically do not target the registered products. They're priced about ten percent cheaper than the comparable brands. So this highlights a very intriguing sophistication of deliberate cheaters. They tend to target actually not the brand name drugs but the well-known generic brands, and they price the same as the generic brands.

So this sort of highlights the difficulty of trying to discipline this market. Even if we think product registration statistically would predict higher quality drugs, they also become targets of falsification or even counterfeits.

In our sample, we find about half of our sample are, quote-unquote, "imported." We can only look at the claimed manufacturing place rather than the actual manufacturing place, and in our sample, six percent of them claim to be made in China, and conditional on failures, about 20 percent of our failing samples are claimed to be made in China.

So this is--at least it's saying that the label of "made of China" is related to some quality issues.

And in the last one minute, I want to just offer a few opinions about the challenges I think facing the Chinese regulators. The first challenge is that this country is very large; it's very complex. It also has very diverse industry market structure.

We're talking about probably 4,000 manufacturers in

pharmaceutical projects, about 400,000 retail pharmacy shops, and according to the Chinese customs data, about 29,000 firms actually involved in exporting medical products. So with this kind of diverse market structure, it's going to be very difficult to inspect each one of them to make sure each one of them conforms with standard of practice.

The second challenge is that the Chinese regulators have a very hierarchical structure of administration. There are several levels of administration from the central government to the provincial to the city government, and as has been testified in the first panel, the staffing at the very central level is actually quite limited. A lot of work is done by the local, provincial, or city level, and, as you know, the local governments actually were appointed from top down so their incentive is to promote their political career.

One of the most salient measures of their performance is actually GDP growth rather than the amount of drug safety, for example. That kind of performance measure is going to encourage them to promote GDP, and we know medical products tend to have high values so that could be a local contributor to the GDP. This would undermine their incentive to try to be really harsh on those local enterprises.

Another incentive they face is that, they actually would want to either ignore or hide the problem, and they don't want the higher-level officials to know the problem at the local level. We have seen that in many other industries, like environmental problems or food safety problems. The local governments definitely have incentive to try to minimize the exposure of those problems, and the whistleblowers or even sometimes the victims have been discouraged, harassed or even jailed for just exposing the problem.

In this kind of environment, it's going to be very hard to have very effective enforcement, even if the central government would have a good intention in promoting product safety.

The last point I want to make is that I want you to consider drug safety not in isolation. More enforcement on drug safety is going to increase the cost of drug manufacturing and drug distribution, and that's going to increase the price for final consumers, which can introduce a new incentive towards legitimate and non-legitimate manufacturers in terms of where they should cut corners, whether they want to cut corners, and so forth.

So I think that the tradeoff between drug safety, drug quality and drug cost is real not only in developing countries but also in a country like the U.S.

Thank you very much. I'm happy to answer your questions.

PREPARED STATEMENT OF DR. GINGER ZHE JIN
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Testimony before the U.S.-China Economic and Security Review Commission
Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products

April 3, 2013

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Medical products are a classical example of asymmetric information: the seller of medical products tend to have better information about product quality than the buyer, and this information asymmetry can lead to market failures. Medical products are also a special case that differs from other products, partly because consumers may remain in the dark about product quality after consuming the product, partly because poor-quality medical products can have adverse consequences on not only consumers but also those who do not consume the products (via contagion or drug resistance).

1. The problem of poor-quality drugs

Research in this area is frustrated by the lack of a standard definition of counterfeit, fake, falsified, and substandard drugs. According to the World Health Organization, counterfeit drugs refer to drugs that infringe the intellectual property (IP) rights of other legal drugs (trade marks, patents, copyrights, etc.).[186] In other words, counterfeit drugs emphasize IP infringement and the intent to deceive, rather than the drug's chemical content or public health consequences. However, the potential public health danger of poor-quality drugs can be arguably larger than that of IP infringements.

In an original study that is forthcoming in the Journal of Economic & Management Strategy [1], we focus on testing a drug sample 's active pharmaceutical ingredients instead of its intent to deceive, and therefore avoid discerning whether a drug sample is counterfeit or not. We define a drug sample as "falsified" if we could not find any significant presence of the correct active ingredient. A drug sample is defined as substandard if it has some but less than 80% of the correct active ingredient. In our study, we obtained 1437 samples of Ciprofloxacin (Cipro) from 22 cities in 18 low-to-medium-income countries and found 59 (or 4.1%) being falsified and 83 (or 5.8%) being substandard. In comparison, visual inspection only identifies 11 problematic samples and all of them turn out to fail the active ingredient test.

These estimates are likely to understate the problem of poor quality drugs in the global market.

[186] http://www.who.int/medicines/services/counterfeit/overview/en/, accessed on March 26, 2014.

Because our samples were drawn from pharmacies with a physical storefront in urban areas, we miss mobile kiosks, bus vendors, and other retail channels that could be more dangerous. Moreover, our test focuses on active ingredients only (due to limited resources), so we may have missed problems in impurity, degradation or inactive ingredients. Also, our samples come from consumer-oriented retail markets, which are the end of the whole drug distribution system. Problems seen in our sample could be driven by any part of the manufacturing or distribution process, and it is difficult to pin down the exact source of the problem. That being said, a falsified drug that claims to be Cipro but has no correct active ingredients of Cipro should reflect deliberate cheating. Insufficient active ingredients in substandard drugs can be a result of intentional cheating or non-intentional negligence.

About half of our drug samples claim to be produced in a country that is different from the country in which we purchased the drug. We call them "imports". The percent of imports in falsified or substandard drugs is similar to the percent of imports in the full sample. Based on the claimed country of manufacturing, we see a lower percentage of failures in "US" or "European" products than products from "Africa", "China" or "India". Note that it is difficult to tell whether the claimed country of manufacturing is the actual country of manufacturing, as counterfeiters pay great attention to mimicking the package.

2. How do drug quality regulators and consumers deal with drug quality problem?

Local drug regulators can deal with drug quality problems in several dimensions. They can regulate drug manufacturing by licensing the firm, inspecting the plant, and registering the product. They can regulate drug distributors by licensing personnel and inspecting stores. They may also monitor the market directly, for example by sampling drugs from pharmacies, and try to trace problems back to manufacturing and distribution. Depending on local laws, regulators may have the authority to suspend licenses, impose fines, and/or close down manufacturing/distributing firms. In suspicion of criminal activities, they can collaborate with police and prosecutors and file lawsuits.

In our JEMS study, we correlate whether a drug sample is falsified or substandard to several regulation variables. The first set of regulatory variables focus on whether the sampled brand has been registered by local governments, whether the brand has been prequalified by the WHO, and whether the drug has been approved by a western country with stringent standard (referred to as SRA approved). The other regulation variables include whether a country has any regulation on drug price, and the maximum penalty for drug counterfeiters as stated in the local law.

Among these regulatory variables, we find that product registration is a significant predictor of passing our test of active ingredient. WHO prequalification or SRA approval have no extra effect on passing the test, probably because our definition of "passing" is crude and all the WHO-prequalified or SRA-approved drugs are also registered with the local government. Price regulation or penalty of counterfeiters does not have a significant correlation with drug quality outcomes once we control for product registration. These statistical correlations suggest that product registration with local governments may be an important tool to deal with the drug quality problem by our crude definition. Nevertheless, this suggestion should be taken with caution, as we also find that falsified drugs are more likely to appear as registered products than substandard drugs. One interpretation is that falsified products attempt to mimic registered

products in order to increase consumer confidence and/or charge higher price. This finding blurs the signal value of product registration.

To what extent can sophisticated consumers discern drug quality problems? In our JEMS study, we asked our covert shoppers to report their subjective impression of the sampled pharmacy, we also coded each pharmacy's chain status and the transaction prices we paid. Drug samples from a pharmacy that looks decent and affiliates with a chain are more likely to pass our active ingredient test. The price of passing drugs is on average higher than the price of failing drugs, but after we control for other factors, only substandard drugs are priced lower than passing drugs by about 10%; falsified drugs are priced roughly the same as passing drugs.

Our findings highlight the sophistication of deliberate cheaters. They tend to target less on the brand name drugs produced by the original innovators, although the innovator brand is typically much more expensive than generic versions. This is probably because the innovator brand invests more in detecting counterfeits. In our sample, those who falsified the drug with zero active ingredients tend to target well-known generic brands that have already registered with local authorities. Because locally registered products enjoy a significant price premium and registered products are less likely to be examined by inspectors, this targeting strategy makes economic sense. By appearing the same on the package and charging the same price as the authentic version, falsified drugs dupe consumers in both price and quality.

3. Chinese exports of medical products

China exports of medical products fall into three categories: Chinese medicine, western medicine, and medical equipment & device. For both Chinese medicine and western medicine, the majority of Chinese exports are ingredients rather than final pharmaceutical products ready for human consumption.

United States is China's biggest trading partner on medical products. Exports from China may end up in the US as pharmaceutical ingredients for US domestic production, or as imports of final pharmaceutical products. The source of ingredients is almost always hidden from end consumers, sometimes even the final drug manufacturers have a hard time tracing down the ultimate source of ingredients. Even if Chinese exports come as final products and from a legitimate source, they may not appear as "made in China" in the eyes of end consumers as medical products are often repackaged and resold as they move along the global supply chain. Chinese exports from illegitimate sources are even less constrained, as they can pretend to be from anything from anywhere.

The relationship between Chinese producers and the rest of the global supply chain is more complicated than simply being the two sides of the trade. According to a news article that cites numbers from the Chinese customs[187], over 29,000 Chinese enterprises have engaged in exporting health products out of China in 2013. About 18% of them are foreign-funded to some extent, and they account for close to 37% of the total export value. Some of the Chinese exports to the US may be produced by US company's manufacturing plants in China. For example,

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187 http://www.menet.com.cn/Articles/information/201402/201402191458575857_109526.shtml, accessed on March 26, 2014.

Pfizer has invested $1 billion, employed 9000 employees, and set up 4 manufacturing facilities in China since 1980.[188] Foreign-funded enterprises also import large numbers of health products into China, mainly in the form of finished products of western medicine and medical equipment/device.

4. Challenges facing Chinese regulators

Recently, Chinese government has shown a determination to impose harsher regulations on medical products. However, there are many challenges on the way.

First of all, China has a large population, enormous heterogeneity, and a relatively diverse system of production and distribution for medical products. According to the National Bureau of Statistics of China, 630 million (or 46.27%) people live in rural areas in 2013. It is usually more difficult to ensure drug access and drug quality in rural areas than in urban areas. Some of the stated goals of the eleventh five-year plan (2006-2010) are to ensure a better coverage of drug monitoring and drug access in rural areas. The diverse production and distribution system also contributes to the difficulty of drug quality monitoring. According to a 2011 annual report from the Chinese government, over 6000 Chinese firms are involved in manufacturing health products, about 4000 of them are related to either Chinese or Western medicine.[189] An online report from a major financial analyst estimates that more than 400,000 retail stores sell medicine in China up to date.[190] Even if Chinese government is willing to adopt stringent laws, it is very difficult to enforce high quality practice across a large number of small manufacturers, distributors and retailers. It is not uncommon to observe retail pharmacies selling prescription drugs without prescription or selling without licensed pharmacist in store, although both have been required under a 1999 regulation.

China has made some progress in cracking down bad players in the market of medical products. During the five-year period from 2006 to 2010, China has identified 1.49 million legal violations and revoked 47,798 unlicensed operators in the area of pharmaceutical products, medical equipment, and medical devices. These cases involve roughly 400 million US dollars.[191] It is difficult to tell whether these detected problems account for a large or small proportion of all the misbehavior prevalent in China.

The second challenge facing Chinese regulators is China's hierarchy structure of administration. Given the size of China, it is inevitable to have multiple levels of governments. Each level of the government may have multiple departments related to food and drug safety, ranging from the National Health and Family Planning Commission (the former Ministry of Health), the China Food and Drug Administration (CFDA), to the National Development and Reform Commission, and the Ministry of Human Resources and Social Security. (There are also non-administrative units such as the China Association of Pharmaceutical Commerce.) Not only is it complicated to

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[188] http://www.pfizer.com.cn/pfizer-china/about_pfizer_china_en.aspx, accessed March 26, 2014.

[189] The 2011 Annual Report of Health and Medical Statistics of China (《中国医药统计年报2011》).

[190] http://www.gtja.com/zt/sbyw/sbywContent.jsp?docId=14477949, accessed on March 26, 2014.

[191] http://www.cphi.cn/news/show-18174.html, accessed on March 26, 2014.

define who is responsible for what, it is but also challenging to coordinate between departments across different levels of the government. To address the problem, in March 2013, China has set up the CFDA as a ministry-level agency that consolidates authorities in food and drug safety. Still, there could be inefficiency and corruption at different levels of governments. For example, in 2007, the former head of the State Food and Drug Administration (which became part of CFDA after the 2013 consolidation), ZHENG Xiao Yu, was convicted to the death penalty for taking more than 1 million US dollars of bribes or gifts and approving six types of fake medicines in exchange. In 2013, China arrested six government officials in Zhejiang province after local manufacturers were found using an illegal industrial chemical to make drug capsules.[192]

A more fundamental problem of China's political hierarchy is that it introduces incentives to ignore or hide quality problems. Local government officials are appointed from the top, and GDP growth is one the most salient measures of performance when they are considered for promotion. Given the high value of medical products, firms producing or distributing medical products may be a good contributor to local GDP and therefore enjoy relaxed monitoring from local governments. Furthermore, local officials have incentives to stifle any public exposure of quality problems. Whistleblowers, activists, and victims are discouraged from exposing quality problems on newspapers, TVs, and the Internet. They can be even harassed and jailed for disrespecting the government. The lack of incentives to discover and solve problems has contributed to scandals in many industries. For example, the 2008 Chinese milk contamination has caused at least four infant deaths, 53,000 hospitalizations[193], and an estimate of 300,000 victims.[194] It is widely believed that lack of government's safety monitoring is an important factor underlying the scandal.

In addition to market fragmentation and political hierarchy, a subtler but potentially more challenging issue is how to strike a balance between drug quality and drug affordability. In the US, prescription drug expenditure accounts for roughly 9.4% of all health expenditure.[195] It is difficult to get a corresponding number for China, but a recent article of The Economist[196] claims that "China's spending on medicines is 40% of total health expenditure, far higher than the average for OECD countries, of 16%." This is partly because China regulates diagnosis and non-drug treatments at a low level of price, which motivates hospitals to use drug sales to cross-subsidize diagnosis and non-drug treatments. Unlike in the US, hospitals are the main health care providers in China; they are also the main retail outlet for patients to access prescription drugs. Hospitals can achieve higher prescription drug sales by prescribing more drugs or raising the unit

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[192] http://www.bloomberg.com/news/2013-03-10/china-plans-to-elevate-food-drug-regulator-to-ensure-safety.html, accessed on March 26, 2014.
[193] http://www.nbcnews.com/id/26827110/#.UzScPEJdXgU, accessed on March 26, 2014.
[194] http://www.theguardian.com/world/2008/dec/02/china, accessed on March 26, 2014.
[195] National health expenditure 2012 highlights from the Centers for Medicare & Medicaid Services, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf, accessed on March 26, 2014.
[196] http://www.economist.com/news/china/21595431-medicines-are-over-prescribed-and-overpriced-physician-heal-thyself, accessed on March 26, 2014.

price of each prescription drug. Because brand name drugs are sold at higher prices and usually imply higher profit margins than generic prices, hospitals have an incentive to sell brand name drugs instead of the generic version of the same drug. The high price and high demand for prescription drugs, together with imperfect quality monitoring, motivate both counterfeits and substandard drugs.

Ironically, tougher quality regulations may have the potential to worsen the drug quality problem. When the government introduces more drug safety regulations, it may increase the total cost of good-quality drugs. The increased cost is probably not hard to absorb by brand name drugs, because brand name drugs already have a good profit margin to buffer the cost and the demand for brand name drugs is less elastic as patients often believe brand name drugs to have a higher quality. In comparison, the extra cost of drug regulation may squeeze the narrow profit margin of generic drugs and pressure generic drug manufacturers to cut corners. As a result, tougher drug safety regulations may introduce a danger to push up drug prices and sometimes even worsen the quality of generic drugs that are accessible and affordable to patients with limited resources. To make things worse, higher drug prices attract outright cheaters even more, as they are not subject to the extra regulatory cost but have the freedom to mimic high-price drugs. This danger is more real, if extra regulations trigger more bureaucratic costs but bring little improvement in detecting and solving quality problems.

It is worth noting that the tension between drug safety and drug affordability is not unique to China, many developing countries face a similar problem. This is probably why we observe distinctive patterns between falsified and substandard drugs in our own study: falsified drugs have fewer active ingredients than substandard drugs but they charge almost the same price as passing drugs while substandard drugs are 10% cheaper.

5. Potential solutions

The recent report from the Institutes of Medicine (IOM) [2] has made a number of suggestions to improve drug safety, including clarifying the definition of counterfeit and substandard drugs, increasing pharmacovigilance, adopting a track and trace system, strengthening wholesale licensing, training regulators, and standardizing an international code of practice.

I agree with most recommendations from the IOM. It is important to realize that the drug safety problem in the international market is much broader than protecting intellectual property rights. Unsafe drugs have adverse consequences for public health, they are also related to drug access and drug affordability. Clarifying the definition of counterfeit and substandard drugs is the first step to distinguish intellectual property issues from the public health aspects of drug safety.

Governments in different countries may have good reasons to adopt different regulations in drug safety, but the world is flat, especially in high-value products like prescription drugs. Manufacturers have strong economic incentives to obtain cheaper ingredients from developing countries and/or shift manufacturing capacity to low-cost places around the globe. It is important to set up an international code of practice and enforce it effectively. I am not sure how to achieve this, one way is to strengthen collaboration between the central governments of various countries and find a way for each central government to effectively enforce the international standard within its country. Another way is to strengthen product liability law and clarify the

responsibility of each player in the production and distribution system. If a product is found problematic under a US manufacturer, the manufacturer should be responsible for the problem even if the source of the problem comes from an international supplier of some pharmaceutical ingredients. This way, the manufacturer will have incentive to monitor the quality of ingredient suppliers, and ingredient suppliers will have incentive to obtain high quality ingredients. A track and trace system will also help in clarifying and enforcing the responsibility of each player in the production and distribution process.

6. Recommendations to the US Congress

More specifically, I would recommend the US congress to consider the following actions in strengthening medical product quality:

First and foremost, find out how serious the problem is. It is amazing how little we know about the extent of drug safety and drug quality problems around the world. We probably know even less about quality problems in medical equipment and medical devices. The process of problem discovery should involve both government and non-government efforts. More research funds, from both public and private sources, are needed to support systematic research in this area.

Secondly, it is crucial for drug manufacturers and drug distributors to play a more active role in drug quality. To what extent and in which format has the manufacturing process been outsourced? What is allowed and what is not allowed on both ends of the outsourcing process? Who is responsible for which part of the manufacturing and distribution process? What information should be gathered and subject to whose scrutiny and when? What liability does each player have if a problem arises? Answers to these questions will require international collaboration between governments, manufacturers and distributors, with the technology of internationally tracking and tracing medical products.

Lastly, medical product quality should not be considered in isolation. Extra regulations on product safety, in and out of the US, will likely increase the cost of prescription drugs, which may add burden on end consumers. The balance between drug affordability and drug quality is not only important for developing countries but also relevant for US consumers. Our study of the online prescription drug market [3] shows that many US consumers, especially the elderly and near-elderly, are concerned with prescription drug cost and they are willing to purchase from foreign pharmacies even if this is highly discouraged by the FDA. Our study also shows that private certification of foreign pharmacies does provide value for consumers trying to distinguish among Internet pharmacies. Imposing more drug safety regulations without consideration of prescription drug cost will likely upset price-sensitive consumers and worsen the tension between drug cost and drug quality. Equally important, one must consider the efficiency of enforcing drug safety regulations. Is it most efficient for the FDA of US to police all the ingredient plants of China? Should the US coordinate with other large medical product markets (e.g. European countries, Canada, India, China and Brazil) in good manufacturing and good retail practice standards? Can academic, private or other government resources be used in this process? These questions should be examined in depth before the US commits to an overhaul of its regulatory system on medical product quality.

Citations:

[1] Roger Bate, Ginger Zhe Jin, and Aparna Mathur "Falsified or Substandard? Assessing Price and Non-Price Signals of Drug Quality", forthcoming Journal of Economics & Management Strategy, available at http://kuafu.umd.edu/~ginger/research/BJM-falsified-substandard-JEMS-final-01222014.docx, also available as NBER working paper #18073.

[2] Institutes of Medicine, "Countering the Problem of Falsified and Substandard Drugs", published by the National Academies Press (2013), available at http://www.nap.edu/catalog.php?record_id=18272.

[3] Roger Bate, Ginger Zhe Jin, and Aparna Mathur "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets", the B.E. Journal of Economic Analysis and Policy, Volume 14, Issue 1 (Dec 2013). Available at http://www.degruyter.com/view/j/bejeap.2014.14.issue-1/bejeap-2013-0085/bejeap-2013-0085.xml?format=INT.

PANEL III QUESTION AND ANSWER

VICE CHAIRMAN REINSCH: Okay. First on the list is Commissioner Wessel.

COMMISSIONER WESSEL: Thank you, all, for being here, and I expect we'll probably want to go through a couple of rounds of questions if time allows. And thank you for being here.

A couple of quick questions, I hope. The new tracking system. How can we ensure that this new system is actually going to protect patients?

MR. COUKELL: Thank you for that question.

The new tracking system phases in over the next decade. Four years from now every package of prescription drugs sold in the U.S. will have a unique serial number. That will give somebody, should they choose, the ability to check that serial number against the database to find out if it is real. It will be harder to fake a unique serial number than just to fake the packaging.

The law as written now does not go as far as requiring routine authentication of serial numbers and does not require those serial numbers to be decommissioned after use. So it is a beginning of a system that will let us authenticate drugs, provide more granular tracking of drugs as they move through the system, and require routine checking in some particularly high risk situations like when the products are returned or when there is a high risk of counterfeiting. There is further we could go.

COMMISSIONER WESSEL: Any of the panelists, walk me through the question of going to the manufacturing plants. We had testimony some years ago, and as I recall, the FDA at that time was able to get into 15 of the many thousands of facilities, and the average time was a minimum of six weeks between the request for a visit.

They were not allowed to call it an assessment, an audit or anything else. It has to be called visit because it's a lower standard than what an FDA official could do here.

Has that gotten better? We heard about Merck and others, for example, this morning and having R&D facilities and being over there. What's to stop a U.S. company that wants to source out of China from being able to verify, validate, do GMP plus, all the various things you want them to do, from doing it on a daily basis?

I mean we sometimes have meat inspectors in a plant who are there watching the carcasses go by. Why don't we do that in a plant if they want to source to China? Any of the panelists?

MR. COUKELL: Yes, there have been problems in the past in getting access and some of that is logistical. If you are flying someone from the U.S., and you need visas in advance and so on, that will slow down the process.

One of the new authorities is that FDA can refuse entry to a plant that has refused or delayed inspection.

COMMISSIONER WESSEL: Have they done that in any case

that you're aware of?

MR. COUKELL: Yes, I believe that is an authority. It is a new authority. It has been used a couple of times.

The importer can also require, as a condition of contracting, access to the plant. And, yes, absolutely, you would take it on a risk basis, but a manufacturer could decide if it were justified to station somebody permanently in the facilities of their key suppliers, and this may be necessary in some cases.

COMMISSIONER WESSEL: And going to Dr. Jin's point about the cost, it seems to me that since a big cost in a drug firm is liability insurance, that if you had an on-site inspector with U.S. qualifications, if I'm the Hartford or any one of the P&C firms, I'm probably going to look at that on-site audit and inspection as a way of reducing my liability insurance, and rather than increasing the cost, it might decrease the cost.

Do you agree with that?

DR. JIN: Yeah, possibly. I would like to emphasize that both ex ante inspection and ex post surveillance would be important. Coming back to your old question about how the U.S. manufacturers can go down the supply chain to figure out the problems, I think there are two issues. One is do they have incentive to do so? And the other is do they have ability to do so?

In their incentive, it depends on how they will be held responsible if something is discovered to be problematic in their products. So just to what extent the FDA or U.S. FDA or other health authorities are willing to go down the chain and make those manufacturers be responsible, I think that would change their incentives.

In terms of ability, I think the global supply chain, within China, is quite complex itself. So some very basic suppliers may not be qualified as pharmaceutical ingredients suppliers. They may be chemical suppliers, and therefore they are not subject to the Chinese FDA's regulation, but the manufacturer is supposed to know those suppliers. Again, it's sort of depending on how hard we push them to go down the chain.

I think if the outside push is hard enough, they should be able to go down. Of course, there's a cost issue there, and that may to some extent be passed through to the final price of end products.

COMMISSIONER WESSEL: We've seen with the GM situation that there is certainly a tradeoff here that probably bears more scrutiny. If there's another round, I'd love to ask a question.

VICE CHAIRMAN REINSCH: Commissioner Fiedler.

COMMISSIONER FIEDLER: I want to see if I can understand the costs of production problems for pharmaceutical companies, and I didn't have time to ask this in the other round.

So R&D is a big cost in discovering the drug in the first instance. And they allegedly for the life of the drug, they want to recover the R&D costs and that's why they have a patent and why they're allowed to charge so much money for it until their patent expires, and then it becomes

generic; right?

Active ingredients are what percentage, you know, roughly of the cost of a drug? And I would think that that varies. So let's pick a drug that anybody is familiar with, and what is the actual cost of the active ingredient, ingredients, as a percentage of the cost production? Factoring in R&D; right?

MR. COUKELL: I'm not sure I can provide a rule of thumb. I think you're absolutely correct that for an on-patent drug, the production costs of the tablet, if you will, are small compared to the total costs of doing business.

For a generic product, the production costs would be a much larger share of the total business cost, a very substantial share.

COMMISSIONER FIEDLER: Okay. So the patent is trying to recover the R&D, and the generic is just trying to make money.

But still, compare that cost to the price. What I'm trying to get at is, is it really effective? It's clearly economically advantageous to shift the production of active ingredients offshore. But I'm not so sure that the economic advantage doesn't increase the risk consequently to stratospheric level versus I can produce this same drug if I can get the active-- there's no scarcity of active ingredients in the United States; are there?

MR. COUKELL: It depends on the product. There is still an API industry in the U.S. There are some classes of products that for all intents and purposes, the only source is now China. One that's commonly cited is antibiotics. Most penicillins, cephalosporins and tetracyclines, for example,originate in China.

COMMISSIONER FIEDLER: Wait, wait, wait. Where were we getting the stuff before we produced it in China?

MR. COUKELL: It used to be a domestic vertically-integrated industry.

COMMISSIONER FIEDLER: So the only source is determined to be the only source because of the price? Rare earth metals is an environmental issue, but--

MR. COUKELL: If I understand the question correctly, there is no theoretical reason we could not make active ingredients in the U.S.

COMMISSIONER FIEDLER: I'm trying to figure out how much money we're gaining to sacrifice the safety, is where I'm going here

MR. COUKELL: I don't have data.

COMMISSIONER FIEDLER: And really what I'm thinking is that if active ingredient costs in a patented drug are infinitesimal, then the production of it, finding the active ingredient in a place that is unregulated or underregulated increases the risk to the patient, way beyond the economic advantage of doing it.

Okay. Unless, because we're not doing anything about it, there is no risk to the pharmaceutical manufacturer versus the patient.

DR. JIN: Yeah, I totally agree that there is a tradeoff between cost and risk,--I don't have the right number to show you--but I believe the

primary reason for the pharmaceutical companies to source their active ingredients from China and other global places is because of cost.

COMMISSIONER FIEDLER: Yeah, but what's the difference? What advantage are they getting? 25 percent advantage? 50 percent advantage? 1,000 percent advantage? What advantage are they getting?

DR. JIN: Well, unfortunately, I don't know. I think this question probably best answered by those pharmaceutical companies.

COMMISSIONER FIEDLER: Yeah, I wish I had--they probably didn't know the answer because they were trade associations. Yes.

DR. JIN: Yeah, I know the R&D expenditure may be part of the cost that the pharmaceutical companies claim go into the brand name prices, but for generics, my understanding is that the generic price is much lower than the brand name prices, and a lot of that price tried to cover the manufacturing costs. If we have more inspection of manufacturing or distribution, that cost would go with generics as well.

COMMISSIONER FIEDLER: Am I right in believing that it's one of the more capital-intensive, less people, less labor-intensive production processes known to man? We're not making these things by hand. We're mixing active ingredients and pumping them out by machine.

MR. COUKELL: I'm not sure the answer to that.

COMMISSIONER FIEDLER: Let me reverse the question and the phenomenon--

MR. COUKELL: Yeah.

COMMISSIONER FIEDLER: --that I listened to this morning. I got this big market in China. Before I only sold my drugs in the United States. Now I can sell my drugs to Chinese, the growing middle class. Has that had any salutary effect on the price of the product in the United States being cheaper now that I can produce a whole lot more product, sell it to more people? One would think that the price would go down.

DR. JIN: Not that I know of. I think, again, the manufacturing cost, it's only a very small fraction of the price that U.S. population paid here.

COMMISSIONER FIEDLER: That's my point.

VICE CHAIRMAN REINSCH: Okay. We can come back to that.

Commissioner Slane.

COMMISSIONER FIEDLER: It's risk.

COMMISSIONER SLANE: Thank you all for being here. Obviously the FDA can do very little to protect the American consumer, but what gives me some comfort is that the manufacturer, and let's take Baxter Laboratories or any company really, has to do some quality control on their supply chain.

And this may be a much more effective way to protect the American public. I mean is that a fair statement or?

MR. COUKELL: What I would say is both things are necessary. It's absolutely essential that companies have robust quality systems in place, but the expectation of an effective regulatory oversight is a very important

incentive for any actor that might be tempted to operate with lower standards.

COMMISSIONER SLANE: But in the United States, we have civil remedies if they don't do it. I mean if I'm a manufacturer of drugs in the United States, and I'm very worried about where my ingredients are coming from outside of the United States because I can be sued if my product is sold and people get sick, that's a very huge detriment, I would think, to not doing quality control.

MR. BELL: I guess I would have a concern just about that insofar as we're interested in having preventive measures that prevent people from getting sick or harmed in the first place, such that would lead to civil litigation, and in the industry that I'm talking about, the dietary supplement industry, we tend to have a lot of smaller manufacturers that are quite interested in cost minimization.

And so every extra dollar that they spend complying on GMP practices, for example, is something that many of the firms would likely want to avoid, and they have quite a range of competitors that are not taking on board those sort of costs. So I feel that corporate responsibility is critical. It's really important, but in some ways in the supplement area, like too much responsibility lies with the manufacturer, and that's, I think, contributing to some of the problems that we're seeing.

They're not doing the quality assurance work they should, and in the case of China, also, the dietary supplement facilities are not subject to GMP. The ones that are supplying the ingredients are not subject to GMP requirements. They can participate in a voluntary certification program if they want.

In the U.S., we have made them mandatory. GMP requirements have just been relatively recently implemented over the last couple of years. And recently an FDA official was quoted as saying 70 percent of companies are having trouble with some aspect of meeting GMP.

So the U.S. GMP requirements, I was going to comment, are quite important, and companies can do a lot to audit what their suppliers are doing, but it appears to me that quite a number of them are not doing that, and that's why we're seeing so many problems with adulteration.

COMMISSIONER SLANE: And let me jump in here. A few years ago, we had a hearing on fish and being imported from China, and the only solution to protect yourself as an American consumer was to stop eating fish, which is what I did.

But now when I go to Sam's Club to buy my Vitamin C, and I know it's coming from China, and I get sick, and I can prove a connection, I mean it seems to me Sam's Club is really vulnerable and would have a vested interest even in your area, Mr. Bell, to protect.

Tell me if I'm wrong or maybe I'm operating on a false illusion here.

MR. BELL: No, I agree with that, but I think that companies are looking at quarterly results. They have a fiduciary responsibility to their

shareholders to boost profits, and if they don't do that, they can be sued in a shareholder action. So I agree. I mean companies want to protect their brand reputation, but, again, a lot of the enterprises, if you look at some of the companies named in my testimony, these are like fly-by-night companies.

I mean they'll just reconstitute themselves under some other name, and they'll shirk legal liability for what they've done.

MR. COUKELL: Many quality assurance personnel from pharma companies have cited the heparin adulteration as a wake-up call. All of a sudden, we realized we had risks that we weren't thinking about, we weren't aware of, and we needed to make some changes.

So if that was the sort of level of awareness of branded pharma at that stage, it's reasonable to assume that there are companies that are less sophisticated, that have less brand equity, that just have not taken those steps, and have less incentive to do so.

DR. JIN: And to add on that, I would like to ask the question of exactly what kind of liability we're putting on the manufacturers? Take the example of heparin, is a liability like you go back to reinspect your suppliers or it's something more serious than that?

And also if they claim they don't know, does that get them off the hook--I don't think the liability at the very end is enough. We need to ask the questions such as do they need to collect information systematically even before the problem shows up, and how systematically that information collection should be? Who should get access to that information, and so forth?

I think that probably goes beyond just the legal sense of product liability issue.

COMMISSIONER SLANE: Okay. Thank you.

VICE CHAIRMAN REINSCH: Okay.

Commissioner Shea.

CHAIRMAN SHEA: Well, it sounds, going back to Commissioner Fiedler's question, it sounds like the risk is not so great that it outweighs the incentive to outsource manufacturing to China. The risk of civil/criminal liability, reputational risk doesn't seem to outweigh the benefit of having a lower cost supply chain.

And then all the companies seem to feel that maybe they are doing a good job with the supply chain security, and so the actual incidents of adulteration of products or counterfeiting of products is not as great as some may say. So why don't you react to that, if you could?

DR. JIN: Let me answer that. First, I think it depends on the definition of risk. Do you mean the risk to the pharmaceutical companies or you mean the risk--

CHAIRMAN SHEA: Yeah.

DR. JIN: --to the public health? The risk to the pharmaceutical companies, again, depends on what kind of liability they will face if a problem arises. If they can get off the hook, then the risk, I would agree with you, the risk is pretty low, and the cost savings seems attractive.

CHAIRMAN SHEA: So maybe they've made an assessment that the risk of serious liability under our civil or criminal laws is relatively low or the cost of that liability is insufficient to outweigh the benefits of outsourcing the work.

But I mean other than the heparin incident, which happened in 2007 and 2008, have there been other incidents, more recently, where in the United States people have been seriously, made seriously ill or even killed by products, drug products manufactured in China?

MR. COUKELL: When you have a quality failure, you are always at risk of harm to patients. That is the risk that we are trying to mitigate. Sometimes I talk to a lay audience, and I try very hard not to be alarming, and I say there is a risk that your house will burn down tonight. Nobody is suggesting that you don't go home and sleep in your own bed, but we do things as a society to address the risk. We have fire departments and we put in smoke detectors, and we have building codes and so on.

CHAIRMAN SHEA: Uh-huh.

MR. COUKELL: And so the question is in the drug context, do we have the appropriate of building codes and fire departments and so on?

CHAIRMAN SHEA: Okay. This is my assessment of the building codes, fire departments in the current system. You have the U.S. FDA, which in China appears to be very understaffed, even with the additional employees that they're going to get-- there are 13 employees existing today, and two-and-a-half of those are focused on inspections of drug facilities, and there are about four or 5,000 or more manufacturing facilities.

So you have the FDA is one fire engine. The other is the Chinese FDA --we met with them last year, and it seems like-- everything flows downhill. Oh, we're just pretty small here in Beijing, and we rely a lot on the provincial FDAs to do the inspection work for us. So that didn't give me a tremendous amount of confidence.

Then the third engine is the supply chain security of the large corporations that manufacture, that outsource the manufacturing of the drugs, and they will tell you they're doing a pretty good job because they don't want to have the reputational risk, the litigation risk. They don't want to have sick people sourced to them.

So are those the three main tiers? Is that the fire code that we have today?

MR. COUKELL: Yes, I would broadly agree with your characterization. I don't know anyone in industry who would argue that we should not have a more robust regulatory infrastructure looking at these plants, and, in fact, the industry has been one of the big drivers of this new framework to increase inspections.

CHAIRMAN SHEA: Can I ask about the dietary because I don't take dietary supplements. I don't take vitamins. I should probably. Maybe not after this hearing. So--

COMMISSIONER FIEDLER: Well, if you, don't buy them at

Sam's Club--

CHAIRMAN SHEA: Yeah. So does the Chinese FDA regulate dietary supplements that are made in China?

MR. BELL: Yes, they do, and in fact in some ways, they've actually kept some of the supplements manufactured by U.S. companies out. So they have, they do have a regulatory structure, but in terms of the inspections of the facilities where they're produced, I think we don't have that. We don't really have --we've only recently got it in the United States, and I don't think an equivalent system exists in China.

CHAIRMAN SHEA: So the U.S. FDA does not send the two-and-a-half inspectors to the dietary supplement manufacturer?

MR. BELL: Yeah, it's my understanding that they have relatively minimal resources focused on inspecting supplement ingredient plants because they're focused on prescription drugs, which is understandable.

CHAIRMAN SHEA: So is the industry where you have Western companies out doing contract manufacturing at facilities in China but also you have indigenous Chinese manufacturers because that product looks like a Chinese product.

MR. BELL: Yeah. And actually I was going to mention there was when FDA recalled this product, there was a reported death. Or there was a death that was linked to this--

CHAIRMAN SHEA: That's a Chinese product.

MR. BELL: Yeah, a Chinese product manufactured in Guangzhou City, China. It says so on the side of the box.

CHAIRMAN SHEA: Okay. And the U.S. industry, is it dominated by large manufacturers or is it--

MR. BELL: I mean it really runs the gamut. There you have some quite large vitamin companies, who I think do quite a bit more in the way of quality assurance, but there's a lot of smaller firms. So it's a really mixed bag. 85,000 products, $32 billion industry. It's a pretty large industry.

CHAIRMAN SHEA: Do the small and mid-size U.S. companies do contract manufacturing in China?

MR. BELL: Yes. Yes, and then some of the incidents I describe in my testimony are things of sort of quasi-legality, for example, one woman in Louisiana making a deal with a Chinese company to purchase diet pills to give to her, sell to her customers for, I think she was fined $365,000, got three years probation for doing that.

So some of these things are sort of under the radar of the regulatory system, and it's a concern to have illegal pharmaceutical agreements sort of flowing in international commerce without much oversight from anybody.

CHAIRMAN SHEA: Okay. Thank you.

I just want to commend our staff before we forget, Bill. Jacob Koch-Weser who has done a tremendous job putting this hearing today. So

we want to thank him for his good work.

VICE CHAIRMAN REINSCH: Commissioner Tobin.

COMMISSIONER TOBIN: Thank you.

COMMISSIONER SLANE: I see you have--

COMMISSIONER TOBIN: Yeah, that's my second question. I brought my product, too. Yeah. Emptied it out though. I left the stuff at home.

But, first, if I may, Mr. Coukell, thinking from an American citizen's point of view, when an average American buys a generic drug instead of a name-brand drug, does that increase the chances that the ingredients were made in the PRC?

MR. COUKELL: I don’t have exact data, but believe it is the active ingredients of generic drugs are more likely than brand drugs to come from the PRC.

COMMISSIONER TOBIN: Okay. And by how much if you were just even estimating? Because you're an expert on this.

MR. COUKELL: Well, about 80 percent of all active ingredients come from outside the country. That includes Europe and Canada. About half of that comes from India and China. I guess the data point I'm missing is how much of the 20 percent are branded versus generic. There are absolutely generic companies still manufacturing in the U.S.

There is, as I said, still a domestic API industry. I know you want a specific breakdown. I don't have the exact data point you're looking for.

COMMISSIONER TOBIN: That's okay. So it would increase it significantly, and the reason I'm asking is because when you think about generic versus brand name drugs, who else plays into this? Our insurance companies; right? And the costs are going to be ten times less for something that is--it goes back to what you were saying, Dr. Jin--much more risky.

And I think this is something when we're putting a report together, we should just keep in mind because the insurance companies are playing a role here in the risk.

If I may, Mr. Bell, two things. One, and this is probably a straightforward question, I don't understand why the FDA hasn't moved or why Congress has not moved to put dietary supplements in the same rubric as other medical prescriptions. So many things, including this calcium or whatever, are prescribed or urged by doctors.

Why hasn't that happened? Is it just a matter of we can't afford to begin to put more money behind it? We don't have the staff to do what we're already doing. Why not?

MR. BELL: Well, there really is historic reasons. You know, there's lot of resistance from the dietary supplement industry now--a $32 billion industry. They've sort of grown up in an environment of being free from lots of types of regulation, and they like it that way, and so when we had, one of the first projects I worked on in this area was the dietary supplement ephedra, which caused heart attacks and strokes, and it took, you

know, substantial number of years to get it removed from the market.

We started out by passing resolutions in county legislatures up in New York to try to get a little bit of momentum going, but there was tremendous resistance to that and to establishing a tougher adverse event reporting system so that now it's required that serious adverse events related to supplements that are life threatening or require medical attention need to be reported to the FDA.

So I think that really accounts for a lot of it. We have a bill that I mentioned and that we recommend be passed by Congress, the Dietary Supplement Labeling Act, introduced by Senators Durbin and Blumenthal, and that gives some additional authority to FDA.

But just to give you a flavor of it, one of the requirements that we don't have is manufacturer registration. We don't require these companies to register their names and their list of products with the FDA, and so in the event of a recall, it's been estimated FDA may have--they'd be missing information for as many as 20 percent of supplement manufacturers in the United States.

So in the interest of due diligence, be prepared when we do have emergencies, I think we need baseline protections like that.

COMMISSIONER TOBIN: Okay. And then related to this, about a year ago, probably due to Iaacob and others making us more aware of product safety, I decided to look at what was in the medicine chest and went to look very closely at things, and this one here says "distributed by CVS." It could have been another brand though.

And it has a place to call if you've got any questions; right? So I said distributed by, and you say it's the United States, in fact, in New York. Where is this coming from? There is no way I can get that information. Why--has there been any movement for any of these companies to show where their ingredients are coming from? Just as there is for I can find dog food where it's made. I can find my clothing, where it's made.

MR. BELL: Yes. I mean I think if it was just country of origin labeling, and we were talking about this earlier, I think that would be relatively uninformative. What we would really like to know is where are their suppliers?

COMMISSIONER TOBIN: Yes.

MR. BELL: Sort of similar to the track and trade system that you have for prescription drugs, and I am familiar with--there's some brands at Whole Foods, for example, where there's a barcode and you can look at where a lot of the herbs in your herbal supplement were grown in the world.

COMMISSIONER TOBIN: Good.

MR. BELL: So that kind of transparency could be really productive, and if more companies would do that, I think that would be positively received by consumers.

My concern is we've traded a pretty robust regulatory system for one that I think is not at all equivalent in terms of the FDA's ability to kind of march into plants if there's an emergency. They have to pay twice as much

to do an inspection in China as they do here, and still it doesn't yield the equivalent results, and it might be quite some time before they're able to approach the types of regulatory structure we have here.

And so I feel also some obligation to speak out for the right of Chinese civil society to do what we're doing here. You need to have watchdogs, and you need to have whistleblowers, and the whistleblower from the Ranbaxy case I think did a tremendous public service, and part of it was reminding us that these are commodity products, and when you're producing commodity products, there are often incentives to cut corners, and he said on his blog--Dinesh Thakur--that was the blower--he said what we really need to learn from this is there's a lot of people just like in the company that I work for that are very eager to do that. There's an intense incentive to cut corners and it goes on all the time.

And so it's easy to lose your grip or lose your oversight even if you are a very big brand, and so we need to maintain our vigilance and have strong incentives for companies to do that.

COMMISSIONER TOBIN: Well, keep the pressure going and into your publications too.

Dr. Jin, we prepare a report, and what you and other witnesses have said today will inform that report for 2014. If you were to suggest one major thing that Congress should move very quickly on to help begin to address this large problem, what would that be?

DR. JIN: I would say, first and foremost, to find out how serious the problem is. It may be true from our tiny study that for this particular drug, we don't see over ten percent of violations, but this is a very limited study. We as researchers, have very limited resources to try to get a more systematic view on this, and it may be true that we don't see a scandal larger than heparin after 2008 in the United States.

But we do see scandals like the Chinese drug capsules happened in 2012, and that affected over ten percent of the industry in China. To what extent that problem spread to the U.S., we still don't know yet.

I think as a researcher in this area, we're really frustrated by how hard it is to get evidence in this problem, and it's lack of attention from public policymakers, as well as lack of resources that we can use to do research in this area, it's really in my view the first obstacle to move forward.

COMMISSIONER TOBIN: It would be a huge task, but maybe we can hope for that. Thank you very much.

VICE CHAIRMAN REINSCH: Okay.

Commissioner Wessel, do you have another question?

COMMISSIONER WESSEL: Thank you.

Following up a bit on Commissioner Tobin's question, and it's been a long time since I've read DSHEA, my recollection is DSHEA does not have a definition of what "made in the USA" means. So that a drug that is, in fact, compounded from completely foreign ingredients could say "made in the USA" on it. It's substantial transformation under our trade laws, et

cetera. So it's actually made here.

They actually put it all together. Is that correct? I see a nodding head on this.

MR. COUKELL: I don't recall that the issue was addressed there.

COMMISSIONER WESSEL: Well, the FTC, again, because the way the "made in the USA" label-- I think you would view it as substantial transformation. If any of you could respond to this later, that would be very helpful.

Also understanding, since money tends to guide so many of these discussions, money is probably the reason that DSHEA has never been strengthened.

Going back to Commissioner Fiedler's question, though, because, again, it's all about money. If there was a better system of ensuring that the importer of record of ingredients had to have adequate insurance or post a bond so we don't have the fly-by-night issues; if they could certify that they had taken reasonable steps, however that would be defined by law, to ensure the adequacy of the investigation and the supply chain, do you think that would make a difference? Mr. Bell and others?

MR. COUKELL: Restricting my response only to the prescription drug space, one of the provisions in FDASIA was for FDA to promulgate good importer practices, and that should set up some guidelines that importers should follow.

The European Union goes further. There the importer actually has an obligation--

COMMISSIONER WESSEL: Right.

MR. COUKELL: --to do testing on each incoming batch or lot that we don't have here.

COMMISSIONER WESSEL: But if you were to do that, I referred to the GM situation earlier, GM apparently--there's a lot more work to be done--made a decision that the cost of remedy did not exceed the risk of liability at that point. Clearly it accumulated over time.

This would be a free market type situation where the market would determine where, again, any of our property and casualty insurers would say to an importer of record, we think your GMP and your supply chain regulations and oversight is pretty good so your liability per dose, per whatever is going to be lower.

If you can't certify that you're doing the right things, it's probably going to result in a prohibitive bond or insurance premium. It seems to me that's a way to work potentially with FDA limited resources and access. In part you privatize but you have to have a great enough liability that you don't get into the GM situation.

MR. BELL: Yeah, I think that is an interesting proposal, and we, I'm not an expert on the GMP so I think it would be interesting to discuss with FDA like what could be working better with respect to this? I honestly

think that when they're going in and doing some of these inspections now, this is one of the problems they're finding in terms of quality assurance.

And as sort of an outsider to the industry, it just surprises me that we see year after year this list of the contaminated products. I mean how can that just happen over and over again that a company cannot exercise the due diligence or impose testing requirements on their suppliers to prevent that?

And so the fact that it's continuing on the sort of steady drum beats seems worrisome. It may reflect that there's a low barrier to entry like a lot of people can be suppliers now, and it's a low barrier to be a distributor of supplements in the United States.

You can be a very small company and open up a storefront and do this for awhile and then get out of it. And probably the FDA is in a difficult position to prove people's intent. They imported something from China, they didn't know what was in it, they're new they're inexperienced, they're new at business. So I'm not sure why we don't see more penalties and jail time for people that are involved in that business.

COMMISSIONER WESSEL: It should be an intent-neutral process. It should be a fact-based supply chain analysis approach regardless of what's your intent so that the public is protected.

Dr. Jin.

DR. JIN: Yeah, making the supply chain do their part of the job is definitely a good first step, but I would like to emphasize that may not be enough by itself. First, why they would have incentive to keep accurate record in this process? What was the catch if they do not do so?

COMMISSIONER WESSEL: Right.

DR. JIN: And also, as you have mentioned before, if we have more information. We wish we have more information about where the active ingredient comes from, where the compounding was done and so forth. But based on my research about disclosure issues in many other industries, just disclosing the information itself to the end consumers would not always do the trick.

Now you shift the burden to the consumers for medical products, whether it's dietary supplements or pharmaceutical products. It's just very hard for the end consumers to really tell where the problem is. If I got a fever, is that because of the supplements that I'm taking? Is that because of the drug I'm taking? It's going to be really hard to trace back and report and complain and trigger an investigation and so forth.

So I think somehow that information must be consumed by knowledgeable people.

COMMISSIONER WESSEL: I agree, but if you were to go, for example, and look at the TREAD Act, it is almost a perfect relationship between increased reporting and reduction in fatalities, accidents and deaths.

DR. JIN: Yes.

COMMISSIONER WESSEL: And injury.

DR. JIN: I agree. If the information is collected, there is a way for them to

collect the information in an accurate way and also to use it in an informative way, I totally agree with you, that would be a good step forward.

COMMISSIONER WESSEL: Thank you.

VICE CHAIRMAN REINSCH: Commissioner Tobin.

COMMISSIONER TOBIN: Okay. Great. You've begun to address this topic, Dr. Jin, but I think I'll pose it to Mr. Coukell.

Is our trade data sufficient, in your mind? Do we know whether what we're importing, do we know it at a detailed level so that we know that something might have started in China, to go to India, and then come to the United States or vice versa, India to China? Do we in our trade data have a sense of the flow, even if our citizens don't? I'm curious.

MR. COUKELL: I think the answer is not in our trade data. Any prescription drug approved by the FDA has on record its supply chain going back to the origin of the API. So that information exists at the FDA.

COMMISSIONER TOBIN: Does it exist and is it visible?

MR. COUKELL: No.

COMMISSIONER TOBIN: It is not visible. So the public cannot see it. Okay. Is there any reason--

VICE CHAIRMAN REINSCH: Trade.

COMMISSIONER TOBIN: Trade. Okay. Intended?

VICE CHAIRMAN REINSCH: No.

COMMISSIONER WESSEL: It can be a trade secret for sourcing decisions.

COMMISSIONER TOBIN: Okay.

COMMISSIONER WESSEL: There is some customs data as it relates to bill of lading and what's on the PIERS database but not in the trade figure. So there is some, but, again, it's proprietary sourcing information.

COMMISSIONER TOBIN: Thank you, colleagues, and thank you, Mr. Coukell.

VICE CHAIRMAN REINSCH: Okay. I think there are no more questions. So we'll thank the panel very much for some very helpful testimony that will be useful in preparing our report, and the hearing is adjourned.

[Whereupon, at 3:08 p.m., the hearing was adjourned.]