



**Submission of the  
U.S. Chamber of Commerce**

for the

**Hearing on China's Implementation of and Compliance with  
its Commitments to the WTO**

**October 4, 2017**

## Table of Contents

<b>INTRODUCTION .....</b>	<b>5</b>
<b>CROSS-SECTORAL ISSUES .....</b>	<b>16</b>
INDIGENOUS INNOVATION & INDUSTRIAL POLICY .....	16
1. Competition Law.....	16
2. Indigenous Innovation Policies and Product Lists .....	17
3. Public Procurement.....	17
4. Standards.....	18
5. Conformity Assessment and Certification Redundancy .....	20
6. Cybersecurity Initiatives.....	21
7. State-Owned Enterprises and Subsidies.....	24
8. Trade Remedies.....	24
INTELLECTUAL PROPERTY.....	24
1. Enforcement of IPR.....	24
2. Trade Secrets .....	26
3. Copyright.....	28
4. Trademark and Counterfeiting.....	30
5. Patent Law & TRIPS-Compliant Compulsory Licensing.....	32
6. Data Supplementation for Patents and Regulatory Data Protection .....	34
INVESTMENT .....	35
1. Investment Approvals and the Guiding Catalogue on Foreign Investment.....	35
2. National Security Reviews .....	37
REGULATORY TRANSPARENCY.....	38
<b>INDUSTRY SPECIFIC ISSUES .....</b>	<b>39</b>
AGRICULTURAL BIOTECHNOLOGY .....	39
AGRICULTURE.....	40
1. Foreign Direct Investment .....	40
2. Tariff Rate Quotas (TRQ) .....	40
3. Unscientific Restrictions on Imports .....	40
4. Standards.....	40
5. Agricultural Equipment .....	41
6. Animal Health .....	41
ALUMINUM.....	42
AUTOS.....	42
1. Investment .....	42
2. Clean Energy Vehicles .....	42
3. Automotive Emissions Standards .....	43
4. Automotive Financing .....	43
5. Government Procurement .....	43
BANKING AND NONBANKING FINANCIAL SERVICES .....	44
CHEMICALS.....	45
1. Chloroform Import .....	45
2. Soda Ash .....	45
3. Coal.....	45

4. Chemical Waste Handling .....	45
CIVIL AVIATION .....	45
ELECTRONIC PAYMENT SERVICES .....	46
ENERGY/ENVIRONMENT .....	47
1. National Treatment .....	47
2. Standards.....	47
3. Bidding Criteria .....	48
5. Equity and Other Restrictions .....	48
6. Oil and Gas.....	48
7. Heavy Duty Commercial Emission Enforcement and Fuel Economy .....	49
8. Transportation of Dangerous Goods .....	49
EXPRESS DELIVERY SERVICES (EDS).....	49
1. Customs and Trade.....	49
2. Logistics.....	51
3. Aviation.....	52
INSURANCE, PENSIONS, AND ASSET MANAGEMENT.....	53
1. Equity Restrictions on Foreign Investment.....	53
2. Online Insurance Distribution.....	53
3. Foreign Currency Denominated Products .....	53
4. Secure and Controllable.....	53
5. Branches, Subsidiaries .....	54
6. Liability Insurance .....	54
7. Enterprise Annuities (EA).....	54
8. Insurance Brokerage.....	55
9. Investment of Assets.....	55
10. Remuneration.....	55
MEDIA/ENTERTAINMENT/ACADEMIC JOURNALS .....	55
1. Filmed Entertainment .....	55
2. Sound Recordings.....	56
3. Cable Television.....	57
4. Academic Journals .....	57
MEDICAL TECHNOLOGY/HEALTH CARE .....	58
1. Market-Based Health Care Reform.....	58
2. Medical Devices .....	59
3. Clinical Trial Approval Processes and Local Participant Requirements.....	61
4. Conformity Assessment, Certification and Licensing Requirements.....	64
RETAIL AND DIRECT SALES .....	64
1. Retail and E-Commerce.....	64
2. Direct Sales .....	65
SOFTWARE .....	65
1. Software Legalization .....	65
2. Copyright, Criminal and Patent Law Reform.....	66
3. Trade Secrets .....	66
4. Market Access .....	66
TAX .....	67
TELECOMMUNICATION SERVICES .....	68
1. Value-Added Telecom Services Licenses .....	68
2. High Capitalization Requirements.....	69

3. JV Partnership Requirement .....	69
4. Independent and Impartial Regulator with Transparent Procedures.....	70
5. Draft Telecom Law .....	70

## **INTRODUCTION**

On behalf of the U.S. Chamber of Commerce and our members, we appreciate this opportunity to share our views in response to the U.S. government's annual process for reviewing China's World Trade Organization (WTO) compliance. This submission reflects extensive input from across our membership and is consistent with past submissions for the annual hearing. It is also consistent with our comments submitted to the U.S. government in support of the U.S.-China 100-Day Action Plan in April, and the Blueprint for Action submitted for the inaugural meeting of the U.S.-China Comprehensive Economic Dialogue (CED) in July.

We appreciate the U.S. government's significant efforts and year-round work, led by the Department of Commerce, the Department of the Treasury, and the Office of the United States Trade Representative (USTR), to advocate on behalf of U.S. business interests with China via the CED and other high-level bilateral and multilateral exchanges. We hope this document is useful to USTR and the interagency as you advance preparations for the Administration's annual report to Congress on China's WTO compliance.

### **China Remains an Important Market**

Strong commercial ties have long been the ballast of bilateral relations—even as that ballast has become less stable in recent years. The American business community continues to attach great value and a high priority to mutually beneficial economic engagement with China, and we are committed to supporting such engagement going forward.

Even as China's economic growth slowed in 2016, a majority of American companies operating in China continued to see revenue and profit growth year-over-year. Looking forward, the Chamber expects our members with operations in China to continue to consolidate revenue and profit gains this year. According to the American Chamber of Commerce in China ("AmCham China") 2017 China Business Climate Survey Report, over half of survey respondents expected revenues across their industry in China to grow in 2017.<sup>1</sup>

Overall, the China market is worth half a trillion dollars per year to U.S. industry, with annual U.S. exports topping \$160 billion and sales by Chinese affiliates of U.S. multinational companies surpassing \$350 billion. China's consumer market, already second largest in the world, is growing rapidly, and continues to be a bright spot for American businesses across a wide variety of industries. Importantly, growth of U.S. service exports to China have far outpaced U.S. service exports to the rest of the world over the last ten years—an area where the U.S. enjoys a trade surplus with China.<sup>2</sup>

In a period of political transition, the Chamber appreciates the challenges China's leadership faces in reforming the country's economy, including its trade, investment, and regulatory regimes. We also appreciate China's commitment to engaging the U.S. government through the CED and other

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<sup>1</sup> In the 2017 AmCham China Business Climate Survey Report, 57% of survey respondents forecast this year's industry-wide revenue in China would grow in 2017.

<sup>2</sup> U.S. service exports to China have grown over 400% from 2006-2015, while U.S. service exports to the world grew 76% over the same time period; ([https://www.uschina.org/sites/default/files/uscbc\\_2017\\_state\\_export\\_report\\_updated.pdf](https://www.uschina.org/sites/default/files/uscbc_2017_state_export_report_updated.pdf))

official channels. We recognize that important progress has been made on several issues this year, including technical standards for the import of U.S. beef into China, market access for credit rating agencies, and four agricultural biotechnology seed approvals. China also has issued a series of draft regulations that, if adopted and fully implemented, have the potential to significantly improve China's biopharmaceutical patent regime.

### As Overall Sentiment on Business Climate Continues to Wane

While top-line revenue growth for some of our members is encouraging, more far-reaching outcomes are urgently needed to address the myriad structural impediments that inhibit U.S. companies from accessing and competing in the China market. Long-standing concerns are intensifying regarding market access restrictions, national security policy, and industrial policy support for domestic champions. For the second straight year, the AmCham China 2017 Survey found companies citing "inconsistent regulatory interpretation and unclear laws" as the top business challenge in China. Concerns also persist in the areas of intellectual property (IP) protection and enforcement.

Overall, an increasingly burdensome and restrictive regulatory environment in China is undermining optimism as well as the hope for market-based reforms and market opening that companies held when the *Third Plenum Decision*<sup>3</sup> was released in 2013. For example, the successive adoption of China's *Counterterrorism, National Security, and Cybersecurity Laws*, along with the draft *Encryption and Export Control Laws*, have created new burdensome market access, operating, and compliance challenges for our members. According to the AmCham China 2017 Survey, 31% of surveyed businesses reported a deteriorating investment environment (a record amount), and 81% of members reported feeling less welcome now than they did in previous years.<sup>4</sup>

As a result, China, while remaining a significant market overall for American companies, is becoming less of an investment priority for some of our members than it once was. According to the AmCham China 2017 Survey, China's status as a top-three investment priority has declined to a record low of 56% from 78% in 2012. According to China's Ministry of Commerce (MOFCOM), China's total inbound foreign direct investment (FDI) from the world for January to July 2017 dropped 6.5% year-over-year.<sup>5</sup> Investment restrictions in China's market, coupled with a restrictive regulatory environment, continue to limit the ability of U.S. companies to provide goods and services in China. Furthermore, these restrictions are a source of increasing tension in the relationship.

### Burdensome and Restrictive Policies

Chamber members continue to harbor concerns over long-standing policies, laws, and regulatory measures governing market access and licensing, subsidies, and intellectual property rights (IPR) protection and enforcement. In addition, they are also facing a wave of industrial policy concerns governing information security, data localization, and high-value manufacturing. Core concerns in both areas are discussed below.

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<sup>3</sup> <http://cpc.people.com.cn/n/2013/1115/c64094-23559163.html>

<sup>4</sup> 2017 AmCham China White Paper, pg. 10

<sup>5</sup> <http://data.mofcom.gov.cn/channel/includes/list.shtml?channel=wzsj&visit=C>

## ***The Next Wave of Industrial Policies: Information Security, Data Localization, and Support for High-Value Manufacturing***

In recent years, China's incorporation of national security measures into its commercial regulatory regime has accelerated rapidly.<sup>6</sup> Regrettably, commitments made at the highest levels of the Chinese government to refrain from imposing nationality-based conditions or restrictions on commercial transactions have not been implemented.<sup>7</sup> Instead, China has seemingly moved to bypass its commitments by continuing to draft and issue new laws, guidelines, and regulations that apply a broad conception of national security—to include economic, cultural, social, agricultural, and other forms of security—to commerce.

We urge the U.S. government to continue its efforts to ensure that China applies a narrow definition of national security to foreign investment reviews, procurement, standards, trade, and data flows, and refrains from pursuing industrial policy objectives under the guise of national security. China's approach of co-mingling security and commercial objectives increasingly risks undermining the long-standing efforts of the American business community to advocate for an open investment climate for Chinese investors in the United States.

### **Cyber and Information Security Compliance Framework**

China's burgeoning cyber and information security frameworks have established a legal basis for applying far-reaching national security policies to restrict commerce. China's laws, rules and regulations in this area are broad in scope—from procurement and IP disclosure to data residency requirements and domestic standards—and frequently extend beyond what is necessary for legitimate national security protections.<sup>8</sup>

In addition to the inefficiencies and security risks these rules create, they also provide Chinese regulators opportunities to impose a cost—often in the form of technology transfer and/or IP disclosure—on a foreign business seeking to access or compete in the China market. China's laws, regulations, and guidelines are forcing companies to balance Chinese requirements to localize production, IP, and data against their need for globally efficient supply chains and operations.

These challenges are most prevalent for ICT and ICT-enabled businesses, such as cloud computing. Cloud computing and other digital technologies that require seamless data flows are already changing the nature of numerous industries, including advanced manufacturing and online services—in particular for small- and medium-size businesses. Yet, Chinese efforts to exert greater control over where commercial data is stored and how it is transferred are skewing the decision-making process for our members. These decisions impact where products are made and innovation takes place.<sup>9</sup>

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<sup>6</sup> [https://www.uschamber.com/sites/default/files/documents/files/preventing\\_degloabalization\\_1.pdf](https://www.uschamber.com/sites/default/files/documents/files/preventing_degloabalization_1.pdf)

<sup>7</sup> <https://www.treasury.gov/press-center/press-releases/Pages/jl0484.aspx>

<sup>8</sup> In 2016, the Chamber issued a report that documents in detail the scope of China's national security policies that are affecting the ability of foreign companies to operate in its market. U.S. Chamber of Commerce, et al:

<https://www.uschamber.com/report/preventing-degloabalization-economic-and-security-argument-free-trade-and-investment-ict>

<sup>9</sup> <http://www2.itif.org/2017-cloud-computing-enables-manufacturing.pdf>

Data localization requirements have appeared in a wide range of recent Chinese policies, making their impact broadly felt across all sectors of China's economy.<sup>10</sup> New policies, ranging from China's draft *E-Commerce Law* to its *Cybersecurity Law* and its accompanying implementation measures (discussed below) are just a few recent examples of Chinese efforts to control business data. These policies are simultaneously restricting the ability of data-reliant companies, from financial services to advanced manufacturing, to compete in the China market as multinational companies.

A non-exhaustive list of recent cyber and information security policies of consequence to our members include:

**Cybersecurity Law:** In November 2016, the Standing Committee of the National People's Congress (NPC) adopted the *Cybersecurity Law*, and on June 1, 2017 the law took force. The *Cybersecurity Law* is a framework law that creates a basis for China to impose security and testing requirements, security reviews on software and IT products, and discriminatory standards, such as "secure and controllable." The *Cybersecurity Law* also has other restrictive measures—including data residency requirements and cross-border data flow restrictions—that will hinder the ability of foreign companies to bring advanced technology to, or further invest in, China.

**Security Assessment Measures for Exporting Personal Information and Important Data (the Measures):** The Measures introduced by CAC in April 2017 served to provide implementing details for Article 37 of the *Cybersecurity Law* outlining security assessment requirements for companies that export data overseas. The Measures significantly expanded the scope of data localization requirements and cross-border data flow restrictions beyond not only what is necessary for security purposes, but also the *Cybersecurity Law*. CAC subsequently granted a 19-month grace period for businesses to comply with the Measures, but it does not appear to have addressed industry's substantive concerns.

**Draft Critical Information Infrastructure (CII) Protection Regulations:** Issued for public comment in July 2017, these draft regulations set forth requirements for CII operators. The CII designation carries significant and stringent regulatory obligations—including requirements to store important data and personal information locally and restrictions on cross-border data flows. The draft regulations provide a broad and unclear scope for CII—including telecommunication networks, broadcasting networks, Internet and other information networks, and organizations that provide cloud computing, big data, and other information services—that creates significant uncertainty for businesses.

**Draft Cryptography Law:** This is China's first law governing cryptography, and takes an overly broad regulatory approach towards commercial cryptography that could have a large impact on trade in ICT products in China. Key provisions of concern include strict

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<sup>10</sup> E.g. China's *Cybersecurity Law*, draft *Notice on Regulating Business Behaviors in the Cloud Service Market*, *Security Assessment Measures for Exporting Personal Information and Important Data*, *Critical Information Infrastructure (CII) Protection Regulations*, draft *E-Commerce Law*, and *Interim Administrative Guidelines for Civil Aviation Network IT Security*, *Measures for the Administration of Population Health Information*, etc.



and intrusive import/export and licensing regimes for commercial products with encryption, requirements to use mandatory national standards, burdensome testing and certification requirements, and broad enforcement powers that could require disclosure of sensitive and confidential business information.

Measures on Network Product and Service Security Review (the Measures): The Measures, first released in February 2017, were adopted in trial form just three months later in May 2017. The Measures include several provisions that use undefined terms resulting in insufficient clarity on what services and products will be subject to a security review. Furthermore, security review criteria in the Measures include non-national security related provisions, such as “abuse of a dominant market position,” that may conflict with provisions already addressed in other Chinese laws.

Secure and Controllable Policies: In February 2017, China’s Civil Aviation Administration (CAAC) issued its draft *Interim Administrative Guidelines for Civil Aviation Network IT Security*.<sup>11</sup> The Guidelines mandate that IT products and services that access China’s civil air network should be secure and controllable, and pass a national security review. The CAAC guidelines are yet another example in a succession of policies in which China’s secure and controllable standard is being extended to a broad array of industries.

The “secure and controllable” concept is one of the clearest and most concrete examples of discriminatory treatment through a standard. The basic secure and controllable concept is incorporated into both the National Security Law and the Cybersecurity Law, giving it a legal basis.

Although never formally defined, regulations and guidelines using the term indicate that companies would not be able to qualify for standards unless they surrender key technologies, such as source code and encryption algorithms, to Chinese authorities. In recent draft guidelines on CPUs, operating systems, and office suites, the “secure and controllable” score was linked directly to IP disclosure (i.e., the more IP an applicant disclosed the higher its score).<sup>12</sup>

The Chinese government has asserted that the secure and controllable concept was introduced to ensure information technology products and services used in Chinese networks—ranging from commercial enterprises to government institutions—were secure. While every country is justified in protecting its national security, it should not be used to disguise industrial policy.

In 2015, the U.S. and Chinese presidents agreed not to impose nationality-based conditions or restrictions on the purchase, sale, or use of ICT products by commercial enterprises. Since the commitment was made, however, U.S. industry has not seen a reversal of the policy. To the contrary, there has been a proliferation of secure and controllable policies across industry sectors, which calls into question China’s

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<sup>11</sup> <https://www.easyaq.com/news/912182527.shtml>

<sup>12</sup> TC260 Security Controllable Standards for CPU, Operating System, and Office Suites: <http://www.tc260.org.cn/zqyj.jsp>

commitment to the 2015 agreement.

We welcome the recent U.S. government filing at the WTO that calls upon China to refrain from implementing the *Cybersecurity Law* and various implementing measures connected with it discussed above.<sup>13</sup> The U.S. Chamber and our members agree with the U.S. government that implementation of these measures would disrupt, deter, and in many cases, prohibit cross-border transfers of information that are routine in the ordinary course of business.

To reverse this deepening trend of deglobalization of China's ICT sector and its enormous downside economic costs, the Chamber recommends that the U.S. government make efforts to achieve the following outcomes related to China's cyber and information security frameworks:

- allow the vast majority of data to be transferred across borders without a security assessment, and limit the definition of critical information infrastructure (CII) to include only infrastructure belonging to the Communist Party of China, the Central Government, and the People's Liberation Army, but NOT including state-owned enterprises, local governments, and healthcare and education institutions;
- restrict China's national security approach only to legitimate national security interests, and remove economic security and other vague criteria such as social and industrial security from laws and measures;
- stay all implementation of current and draft regulations requiring "secure and controllable" products until these regulations are consistent with official commitments made between the U.S. and Chinese government; and
- obtain a commitment endorsed through a State Council guideline that China unequivocally embraces a globalized ICT sector and allows commercial enterprises to set their own requirements for the equipment and software they purchase.

### **Made in China 2025**

Through Made in China 2025 (MIC2025) and related plans,<sup>14</sup> China is promoting a new generation of industrial policies and subsidies to promote indigenous technologies and foster domestic champions.

The "Made in China 2025 Major Technical Roadmap," issued in September 2015, sets specific domestic and international sales growth and market share targets for a variety of industries and sectors that are to be filled by "domestic production," "domestic equipment," and "domestic brands." In some sectors, including medical devices, the MIC2025 Plan is being used as the basis for preferential procurement lists that appear to exclude foreign invested enterprises, even in cases where production is entirely localized.<sup>15</sup>

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<sup>13</sup> Communication from the United States to the Members of the Council for Trade in Services at the WTO; September 27, 2017; <https://regmedia.co.uk/2017/09/26/wto-us-china.pdf>

<sup>14</sup> "Made in China 2025: Global Ambitions Built on Local Protections," U.S. Chamber of Commerce (2017)

<sup>15</sup> [http://www.sohu.com/a/129305619\\_464411](http://www.sohu.com/a/129305619_464411)

China's industrial policies are also associated with financial incentives and support that raise the specter of fueling overcapacity in high-value added sectors of critical importance to Chamber members and the U.S. economy, including semiconductors, medical devices, new energy vehicles, robotics, and others. Previous industrial policies have contributed to enduring overcapacity challenges in aluminum, agriculture, steel, and other industries. The U.S. Chamber strongly supports ongoing U.S. government efforts to address excess capacity concerns with China.

As part of U.S. government efforts to comprehensively and systematically address concerns regarding a new generation of industrial policies targeting markets in which our members compete, we urge the U.S. government to set up a robust monitoring and forecasting initiative to assess how such policies articulated in MIC2025 and other planning documents will impact critical sectors of the U.S. economy over the coming decades. This effort should marshal the full economic and regulatory analytical capabilities from agencies across the U.S. government, including the International Trade Commission. We urge the U.S. government to use the analysis derived from this initiative to set benchmarks for implementation of China's commitments in future high-level negotiations and dialogues.

### ***Long-Standing Challenges***

From market access restrictions to IPR protections, there are a number of long-standing issues that continue to restrict and burden U.S. companies attempting to enter and compete in the China market. Increasingly, because of China's size and importance to the global economy, such frameworks are creating distortions in global markets that are adversely impacting our members.

#### **Market Access**

For American and Chinese companies, there exist fundamental asymmetries in the ability to access and compete in each other's market. Despite being the world's second largest economy, China maintains the world's second most restrictive investment environment of all G20 countries—ahead of only Saudi Arabia—according to the OECD.<sup>16</sup> Chinese restrictions on foreign investment are limiting opportunities for American business in China, even as Chinese companies enjoy significant opportunities in identical or similar sectors of the U.S. economy.

Paired with a record \$46 billion in Chinese investment in the U.S. in 2016,<sup>17</sup> this imbalance is adding substantially to the erosion of trust and contributing to ever higher levels of friction in the bilateral relationship.

The U.S. Chamber and our members welcome the Chinese government's commitment to openness and support for globalization, including at the 2017 World Economic Forum, the annual China Development Forum, and the G20 Summit in Berlin. Unfortunately, China's policy direction has yet to match its rhetoric; instead, China is continuing to pursue a broad

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<sup>16</sup> OECD's FDI Regulatory Restrictiveness Index (<https://data.oecd.org/fdi/fdi-restrictiveness.htm>)

<sup>17</sup> [https://www.ncuscr.org/sites/default/files/RHG\\_New-Neighbors\\_2017-Update\\_FinalDraft\\_Apr18\\_ES.pdf](https://www.ncuscr.org/sites/default/files/RHG_New-Neighbors_2017-Update_FinalDraft_Apr18_ES.pdf)

policy agenda that seems to be prioritizing state intervention and control at the expense of domestic and cross-border openness, market-based outcomes, and competitive markets for all commercial actors, regardless of national origin. For example, in January 2017, the State Council released its *Measures for Further Opening Up and Active Use of Foreign Investment* (Circular No. 5)<sup>18</sup> that listed 20 measures to encourage foreign investment. However, to date, there has been little in the way of tangible implementation of market opening measures of value to foreign companies under the Circular.

Additionally, in late June 2017, roughly two weeks before the inaugural U.S.-China CED, the Chinese government released an updated *Catalogue on Guiding Foreign Investment in Industry*<sup>19</sup>—the primary document governing foreign access to China’s market. While the Chamber welcomed new openings for credit ratings agencies, agricultural processing, and accounting firms, the openings offered in the revised Catalogue, overall, were incremental and unreflective of the need for quick and substantial market openings—particularly for services industries.

More recently, China’s Vice Premier Wang Yang stated that “[China needs to] pay more attention to creating a level playing field after [foreign] companies get access to the market.”<sup>20</sup> Vice Premier Wang’s comments were accompanied by a MOFCOM decision to eliminate a long-standing administrative rule requiring foreign companies to set up representative offices before they can operate in China.<sup>21</sup> While the procedural relief is welcome, the MOFCOM decision does little to address market access restrictions for American businesses.

### **Administrative Licensing and Approvals**

Despite official commitments “that its industry development-related documents treat all enterprises equally,”<sup>22</sup> China continues to use regulatory levers—including approvals and licenses—to disadvantage foreign companies. According to the *AmCham China 2017 Survey*, “difficulty obtaining required licenses” was a top five business challenge each of the last two years. Notable examples of challenges in approvals and licenses include:

**Agricultural Biotechnology:** Over the last several years the U.S. has elevated agricultural biotechnology as a high-level strategic economic priority with China. Through various fora, including presidential level meetings, and most recently the U.S.-China Comprehensive Dialogue and the CED, the Chinese government has committed to advance agricultural biotechnology approvals based on science and in a timely manner. As an early harvest outcome in the U.S.-China 100-Day Action Plan, China committed to conduct science-based evaluations of pending U.S. biotechnology product applications to assess the safety of the products for their intended use.

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<sup>18</sup> [http://www.gov.cn/zhengce/content/2017-01/17/content\\_5160624.htm](http://www.gov.cn/zhengce/content/2017-01/17/content_5160624.htm)

<sup>19</sup> <http://www.gov.cn/xinwen/2017-06/28/5206424/files/e4489bbd621542a480ff4c45c42fa202.pdf>

<sup>20</sup> <http://www.scmp.com/news/china/economy/article/2113093/beijing-cuts-red-tape-foreign-firms-it-vies-investors>

<sup>21</sup> <http://www.mofcom.gov.cn/article/b/c/201709/20170902650171.shtml>

<sup>22</sup> <https://www.treasury.gov/press-center/press-releases/Pages/jl0484.aspx>

The Chamber appreciates the progress demonstrated through this process and noted China's ability to move quickly on risk assessments. However, U.S. agriculture needs a regulatory approval process that provides predictability and relies on science as the basis for determining the safety of agricultural biotechnology traits.

Notwithstanding recent commitments by China to improve the administration of its biotech regulations, systemic challenges remain that are undermining American agriculture by: 1) slowing the introduction of new production tools available to American farmers and farmers globally, 2) jeopardizing market access for U.S. agricultural products exported to China, and 3) reducing long-term private sector investments in agricultural production technology.

As the world's largest importer of agricultural commodities, we hope China will responsibly administer its biotechnology regulations in a timely and science-based manner, and fulfill the commitments made in the U.S.-China 100-Day Action Plan, the 2015 and 2016 S&EDs, and the 2015 Presidential Summit.

Electronic Payments: Approximately 10 years after China agreed to open its market to foreign electronic payment service (EPS) providers under its WTO accession agreement, and following an adverse ruling at the WTO in 2012 against China's EPS practices, U.S. EPS providers still are unable to participate in China's EPS market. Meanwhile, China's electronic payment service (EPS) suppliers, mobile payment companies, and bank card issuers dominate the domestic market and are making significant inroads into global markets, including the United States.

As part of the U.S.-China 100-Day Action Plan, China committed to "issue any further necessary guidelines and allow wholly U.S.-owned EPS suppliers to begin the licensing process, which should lead to full and prompt market access." While China complied with its commitment to issue new guidelines, China has yet to clarify if greenfield investments by U.S. EPS suppliers are subject to national security reviews in order to obtain their licenses. Further, there remain questions surrounding the review process, including which Chinese governmental and non-governmental entities would be involved, as well as the sequence and timeframe by which the review will occur.

### **Intellectual Property Rights and Antitrust**

Over the years, the Chinese government has aimed to strengthen its protection of IPR. According to the AmCham China 2017 Survey, 95% of respondents report that China's enforcement of IPR has improved. Additionally, recent draft announcements from the CFDA, if adopted and implemented, would strengthen China's regulatory data protections and enhance patent enforcement. The Chamber welcomes these policy reforms and looks forward to more details on how they will be implemented in the near future.

However, our members still face challenges protecting and enforcing their IP rights in China. This is most prominent with trade secrets, where two-thirds of surveyed companies

find China's enforcement of trade secrets either ineffective or very ineffective.<sup>23</sup> Provisions on trade secrets misappropriation have been addressed in drafts of China's *Anti-Unfair Competition Law* (AUCL). The Chamber is concerned that placing such a wide variety of legal claims on IPR issues under one law could lead to 'one-size-fits-all' enforcement practices which may not best suit all rights conferred within the law. Moreover, under the existing legal framework, foreign companies must confront the unaddressed difficulties associated with the right to discovery, burden of proof, and protection of evidence in any alleged trade secret misappropriation. The Chamber believes a standalone trade secrets law is the best solution for the business community.

Additionally, our member companies are concerned with policy developments on the relationship between IP and antitrust. Recently, the State Council's Antimonopoly Commission issued draft *IP Abuse Guidelines* that endorse a broad, unbalanced essential facilities doctrine, and impose antimonopoly sanctions for refusing to license IP or charging "excessively high" royalties. The Chamber is concerned that any unilateral refusal to license could be characterized as an abuse of IPR under the proposed guidelines, and thereby be subject to AML sanctions.

### **State-Sector Challenges**

As noted, the U.S. Chamber and our members welcomed China's 2013 *Third Plenum Decision* document,<sup>24</sup> which called for the market to play a decisive role in allocating resources. Regrettably, nearly four years removed from the Decision, the State's role in China's economy appears to have strengthened well beyond 2013 levels in certain areas.

For example, on August 18, the State Council issued guidelines<sup>25</sup> restricting outbound Chinese investment, including for private real estate, sports, hotels, and film and entertainment companies. Subsequent asset divestitures by private companies raise concerns regarding the autonomy of private enterprises in China and ongoing State intervention to dictate commercial outcomes.

Additionally, China is continuing to consolidate state-owned enterprises, including in the steel and energy sectors, to create mega-corporations. These mega corporations are likely to hold more dominant positions in the Chinese economy than before and raise questions about the role of market forces in China's economy going forward.

### **Conclusion**

The Chamber appreciates the efforts of the Trump Administration to prioritize the full scope of industry concerns with China. The following sections of this submission highlight both cross-sectoral and industry-specific concerns in greater detail.

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<sup>23</sup> AmCham China 2017 Business Climate Survey Report

<sup>24</sup> <http://cpc.people.com.cn/n/2013/1115/c64094-23559163.html>

<sup>25</sup> [http://www.gov.cn/zhengce/content/2017-08/18/content\\_5218665.htm](http://www.gov.cn/zhengce/content/2017-08/18/content_5218665.htm)

Going forward, we believe it is particularly important to address concerns regarding China's information technology and data regulatory frameworks, as they pose serious challenges not only for U.S. ICT companies, but also for numerous industries that depend on ICT and data.

As always, the Chamber is committed to supporting U.S. government efforts to address the policy concerns outlined in our submission. We look forward to close engagement with the Trump Administration on issues of shared concern through the duration of 2017 and to providing timely updates on our membership's policy priorities as warranted.

## **CROSS-SECTORAL ISSUES**

### **INDIGENOUS INNOVATION & INDUSTRIAL POLICY**

#### **1. Competition Law**

##### **Intellectual Property Rights**

- We request that the U.S. government secure a commitment from China to address industry concerns in the multiple draft guidelines on IP abuse from China's anti-monopoly enforcement agencies (AMEA's):
  - removing its unbalanced essential facilities doctrine;
  - deleting provisions on excessive pricing; and
  - eliminating provisions that prohibit or restrict the refusal to license.

The IP system rests on the basic principle that IP is a right to exclude all others from commercially benefiting from it and the right to determine the rates for and other terms of the license. We, therefore, request China's AML IP Abuse guidelines not be issued until they, at a minimum, reflect these principles.

- Secure a commitment that China will refrain from (i) compelling new licensing of IP solely because of an unconditional refusal by the owner to grant a license to a third party that needs access to the IP to innovate and/or compete; and (ii) requiring a business justification for a refusal to license when non-essential IP is involved. Recognize that these behaviors can discourage technology owners from deploying their newest and best technologies in China.
- Secure commitments from China to agree not to interfere in licensing negotiations between standards implementers and the owners of "essential" patents or other IPRs in the standard, per its 2004 JCCT commitment that has not been followed,<sup>26</sup> and agree not to adopt policies that would have an effect similar to direct interference in licensing negotiations..
- Allow foreign and Chinese companies to enter into IP licensing arrangements freely and without government involvement, per China's 2014 JCCT commitment.

##### **Transparency and Due Process**

- Secure a commitment from China to provide additional guidance regarding the required content of notifications so that more notifications will be complete and accepted when initially filed.
- Encourage China to enable MOFCOM to collaborate more deeply and substantively with competition regulators in other major jurisdictions on M&A cases requiring multi-jurisdictional approvals, including through the remedy phase.

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<sup>26</sup> China committed at the 2004 JCCT to remove PRC regulators from negotiations regarding payment terms with relevant IPR holders.



### Draft Anti-Unfair Competition Law (AUCL)

- Secure a commitment from China that the term “comparative advantage position” will not be re-inserted in a final Anti-Unfair Competition Law (AUCL), or confirm that if it must be included it will be replaced with the term “dominant market position,” as used in China’s AML.

### 2. Indigenous Innovation Policies and Product Lists

- Secure a commitment from China that it will repeal all remaining central- and local-level policies that provide preferences for domestic products or indigenous IP; for instance, in medical devices.
- Secure a commitment that China should immediately make all plans and accompanying rules and regulations for its Strategic Emerging Industries (SEI) Initiative publicly available. Secure a commitment that SEI plans, rules, and regulations provide a level playing field for all companies, regardless of nationality, and allow the market to select the most appropriate, sustainable technologies.
- Request that China further modify the High- and New-Technology Enterprise (HNTE) program such that it:
  - eliminates the current HNTE requirement to own proprietary core technology in China and replace it with criteria that emphasize usage rights;
  - expands the criteria of the licensing conditions to include non-exclusive licensee or usage rights; and
  - reduces the amount of sensitive information that companies must release when they submit an application, limiting it to that which is truly necessary to evaluate a company’s high- and new- technology activities, and provides more explicit assurances that this information will be adequately protected.

Despite efforts made in the S&ED innovation dialogue and other fora, the latest revisions to the HNTE program in February 2016 do not address or eliminate the concerns listed above. In fact, it appears the situation may be somewhat worse.

### 3. Public Procurement

- Finalize a clear, consistent, and inclusive definition of what constitutes a “domestic product” by issuing the “Administrative Measure for the Government Procurement of Domestic Products.” Ensure that any definition would provide equal treatment to all legal entities in China providing goods and services regardless of ownership.

### WTO Government Procurement Agreement (GPA)

- In light of China’s continued efforts to negotiate entry into the, secure a commitment from China to reconsider its position and make additional changes to their offer covering additional entities to Annexes 1-3 in their offer.

- Secure a schedule for regular technical discussions between the U.S. and China on GPA accession with a view towards China acceding to the GPA in 2018. Create opportunities for private sector participation in these discussions.

#### China's Domestic Government Procurement and Tendering & Bidding Laws

- Secure a commitment from China to revise China's Tendering and Bidding Law regime to be consistent with the Government Procurement Law so that "public works projects" are treated the same as other government procurement items and that public procurement under the Tendering and Bidding Law is open, transparent, and completely free of government requirements to transfer technology or know-how. The Chamber was encouraged by China's recognition in the 2012 JCCT that some Chinese government procurement projects are for public service and that some enterprises, including state-owned enterprises (SOEs), procure in the public interest. We hope this recognition will ease the path to revision of the Tendering and Bidding Law.
- Secure a commitment that foreign-invested enterprises have equal access to information at the start of a bidding process, that there is transparency and fair evaluation during the tendering process, and that there is efficient and meaningful remediation to raise objections in cases of perceived irregularities.

#### 4. Standards

- The Chamber is concerned about new revisions to the draft Standardization Law that expand public disclosure requirements, establish a path for social organization standards to be transposed and adopted as national standards, provide support for indigenous innovation, and lack consistency with the WTO TBT. The Chamber suggests the following areas that would benefit from further revision:
  - **Public Disclosures** The latest Draft Revisions (Articles 27, 34, and 37) expand public disclosure requirements for enterprises. These requirements are unique to China and will likely add significant costs not only to enterprises but also to government agencies. We recommend NPC limit any mandatory public disclosure requirements only to mandatory standards. All other standards should be disclosed on a voluntary basis.
  - **Transposition** The Chamber is concerned by public statements that implementing policies for the Standardization Law will establish a path for social organization standards to be transposed and adopted as national standards (recommended/mandatory) or recommended standards. We recommend NPC clarify the basic principles of transposition before the third reading of the Draft Revisions. The addition of Article 19 on indigenous innovation (see the bullet below) to the draft law creates a scenario where the WTO TBT requirements on a central government for the publication of a work program and sufficient public notice would be subverted.

- **Indigenous Innovation** Newly added article 19 is highly problematic for our organizations, and we strongly recommend it be removed from the Draft Revision. The inclusion of a stated preference for indigenous innovation in social organization standards creates a trade barrier that would conflict with the WTO TBT 4.1, WTO TBT Annex 3, D, and TBT Annex 3 F. The WTO TBT requires all measures to be consistent with the Code of Good Practice. Article 19 conflicts with WTO TBT Annex 3, D which requires equal treatment of products originating from different countries and TBT Annex 3, F provisions for use of international standards.
  - **WTO Technical Barriers to Trade (TBT) Consistency** As a signatory to the WTO, China should use its commitments in the WTO Agreement on the TBT as a basis for its legal and policy frameworks for standardization. WTO consistency is particularly important for the Standardization Law because it serves as the legal framework for China's standardization development. In its current form, the Draft Revisions (Articles 9, 10, 11, 12, 13, and 21) would be improved through greater consistency with the WTO TBT agreement.
- Although there are some positive developments on enterprise standards in the latest draft revisions, the Chamber continues to recommend that China to remove “enterprise standards” from the draft revisions to the Standardization Law. Enterprise standards are generally understood as descriptions of the proprietary specifications of individual products and services. Forcing their use and disclosure could undermine incentives that drive innovation and economic growth.
  - Secure a commitment from China to (i) align Chinese standards—including national, industrial, and provincial standards—with international standards, and (ii) base Chinese standards and regulations on international standards wherever practical.
  - Secure a commitment from China to allow foreign companies access to and voting rights in Chinese standards setting bodies, including mandatory and voluntary standards, on par with Chinese companies, and ensure that there is no “presumption of participation” in Chinese standards setting laws, rules or administrative regulations that would allow a Chinese standards body to adopt or implement the IP of a foreign company into a Chinese standard on non-market or royalty-free terms.
  - Secure a commitment from China to create a unified channel for making draft versions of all mandatory standards (national, industrial, etc.) and technical requirements available to domestic, foreign-invested, and foreign-based companies for comment at least two months prior to its adoption along with opening all domestic standards development organizations to foreign voting participation.
  - In light of the Office of the State Commercial Cryptography Administration's (OSCCA) decision to revise the 1999 regulations, secure a commitment from China to provide a fair and transparent process for commercial encryption whereby China abides by its WTO commitments to adopt global market based technical standards on a non-discriminatory basis.

## 5. Conformity Assessment and Certification Redundancy

### Encryption

- Ensure that China upholds its “core function” commitment in all new or revised encryption laws and regulations. This commitment, announced in 2000 after the publication of the 1999 *Commercial Encryption Regulations*, limits the scope of encryption-related restrictions and requirements to only those products for which encryption is a “core function.”
- Secure a commitment that China will remove all requirements to use localized encryption, including in the draft CIRC regulations. This would impose a disproportionate burden on foreign-invested insurers because Chinese algorithms may differ from those of their parent companies, thereby reducing their competitiveness
- Secure a commitment from China to avoid onerous and/or discriminatory testing and certification standards for commercial encryption, including a commitment to not require the disclosure of source code or other proprietary information for testing by state laboratories to gain market access.

### Intellectual Property

- Institute new and meaningful safeguards, in consultation with the U.S. government and industry, to prevent coerced disclosure of unnecessary proprietary information as a condition of market access under compulsory certification regimes.
- Secure a commitment from China to only require the minimum amount of information necessary to show conformance and take the measures necessary to adequately protect any confidential business information it receives.

### Information Technology/Electronics

- Ensure that China implements its 2006, 2009, and 2010 JCCT commitments to maintain a policy of technology neutrality towards 3G/4G and other telecom standards by allowing operators and end users to adopt technology freely and based upon market principles.
- In light of China’s “Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products,” seek clarification that the voluntary China RoHS testing regime remains voluntary and is implemented based on a self-declaration of compliance by importers and sellers of those products included in the RoHS product scope. RoHS compliance should not require on-site factory inspections or the disclosure of companies’ proprietary information, including material make-up of components as well as the identity of suppliers.

## Standards/Testing

- Secure a commitment from China to refrain from categorizing a standard as “voluntary” in the instance where it is actually a mandatory requirement for conformity assessment programs. By doing it in this manner, China bypasses the need to identify the WTO TBT process.
- Secure a commitment from China to engage the U.S. in negotiations on a mutual recognition agreement (MRA).
- Recommend China join the APEC Pathfinder for Remanufacturing, alongside most other countries in the region, ensuring that remanufactured products follow the same technical standards as original new products. As such, China would allow the free flow of cores and remanufactured finished goods (RFG) across borders.

## 6. Cybersecurity Initiatives

### China Insurance Regulatory Commission (CIRC) Informatization Regulations

- Secure a commitment that China will stay all regulations—including the China Insurance Regulatory Commission (CIRC) *Insurance System Informatization Regulatory Requirements* (draft) and the China Banking Regulatory Commission *Guidelines for the Promotion of the Use of Secure and Controllable Information Technology*—requiring “secure and controllable” products until these regulations are consistent with WTO agreements/rules (including but not limited to those in the TBT Agreement), are narrowly tailored, take into account international norms, are nondiscriminatory, and do not impose nationality-based conditions or restrictions, on the purchase, sale, or use of ICT products by commercial enterprises unnecessarily—per commitments made at the presidential bilateral in September 2015.
- Secure a commitment that China will remove data localization requirements from the China Insurance Regulatory Commission (CIRC) *Insurance System Informatization Regulatory Requirements* (draft). We are concerned about provisions in the revised draft CIRC regulations that would require data sourced within China be stored in a data center located in China. This requirement is unwarranted and costly. Moreover, CIRC can and already does require that all insurance institutions licensed in China provide relevant information to enable CIRC to perform its supervisory responsibilities.
- Secure a commitment that China will remove procurement preferences for products that are “secure and controllable” (Article 53) from the CIRC *Insurance System Informatization Regulatory Requirements* (draft). It remains unclear what definition or standard applies to “secure and controllable.” At the 2015 S&ED the Chinese “committed to ensure that ICT regulations will be non-discriminatory, are not to impose nationality-based requirements, and are developed in a transparent manner,” and re-affirmed this at the 2015 JCCT. We ask that this commitment be applicable to commercial insurance.
- Ensure that China remove all restrictions on cross-border data transfer (Article 58) and explicitly allow for copies of financial data to leave China’s shores for business and analytical purposes

- Secure a commitment that the CIRC regulations will not require adoption of Chinese domestic cryptographic standards.
- China should remove provisions that set information system security requirements in accordance with the Multi-Level Protection Scheme (MLPS).

#### China Banking and Regulatory Commission's Banking Regulations

- Secure a commitment from China that the China Banking and Regulatory Commission's *Promotion Guidelines for Banking Applications of Secure and Controllable Information Technology (2014-2015)* will not be released or enforced at a later date. While the Chamber appreciates their suspension, we request clarity that the Regulations will not reemerge at a later date.
- Secure a commitment that regulators are not currently enforcing the Banking Regulations despite their suspension and that banks are once again allowed to buy U.S. information communication technology (ICT) for critical infrastructure purposes.

#### Cybersecurity Law

- Secure a commitment that China's Cybersecurity Law will not enforce source code disclosure requirements. Ensure security requirements are technology-neutral and yield a measurably improved security outcome. We recommend that China:
  - provide a clear and narrow definition of "critical information infrastructure";
  - consult international best practices and certification procedures in global standards and certification;
  - remove requirements for data localization;
  - allow for foreign-invested enterprise participation, on an equal basis, in the standards setting process for cybersecurity; and
  - ensure that any cybersecurity-related policies balance the impact of on a country's national security and public safety with their potential impact on global trade, technological innovation, and the benefits of informatization.

#### Security Assessment Measures for Exporting Personal Information and Important Data

- Secure a commitment that the Measures, if implemented, will be done so in consultation with the international business community, and will take feedback from public comments into consideration for any final implementation of the Measures.

#### Measures on Network Product and Service Security Review (Measures):

- Secure a commitment that China will clarify products that will be subject to a security review, and that security reviews covered in the Measures that do not belong in a national security context—such as "dominant market position"—are removed.

## Critical Information Infrastructure (CII) Protection Regulations

- Secure a commitment from China that will limit the definition of critical information infrastructure (CII) to include only infrastructure belonging to the Communist Party of China, the Central Government, and the People's Liberation Army, but NOT including other government-affiliated institutions like state-owned enterprises, local governments, and healthcare and education institutions. The institutions listed that should not be included in the CII definition are not exhaustive, but merely illustrative of institutions that are often associated with State control and thus have potential to be included in a CII definition.

## Testing/Standards

- Secure a commitment from China to remove all indigenous IPR and information security import, sale and usage restrictions for widely available information security technology and services that are used in the general commercial market including SOEs and non-sensitive government procurement (e.g. Multi-Level Protection System [MLPS] regime and a requirement to use the ZUC algorithm for 4G LTE equipment).
  - China has yet to reveal a plan to remove the onerous MLPS requirements. The U.S. government should insist that China remove requirements for domestic IP at Level 3 and above for commercial systems along with mandatory product testing in government-owned or affiliated labs. It should also guide China towards adopting internationally accepted best practices and global standards such as Common Criteria.
  - The U.S. and China should arrange a technical exchange on MLPS. U.S. industry would welcome the opportunity to provide input in this planning process.
  - Building off China's 2013 JCCT commitment to not require applicants to divulge the source code or other sensitive business information in order to comply with ZUC provisions, the U.S. government should continue to press China on the importance of not implementing onerous testing and certification requirements for encryption technology and standards that require a review of source code, low/high level design, and other sensitive business confidential IP.
- Secure a commitment that China will not subject hardware and software procurement decisions to the MLPS for the financial services industries. Secure a commitment that MLPS is applied only in the interest of genuine national security.
- Secure a commitment from China to:
  - Adopt international standards for information security certification;
  - Apply international norms to those parts of the market where products must carry a certification to be used or purchased;
  - Not require the transfer of protected information to the government to obtain any certification by allowing third-party internationally accredited laboratories to operate in China;

- Adopt globally accepted norms and best practices in the area of cybersecurity policy and remove requirements for domestic IP at Level-3 and above for systems and mandatory product testing in government affiliated laboratories; and
- Carry out transparent and robust dialogue with all industry stakeholders – both foreign and Chinese – regarding any new or revised measures for the protection of critical information infrastructure.

## 7. State-Owned Enterprises and Subsidies

- Work toward new principles, criteria, and classification measures that would clarify the independence of SOEs from the direction and support of the Chinese government and the Communist Party, thereby facilitating increased Chinese investment by SOEs in the United States.
- Seek public clarification from China on SOEs and the precise meaning and scope of its July 2014 S&ED commitment “to ensure that enterprises of all forms of ownership have equal access to inputs...and to develop a market-based mechanism for determining the prices of those inputs.”
  - Encourage China to allow private sector input as it considers this new mechanism.
- Secure a commitment from China to comply fully with its existing international obligations to notify the WTO, in a WTO-authorized language, of all subsidies and industrial policies, including those under the 13<sup>th</sup> Five-Year Plan and at the provincial and local levels, that impact trade and investment by the end of 2018.
- Negotiate new agreements with China on SOE-related issues that can address export and investment challenges. Given that many of China’s SOEs appear not to operate solely as commercial entities, ensure that any future investment agreements with China address concerns over the noncommercial nature of SOEs.
- Coordinate with the S&ED effort on regulatory issues arising from China’s SOEs as they list assets, since many of the issues are also relevant to the trade agenda.

## 8. Trade Remedies

- Secure a commitment from China that use of its trade remedy laws will be governed by facts; meet transparency requirements consistent with other major jurisdictions internationally insulated from political pressures, including retaliatory purposes; and adjudicated in a manner consistent with WTO rules.

# INTELLECTUAL PROPERTY

## 1. Enforcement of IPR

- Criminal Enforcement: Amend the criminal code to eliminate value-based thresholds laid out in the Supreme People’s Court 2004 judicial interpretation that counterfeit and pirated goods as the



provisions became a loophole used by infringers to escape criminal liability. In addition, institute concurrent “civil claim” to a criminal prosecution by allowing right holders as victims to file collateral civil claims for compensation during the trial of criminal IPR cases.

- Evidence Preservation: Strengthen rules related to evidence preservation orders and provide more severe civil sanctions against those who breach court orders, hide or destroy evidence, or repeatedly infringe.
- Injunctive Relief: Increase effectiveness of civil remedies by providing for more effective injunctive relief by successful claimants, including efficient and low cost enforcement via continuing contempt jurisdiction. In addition, it is important that China enforces injunctive orders obtained in an international arbitration forum preventing disclosure or use of the IP. In addition, China should provide injunctive relief based on private settlement agreements and MOUs.
- Investigations and Penalties: Secure a commitment from China to explore new ways to strengthen the investigation and penalty powers of administrative enforcement authorities, for piracy, counterfeit and trade secret theft, with appropriate safeguards, such as a court-supervised discovery process, imposing statutory minimum fines, raising or eliminating the statutory maximum on fines, and encouraging enforcement officials to levy larger fines to serve as a deterrent. Such changes could later be implemented through amendments to the Trademark Law, Anti-unfair Competition Law (for trade secrets, as well) and Copyright Law.
- Patent Administrative Enforcement: As mentioned in our comments on the draft Fourth Amendment to the Patent Law, while we appreciate the Chinese government’s heightened attention to patent enforcement, China should not vest the administrative bodies in the patent area with investigative responsibility on infringement and allow them to impose fines and punitive damages, due to the complexities of patent disputes and the adequacy of judicial sanctions.
- Raise Penalties: Increase the effective level of penalties for IPR infringement – both judicial damages and administrative penalties – by instituting statutory minimums and raising or eliminating the statutory maximums on fines and damages for IPR infringement, and by encouraging enforcement authorities to levy larger fines that will serve as more effective deterrents. Revise existing standards for calculating the value of infringing goods so that standards are based on the market value of the infringed goods (i.e. what the original goods would sell for in the same marketplace).
- Increase resources for IPR enforcement personnel at all levels, including enforcement officials and IPR regulators and judges. In particular, increase resources and authority for local public security bureaus, industry and commerce administrations, and local copyright bureaus to proactively tackle counterfeiting, piracy, and other IPR infringement, including online sites and services, mobile networks and apps that intentionally facilitate infringement. Establish benchmarks for IP protection in regular performance evaluation of government officials.
- Increase monitoring and enforcement investigations of Internet sales and distribution platforms for counterfeiting and piracy, and provide regular reporting of enforcement activity. Ensure that

efforts to boost enforcement balance the needs of legitimate IPR holders and responsible Internet intermediaries.

- Destruction of Equipment/Blue Prints and Drawing Specification: If the final appeal court upholds a decision to exclude products, mandate that infringing goods—and, provided that the equipment, blue prints or drawing specification was used exclusively to create the infringing goods or the equipment used to produce them, —be destroyed and not be permitted to re-enter the market under any circumstances. Blueprints or drawing specification should be returned to owner.
- Encourage PRC courts to accept petitions to enforce foreign court judgments related to IPR protection, and to issue court orders to enforce those judgments in greater numbers.
- Proof of IP Ownership and Proof of Infringement: Simplify evidentiary standards to establish ownership of IP and infringement. Allow and admit forms of evidence such as affidavits (under penalty of perjury), brochures of infringers, and live testimonies to prove ownership of IP and infringement in judicial proceedings.
- Appellate Level Specialized IP Court: Create an appellate level specialized IP Court to provide consistency and uniformity of judicial decisions in the area of IP from the specialized IP courts recently established and expanded around China.
- 3-1 Court System: Some jurisdictions in China have been experimenting with what is called a 3-in-1 court system for IPR cases. These courts enable an IP tribunal with expertise on the issue to hear all civil, criminal, and administrative cases on IP. This promotes consistency in enforcement decisions and may encourage adoption of more consistent procedures for IP cases across China. The U.S. should encourage the Supreme People's Court to continue to promote the implementation of 3-in-1 specialized IP courts in additional jurisdictions.
- Accountability and Transparency: Recently, China has made progress toward a more open and transparent enforcement system by announcing that administrative enforcement agencies should proactively disclose information regarding cases involving IP infringement and also begin to publish IP court decisions. The U.S. should encourage continued progress in this area through the expansion and implementation of recent initiatives to publicly release and publish IPR-related decisions, including administrative, civil, and judicial decisions and encourage publication through a unified, searchable channel that is updated on a regular basis.

## 2. Trade Secrets

- Suggest the State Council Leading Group on Combating IPR Infringement and Sales of Counterfeit Goods take the lead on working with US government and industry in both countries on developing and sharing best practices on protecting trade secrets and confidential business information.
- Improve the use of “expert panels” in the permitting process by 1) clearly defining and limiting the specific scope of authority and technical area under panel review; 2) allowing companies to reject experts with a competitive conflict of interest from sitting on the panel; and 3) requiring

regular training of panel members on their responsibilities, including expectations regarding the scope of “necessary” information and for protecting confidential business information and trade secrets.

- Engage in follow up discussions across a variety of Chinese agencies to clarify and articulate what constitutes “necessary” information to be disclosed in the various permitting processes, focusing on what is essential for evaluation of the permit and/or administrative license.
- Given that many approvals have been delegated to the local level, designate an office/point-of-contact at the local level (either in the municipal government’s general office or at the working office of the local IP leading group if the municipality has one) from whom the company can seek clarification (or appeal) on questions related to what is “necessary” to be disclosed for a permit and/or license.
- In line with the government’s goal to simplify and streamline administrative licensing processes, discourage government agencies from creating new licensing and permitting requirements that duplicate existing ones. In areas where duplication exists, such as between the SAWS’ Safety Assessment and the First Introduced Process, eliminate duplicative processes.
- China committed to “enforcement, transparency, and specialized IP courts.” The U.S. should encourage the Supreme People’s Court to include complex trade secret cases within the type of cases eligible for the cross-territorial jurisdiction and advocate for a broad definition of “technical trade secrets” that are within the jurisdiction of the specialized IP courts.
- China committed to vigorously investigating and prosecuting trade secret theft cases and ensuring that civil and criminal cases are tried and the judgments are published according to law. The U.S. should advocate for the development of more robust discovery procedures related to infringement and damages, with appropriate judicial oversight and protections of confidential information. The U.S. should also support training on trade secret cases for judges and court staff.
- China has also indicated it is developing a “blacklist,” or social credit system to hold individuals and entities accountable. Currently, [they] are promoting construction of the enterprise credit file data exchange platform. Information related to administrative penalty cases disclosed in various regions will be gathered after construction of such platform, and the disclosed information will be integrated and used to serve society. It may be appropriate for the U.S. to engage China in a roundtable discussion to share knowledge and best practices on such credit systems and discuss how this platform could be most effective at combating trade secret and other IP infringement.
- Encourage more consistent IPR and trade secret enforcement across regions and jurisdictions by providing clearer guidance and fostering increased communication between central- and local-level government agencies, including greater information sharing and dialogue between provincial and local IPR regulators to share experiences and best practices.

- Encourage publication of a judicial interpretation (JI) on civil trade secret protection to provide greater transparency to users of the court system, establish consistent application of current laws as well as assist courts in keeping a trade secret owner's sensitive information confidential.
- Amend the Criminal Code to unequivocally discourage the theft of trade secrets.

### 3. Copyright

- Online Infringement: Run a new campaign and impose maximum administrative penalties on Internet infringers; increase resources to agencies to revoke business licenses and halt online services by enterprises whose business is primarily focused on providing access to infringing materials and shut down websites that engage in such activities; implement a framework for the forwarding of infringing notices by ISPs to subscribers identified as distributing infringing content using peer-to-peer systems, including measures to deter repeated acts of infringement; and encourage the use of cutting-edge technologies to identify online infringement.
- Media Box/Set Top Box (STB)/Over-The-Top (OTT) Box Piracy: Request China's Leading Group to take a firm stand against this type of infringing activity and take steps to eradicate the problem, including by preventing exports. The manufacture, distribution, and use of these devices facilitate massive infringement. These devices are generally manufactured in China and exported to overseas markets, particularly throughout Asia. These devices are often manufactured or promoted and advertised to enable infringement of copyright or other illegal activities. Chief among these are: 1) enabling users to decrypt without authorization encrypted pay television programming; 2) facilitating easy access to remote online sources of unauthorized entertainment content including music, music videos, karaoke, movies, games, published materials and TV dramas; and 3) permitting storage of unauthorized content, including the ability of manufacturers to pre-load devices with hundreds of high definition (HD) motion pictures prior to shipment, allowing vendors to load content upon import and prior to sale or as an "after sale" service, or allowing users to employ direct download sites or torrents to download materials onto the devices.
- Copyright Law Amendments: The U.S. Chamber submitted comments on China's latest copyright revisions. It has been several years with little movement on these revisions. The Chinese government should make prioritize making updates to its copyright law.
- Evidentiary Standards: Reduce unreasonably high evidentiary standards and allow and admit other forms of evidence (such as affidavits, brochures of infringers, and live testimonies) besides documentary evidence to prove infringement and ownership of intellectual property in judicial proceedings, including those dealing with copyright and with trade secrets.
- Online Video Regulations: Modify restrictions, registration, and review requirements relating to foreign content for online audiovisual services. Specifically, advance registration and full-season review requirements, and allow rolling approval for content. These have reduced market access to this growing sector, undercut legitimate service providers, and delayed providing consumers with day-and-date entertainment they demand which in turn has encouraged Chinese consumers to turn to illegal sources which do not go through censorship.

- **Increase Resources:** Urge the Chinese government to commit to expand resources at the National Copyright Administration of China (NCAC), local Copyright Administrations, and Law and Cultural Enforcement Administrations (LCEAs), commensurate with the scale of the piracy problem.
- **Hold Government Accountable:** Follow through with respect to China's commitment to implement mechanisms, including transparent performance indicators, to hold local government officials responsible for effectively enforcing IP violations, including the Internet and mobile piracy and the unlicensed use of software by enterprises.
- **Live Sports Event Broadcast and Non-Interactive Streaming:** Provide clarification that live sports event broadcast and non-interactive streaming are forms of creativity protected by the Copyright Law and can be protected without revision to the copyright law under Article 3(9) where copyright protection is provided to "other works as provided for in laws and administrative regulations."
- We propose that the appropriate authority issue a regulation making clear that live television broadcasts are copyrightable works in China. This would provide the needed legal protection to prevent pirated Internet retransmissions of valuable live broadcasts.
- The protection of all audiovisual works is clearly envisioned by the publicly released draft of the amendments to the Copyright Act and is also necessary if China plans to implement the Beijing Treaty on Audiovisual Performances.
- **Combating Unauthorized Camcording:** Urge the Chinese government to make it unlawful to use, or attempt to use an audiovisual recording device to make or transmit a copy of a cinematographic work or other audiovisual work, or any part thereof, from a performance of such work in an exhibition facility; and implement watermarking in theatrical prints and ensure that the Chinese government and those involved in the value chain for theatrical distribution step up efforts to deter illegal camcording, which is responsible for over 90% of all piracy during the theatrical window.
- **Criminalization of Key Copyright Offenses:** The Chinese government should commit to lower the threshold for criminal enforcement actions to be taken against infringers, including Internet infringers, and including infringements on a commercial scale undertaken for purposes other than financial gain. China should also criminalize:
  - *unauthorized use of software* by enterprises. China recognizes that the "for profit" requirement for criminal prosecution fails to recognize the significant value of copyrights, adds to the vulnerability of copyright works in the digital era - constraining enforcement efforts in China to deal with many types of blatant piracy such as hard disk loading of software and uploading to file-sharing sites;
  - *hard disk loading* of software or other copyright materials, including third party confidential information;
  - *internet piracy* including the communication to the public or the making available of any work/related right; and

- *circumvention of technological protection measures*, trafficking in circumvention technologies and providing circumvention services.
- Concurrent “Civil Claim” to a Criminal Prosecution: Urge the Chinese government to commit to allow right holders as victims to file collateral civil claims for compensation during the trial of criminal IPR cases.
- Copyright Law Revisions: Among the many opportunities for improvement to the substantive coverage of the Copyright Law, the term of protection accorded to copyrighted works ought to be brought into accord with global standards. It is also critical that improvements to the Copyright Law facilitate civil and criminal enforcement, including clearly establishing in the Copyright Law that unlicensed software use is an infringement of the right of reproduction (whether the unauthorized copy is a permanent or temporary reproduction), clarifying that enterprise use of unlicensed software and Hard-Disk Loading (HDL) may be subject to criminal penalties, strengthening rules related to evidence preservation orders, increasing statutory damages for copyright infringement, and providing for criminal liability for circumvention of technological protection measures (TPMs) as well as production and distribution of tools and methods to circumvent TPMs.

Lastly, we would advise against the requirement in the Copyright Law to regulate the awards provided for developers.

#### 4. Trademark and Counterfeiting

- Trademark Law: Ensure effective implementation of the new trademark law, particularly measures relating to bad faith filings, destruction of goods and equipment used in counterfeiting, tougher penalties and enforcement measures, contributory liability, and streamlining the registration process.
- Online Counterfeiting: As Beijing courts have done with the Silk Street market—a physical market—Chinese courts should impose clear duties on online markets regarding intermediary liability. Clear duties regarding a deemed knowledge standard for online markets will lead to a prevention of repeat offences.
- Advocate for a substantial increase in the number of referrals of cases – large and small – to authorities in Guangzhou, one of the primary locations where online traders in fakes are located.
- Fully implement SAIC Order 49 to promote the registration of complete and accurate details of the identities of online traders and the linking of counterfeiting data to corporate registration records, particularly at the provincial level. Most importantly, Order 49 should be implemented to fulfill its promise as a tool to facilitate the deletion of counterfeit material online upon a notice from the brand owner.
- State-Promoted Counterfeits: Counterfeits and infringing goods on major online platforms claim association with provincial governments. If this is true, the provincial governments have engaged in the official promotion of businesses on such platforms which are selling counterfeit

and/or infringing products. We ask the U.S. government to address this practice with the provincial governments and other government officials. Reference to provincial government is providing credibility in the eyes of consumers to illegal products and damaging the brand integrity of U.S. businesses.

- Global Spread of Counterfeit Products through online platforms based in China: Online platforms based in China are among the largest source of online counterfeit products across a number of products and is fast-becoming the internet platform of choice in many countries around the world. There is no way that right holders have the resources individually to combat this global supply of counterfeits and no government has adequate resources to seize all small package infringing goods at the border. The U.S. should work with China to ensure that online platforms that have been the source of distribution of massive amounts of counterfeits establish takedown processes consistent with global best practices—including amount of resources required from right holders, information sharing with rights holders test buy programs, and follow-up with authorities (e.g., PSB, AICs and Customs) to find the source offender.
- Enforcement: The Chamber underscores the need for more innovative measures to allocate responsibilities for individual counterfeiting cases and to promote cooperation between administrative authorities and the public security bureaus (PSBs) in the course of investigations.
- Pharmaceutical Counterfeiting: As China reviews changes to the intellectual property provisions in the Criminal Code and other enforcement reforms, underscore the need for clarification on how administrative authorities and the PSBs will allocate responsibility for investigations in the absence of formal numerical thresholds.
- Assess outcomes and develop best practices based on China's recent crackdown of illegal online drug sellers. Implement best practices as part of the National Drug Safety Strategy
- Like finished drugs, APIs must be strictly regulated in order to protect against adulteration or counterfeiting that may cause injury to or loss of human life. Although APIs may be considered drugs under China's Drug Administration Law (DAL) and registered in compliance with that law, some API manufacturers in China do not register their APIs with the Chinese regulatory authority (CFDA). These manufacturers are not required to produce APIs and bulk chemicals in accordance with relevant good manufacturing practices, creating significant quality and safety risks. In addition, it is difficult for foreign manufacturers to verify good manufacturing practice certifications where they do exist, and to track the APIs' movement throughout the supply chain.
- Ensure that China follows through on its commitment, made at the 2014 and 2015 S&ED, to develop and seriously consider amendments to the DAL requiring regulatory control of the manufacturers of bulk chemicals that can be used as active pharmaceutical ingredients (APIs), including "export only" producers and distributors.
- Continue to examine its authority to exclude from importation bulk chemical firms not registered with CFDA. China can also demonstrate its commitment to addressing these issues by participating in and making progress on the technical exchanges, trainings, and regulatory cooperation efforts as part of the JCCT Pharmaceutical Subgroup.

## 5. Patent Law & TRIPS-Compliant Compulsory Licensing

### Utility Model Patents (UMPs)

- Secure a commitment from China to strengthen examination of utility model patents (UMPs) and to ensure that remedies for UMPs are not as substantial as for invention patents. Under the current Patent Law, the same damages are allowed for both invention and UMPs. Because a UMP, by definition, should represent a lesser technical achievement than the invention patent, the penalty for infringing the utility model patent should also, by definition, be lower. Furthermore, many UMP's are granted for subject matter that is outside the narrow scope (i.e. non-functional structural subject matter) of UMP subject matter. SIPO should provide more training for examiners to ensure that more attention is paid to the subject matter for which UMP protection is sought. Enhanced guidelines and public notice on subject matter eligibility should be also considered.
- While the draft Patent Examination Guidelines provided patent examiners the authority to assess novelty in their examination process, they do not require that the examiners assess the novelty of the patent. Without explicit direction in the patent examination guidelines, the examination process will be inconsistent and will still allow in some cases for low-value patents to enter the patent system. This examination could match that undergone by invention patent or could be a modified version of a full examination.
- The Chamber was concerned that the 2014 “Certain Provisions of the SPC on Issues Concerning Application of Law in Trying Cases Involving Patent Disputes” no longer requires a utility model or design patent owner to present the patent search report or the patent evaluation at the time of filing the lawsuit. Since a UMP has not been fully examined before registration is allowed, the court should place the burden of proving validity of the UMP and incurring associated costs on the UMP holder, or alternatively stay the case and mandate a substantive examination at the cost of the UMP holder, before the lawsuit may proceed and before the alleged infringer incurs any costs. Secure a commitment from China to develop a mechanism to deter frivolous lawsuits, especially from owners of utility model or design patents (e.g. require utility model or design patent owners to deposit a bond that is sufficient to compensate the accused infringer that wins in defense of an improperly brought lawsuit).
- Secure a commitment from China to reduce or eliminate government subsidies for UMPs and design patent filings and mandate substantive examination of these patents prior to initiating litigation. Further, UMPs and Invention Patents shall be subject to the same standards for patentability.

### Services Invention Remuneration and Awards:

- Draft regulations released on April 1, 2015 by SIPO were greatly improved from the 2014 draft, however, we still have significant concerns. It contains provisions that link compensation for inventions to ambiguous and difficult to define market valuations, thereby introducing potential unlimited risk and cost for research and development undertaken in China.



- Secure China's commitment to conduct more extensive research before passage of any regulation in this field. Absent that commitment, secure an agreement from China to amend its Service Invention Regulations to clarify that a contract between the employer and the inventor overrides all the provisions laid out in the Service Invention Regulations.
- Building from the 2014 U.S.-China Innovation Dialogue "to respect the rules and policies" developed between employers and inventors concerning award and remuneration "in line with their domestic laws," seek further clarity about how existing contracts will be evaluated *vis-à-vis* the Service Invention Regulations and how companies will be able to avoid going against domestic laws while also having their existing contracts respected.

### Patent Law

- Proposed 4th Amendment to China's Patent Law: Ensure changes to the patent laws designed to enhance patent enforcement do not create an environment of over-enforcement, significant sham litigation, and unfair leverage over alleged infringers, particularly through the offensive or defensive assertion of low-quality UMPs.
  - Secure a commitment from China to permit no further expansion to the "ex officio" powers beyond those existing in the 3rd Amendment to China's Patent Law.
  - Press the Chinese government to remove the State Intellectual Property Office's (SIPO) proposed "ex officio" patent enforcement powers against ill-defined "market-disruptive" activities.
  - Secure a commitment from China to eliminate new proposed Articles 14 and 82 of the draft Patent Law amendment. The provisions of Article 14 are better left to consideration under the existing AML, not the Patent Law. Disclosure requirements for standard essential patents and penalties for failure to comply with disclosure requirements is better left to the IPR Policies of Standard Setting Organizations, as determined by their members, and should not be part of the Patent Law.
  - Urge SIPO to coordinate with CFDA on making appropriate revisions to the Patent Law as part of the 4th Amendment to allow a patent-holder to file an infringement suit under the CFDA's proposed patent linkage system (discussed below).
- Compulsory Licensing: Secure a commitment from China to ensure that both the wording and the implementation of the compulsory licensing provisions in the 3rd Amendment to China's Patent Law Implementing Regulations, in particular Article 49(2), are consistent with the WTO TRIPS Agreement.
- Secondary Liability Guidelines: Secure a commitment from China and the SPC that indirect patent infringement cases will be accepted and that clarifying guidelines will be provided regarding the application of secondary liability principles to indirect patent infringers.
- Evidence Collection: Provide authority to administrative judges to obtain sales figures during the evidence gathering phase so that more realistic damage awards can be awarded. Current

statutory awards significantly undervalue patents and tend to create an incentive to infringe until caught.

- Patent Linkage: The Chamber supports CFDA's efforts in pushing forward with a drug-patent linkage system for China. A patent enforcement system is essential in creating a regulatory system that promotes innovation—a key theme in China's 13th Five-Year Plan.

Ensure that China improves and enforces its mechanism to ensure that patent disputes may be resolved prior to market entry by follow-on pharmaceutical products. If a follow-on company actually begins to market a drug that infringes the innovator's pharmaceutical patents, the damage to the innovator may be irreparable even if it later wins its patent litigation.

Putting in place a patent enforcement system that includes an effective early dispute resolution mechanism (i.e. patent linkage) will significantly advance Chinese biopharmaceutical innovation by incentivizing the development of new life-saving medicines in China, as well as encouraging the early introduction of generic drugs, thereby contributing to building a thriving generic industry.

China's proposals set forth in Circulars 52-55 specifically provide the basic framework for establishing patent linkage, regulatory data protection, and the establishment of a compendium of medicines in China similar to our Orange Book in the United States.

While we view the patent linkage section of Circular 55 as overall positive, we recommend CFDA review the timeline for issuing a notice to challenge, filing a case, and staying an approval. The timeline proposed is not aligned with international best practice and may need to be adjusted given China's litigation procedures and timeframes. For example, in the United States, after receiving a receipt of the Notice of Patent Challenge, a listed patent holder has 45 days to bring a suit for patent infringement. Circular 55 gives only 20 days, yet the documentation needed to file suit in China may take longer to prepare.

- Following the model of other countries, China, through the Drug Administration Law (DAL) reforms, should enable patent holders to file patent infringement suits before marketing authorization is granted for follow-on products.
  - Revise the DAL to institute mechanisms that ensure the originator manufacturer is notified of relevant information within a set period of time when a follow-on manufacturer's application is filed.
  - Further, provide sufficient time for patent disputes to be resolved before marketing occurs through, for example, automatic postponement of drug registration approval, either pending resolution of the patent dispute or for a fixed period of time.

## 6. Data Supplementation for Patents and Regulatory Data Protection

- Data Supplementation for Patents: We continue to see problems in the area of data supplementation as implementation of the 2013 JCCT commitment is incomplete. Therefore, it is time for SIPO to revise its examination guidelines to allow supplementation data (a provision changed back in 2006). At the 2013 JCCT, China agreed to permit applicants to submit

additional data after filing their patent applications and confirmed that this change is in effect for representations before SIPO, PRB, and the courts. However, clarity is needed within SIPO, PRB, and the courts and a revision of the guidelines would be confirmation of SIPO's commitment to this practice. It would also bring SIPO in line with the other IP5.

Despite U.S. efforts to monitor this commitment, China has not addressed pending cases and also adopted the same approach of not allowing data supplementation from objections raised on the basis of Article 26.3 to objections raised on the basis of Article 22.3. We have found a growing number of cases where SIPO and PRB are denying admissibility of later filed comparative data to address objections on non-obviousness grounds under Article 22.3 and thereby denying or invalidating patents.

The JCCT commitment is broad and comprehensive enough to include supplementation of data that may be required with respect to inventiveness as required in Article 22.3. However, it is clear that this has not been fully adopted at SIPO, PRB, or the courts and a revision of its examination guidelines will provide necessary demonstrable implementation.

- Regulatory Data Protection (RDP): China's current regulatory data protection system is not effective and has various limitations/ambiguities. In May, the CFDA has recently issued draft policy Circulars 52-55, which provides, among other things, a newly proposed structure for regulatory data exclusivity.

We are encouraged by the overall direction and approach of the documents that aim to reform China's regulatory framework in a manner that encourages drug/medical device innovation and accelerates the review/approval of drugs and medical devices to meet the healthcare needs of Chinese citizens.

## INVESTMENT

### 1. Investment Approvals and the Guiding Catalogue on Foreign Investment

- Secure market openings, consistent with China's previous S&ED commitments to implement a more proactive opening up strategy for foreign investment, that reduces substantially or eliminates foreign ownership restrictions in sectors such as agriculture and agricultural biotechnology, financial services, basic and value-added telecommunications, express delivery services, cloud computing and data centers, refining of petrochemicals, energy-intensive industries, and audiovisual and other media industries.
- Pursuant to the announcement of the adoption of the negative list approach across China, secure a commitment from China to significantly reduce the contents of the Guiding Catalogue that will provide commercially meaningful opening for foreign enterprises. Foreign firms, particularly in the financial services sector set up in Pilot Free Trade Zones (PFTZs), should be permitted to operate beyond the geographical boundaries of the PFTZs, which will be critical to making the pilot efforts a meaningful testing group for national level reforms.

- Pursuant to China's efforts to transform its investment regime and unify the existing primary laws governing foreign investment into the draft Foreign Investment Law (FI Law), secure a commitment that:
  - ensures that the FI law create a level-playing field, further open the market, and improve the predictability, transparency and fairness of the foreign investment regime;
  - ensures that the FI Law treat foreign invested enterprises and all other enterprises equally in the areas of: market access, including government procurement, innovation incentives, law enforcement standards, especially enforcement of competition laws, and product certification, examination and approval, and license granting;
  - requests that the restricted and prohibited categories be abandoned and unified into a simple and efficient negative list. The arrangement of two categories contradicts the negative list model; and
  - guarantees that all other issues should be governed by the *Corporate Law* (such as organizational form, registration, accounting, taxation) in a manner that provides national treatment to foreign companies in China.
- Secure a commitment from China to modify investment approval processes under the NDRC, MOFCOM, the Anti-Monopoly Law Commission, and industry regulators to require that projects and investments be approved unless they violate specific laws and regulations.
- Secure a commitment from China, in the event an investment application is denied, to provide a written statement within a prescribed deadline detailing the specific laws and regulations that would have been violated if the investment had been approved. In addition, urge China to put in place a robust redress mechanism so that the applicant can appeal to higher level authorities if there is disagreement with an administrative decision.
- Secure a commitment from China that the reviewing agency should provide a complete list of information required at the very beginning of the investment application process and the reviewing agency is only able to ask for additional information when there is an event which might overhaul the case, consistent with the *Administrative Licensing Law*.
- Secure a commitment from China to publish timelines for stakeholder, expert, and outside government agency consultations and other approval process steps that currently lack deadlines.
- Secure a commitment from China to eliminate the requirement to establish separate legal entities across various levels of government (i.e. city, provincial, national) for individual business operations to satisfy local authorities' desire to generate tax revenues. These practices increase unnecessary administrative costs and raise the overall cost for business operations, which deters foreign investment.
- Secure a commitment from China to allow foreign investors to participate with their proposed JV partners in submitting JV investment approval applications and communicating directly with approval authorities.

## 2. National Security Reviews

- In light of the commitments made between the presidents of the U.S. and China in September 2015, ensure that any measures or laws pertaining to national security review of foreign investment balance the twin objectives of maintaining openness to foreign investment and protecting national security.
- Ensure that China does not adopt a sweeping, all-encompassing conception of national security—as articulated in regulatory documents<sup>27</sup>— which have provided a broad definition of what constitutes national security: such as economic security, cultural security, social order, public morality. This is inconsistent with principles of non-discrimination, fairness, and openness, and raises fundamental questions about whether future commitments by China to open its markets to foreign investment will produce the intended results.
  - Any laws or measures governing national security review should provide precise, narrowly tailored definitions for the key considerations governing the national review of foreign investment process
- Secure a commitment from China to remove economic security (or related economic references) as a criterion when defining national security, which is inconsistent with U.S. practice as well as OECD guidelines because such economic tests could become a vehicle for domestic industries seeking to block foreign competition:
  - Banking regulations requiring the use of technology products and services developed and controlled by Chinese companies, in the name of national (economic) security concerns, are evidence that economic considerations in national security reviews could result in discrimination against foreign companies and undermine competition in the market.
- Secure a commitment from China to clarify definitional wordings in connection with the types of transactions that will attract review that go beyond traditional national security interests and other terms in these measures and laws that are vague, at best (e.g., “important agricultural products,” “important energy and resources,” “important infrastructure,” “important transportation services” and “key technologies”).
- Secure a commitment from China to eliminate provisions in the Final Provisions of the Ministry of Commerce on Implementing a Security Review System for Mergers and Acquisitions of Domestic Enterprises by Foreign Investors that (i) allow interested third parties, such as national industry associations or domestic enterprises operating in the same sector as a proposed domestic target company, to submit to MOFCOM comments and objections in connection with a proposed transaction and (ii) unwind a transaction after it has closed if it is determined to have a potentially serious impact on national security.
- Secure a commitment from China that the National Security Review Commission (NSRC) provides more details about its role, specifically with regard to market access.

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<sup>27</sup> Draft FI Law and Trial Measures for the National Security Review of Foreign Investments in China’s PFTZs

## **REGULATORY TRANSPARENCY**

- Encourage the PRC government to publish in advance for public comment by local and foreign stakeholders, all trade and economic-related administrative regulations, departmental rules, normative documents, and standards that are proposed for adoption and to provide a public comment period of not less than 30 days from the date of publication.
- Encourage the PRC government to ensure that MNCs have the right, when resolving administrative disputes, to engage the regulatory office and third party regulatory experts beyond the local enforcement department, as they will have a neutral position in interpreting the regulation.

## **INDUSTRY SPECIFIC ISSUES**

### **AGRICULTURAL BIOTECHNOLOGY**

- Over the last several years the U.S. has elevated agricultural biotechnology as a high-level strategic economic priority with China. Through various fora, including presidential level meetings, and most recently the U.S.-China Comprehensive Dialogue and the CED, the Chinese have committed to advance agricultural biotechnology approvals based on science and in a timely manner. An early harvest outcome in the U.S.-China 100-Day Action Plan committed to conduct science-based evaluations of pending U.S. biotechnology product applications to assess the safety of the products for their intended use. The Chamber appreciates the progress demonstrated through this process, and noted China's ability to move quickly on risk assessments. However, U.S. agriculture needs long-term regulatory commitments from China that prioritize science as a basis for determining the safety of agricultural biotechnology traits.
- Despite recent commitments by the PRC to improve the administration of its biotech regulations, systemic challenges remain that undermine American agriculture by: 1) slowing the introduction of new production tools available to American farmers and farmers globally, 2) jeopardizing market access for U.S. agricultural products exported to China, and 3) reducing long-term private sector investments in agricultural production technology. Such systemic challenges not only harm farmers in the U.S. and other major cultivating countries like Argentina, Brazil, and Canada, but they also stifle the development of China's own biotechnology sector. As the world's largest importer of agricultural commodities, it is vital that China responsibly administer its biotechnology regulations, and fulfill the commitments made at the 2016 Strategic and Economic Dialogue.
- In the immediate term, the Chinese government should honor the commitments made as part of the 100-Day Action Plan and complete the risk assessments of pending biotech traits. The Chinese government should also commit to outlining steps to standardize data requirements and speed up its approval process in line with the commitments secured during President Xi's state visit in September 2015.
- Secure a commitment from the PRC government at a high level and across ministries to implement Decrees 8, 9, and 10 in a manner consistent with the 2001 State Council Regulations and the Administrative License Law. Doing so would synchronize risk assessments and approvals of agricultural biotechnology events with those of major exporting countries, and provide for clear regulatory and decision making timelines.
- In addition, consistent with regional partners, China should explore options to limit and potentially eliminate requirements for in-country field trials for biotech crops for the purposes of food and feed import approvals.
- China should establish a low-level presence (LLP) policy on biotechnology-derived products according to the Codex Alimentarius Commission guidelines to eliminate the risk of import disruptions resulting from asynchronous approvals. LLP refers to the potential low level presence in imports of GM material already authorized and being produced in other countries, but not yet approved in the importing country such as China. Asynchronous approvals will only

become more prevalent as more new GM plants are developed and enter into commerce around the world.

## **AGRICULTURE**

### **1. Foreign Direct Investment**

- Secure a commitment from China for favorable treatment for investment in livestock husbandry, which is listed in the encouraged category of the Guiding Catalogue and a priority in the 13th Five-Year Plan.
- Secure a commitment from China to reduce complex and inconsistent administrative licensing requirements for investment approvals for new food production plants.
- Urge China to follow the objectives in its 13th Five-Year Plan, which emphasize the need to shift more resources to agriculture and food production in order to improve people's lives.

### **2. Tariff Rate Quotas (TRQ)**

- Secure a commitment from China to abolish nontransparent quotas and registration systems and ensure that tariff-rate quota (TRQ) allocations for corn and other commodities are large enough to be commercially viable. To increase transparency and administrative efficiency, China should consider releasing lists of TRQ holders.
- Secure a commitment from China to increase the corn import quota and open the corn import market according to domestic market demands.

### **3. Unscientific Restrictions on Imports**

- Secure a commitment from China to remove unscientific restrictions on importation of U.S. poultry, pork and genetically modified organism (GMO) products.
- Secure a commitment from China to eliminate the “test and hold” policy on U.S. pork for ractopamine.

### **4. Standards**

- Secure a commitment from China to integrate overlapping and conflicting national and industrial standards in agriculture set and supervised by various ministries and administrations, and to prioritize the setting and amending of thousands of national food safety standards—in particular in the vegetable oil, grains and food additive areas—so that compliant enterprises are able to conform to binding regulations and mandates.
- Implement standardized customer information quality (CIQ) regulations consistently in all ports throughout China.



## 5. Agricultural Equipment

- Secure a commitment from China that any subsidies offered to customers, dealers/distributors, or manufacturers of agricultural equipment are equally available to domestic Chinese brands and to multinational brands.
- Encourage the Ministry of Agriculture to structure existing subsidy programs so that lessees, not just owners, of agricultural equipment are able to take advantage of those subsidies.
- Secure a commitment that Stage III emissions standards for off-road equipment, and specifically agricultural equipment, are fully enforced. The full implementation of Stage III emissions standards will support the Chinese government's goal of reducing air pollution.

## 6. Animal Health

- Secure a commitment from China to give foreign companies equal treatment in the registration, importation and distribution of animal vaccines, to include imports.<sup>28</sup>
- Secure a commitment from China to allow foreign developers of animal vaccines to submit an application for registration without requiring that product to be registered in another country.
- Secure a commitment from China to lift the ban on registering and marketing vaccines for diseases listed on the World Animal Health Organization's List A (e.g. foot-and-mouth disease, Newcastle disease).<sup>29</sup>
- Secure a commitment from China to apply the VAT equitably to imported animal vaccines. Current VAT on domestic vaccines is 3% vs 17% for imports.<sup>30</sup>

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<sup>28</sup> Although the pre-marketing approval requirements for imported vaccines are nominally similar to those for domestic vaccines, the registration process itself operates in a discriminatory manner. It is therefore inconsistent with China's obligation under the Agreement on Technical Barriers to Trade (TBT Agreement), Article 2.1, to accord imported products "treatment no less favorable than that accorded to like products of national origin." It is also inconsistent with Article 2.2 of the same agreement, which requires China to "ensure that technical regulations are not . . . applied with a view to or with the effect of creating unnecessary obstacles to international trade," and to ensure that technical regulations are not "more trade-restrictive than necessary to fulfill a legitimate objective" (Article 2.2). Chinese restrictions on the distribution of imported vaccines violate the same provisions of the TBT Agreement, as well as Article III.3 of the General Agreement on Tariffs and Trade (GATT), which requires that import products "be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

<sup>29</sup> The ban on the registration and marketing by foreign companies of vaccines for List A diseases is also clearly discrimination and unduly trade-restrictive, in violation of the same provisions.

<sup>30</sup> The differential VAT rate is a clear violation of GATT Article III.2, which requires that imported products "not be subject, directly or indirectly, to internal taxes or other internal charges of any kind in excess of those applied, directly or indirectly, to like domestic products."

## ALUMINUM

- The U.S. aluminum industry welcomes State Council Measure No. 42 on aluminum and other non-ferrous industry structural adjustment which espouses, among other things, a guiding ideology to resolve the structural surplus of production capacity, to promote advances in industry technology and expand the consumer market, and to strengthen international cooperation on production capacity.
- The industry also welcomes the statements made at the 2016 G20 regarding excess capacity in the electrolytic aluminum industry, and requests that the U.S. government secure further commitments from China to address this issue.
- We request the U.S. Government set a date for the first Dialogue and include the following issues on the Aluminum Dialogue agenda: information and transparency about Central and local government subsidization of inputs critical to the manufacture of aluminum, tax policies on aluminum exports, plans to stockpile primary aluminum, and plans to reduce the environmental footprint of China's aluminum sector.

## AUTOS

### 1. Investment

- Secure a commitment from China to allow foreign auto companies to invest more than 50% in complete auto manufacturing.
- Decouple automotive distribution network ownership from manufacturing JV's and allow for greater than 50% ownership.
- Secure a commitment from China to ease the conditions required for approval of new JVs, branches and expansion of both manufacturing and distribution capacity (e.g., 80% saturation clause, consolidation requirement, local brand requirement, new energy production requirement, etc.).
- Secure a commitment from China to reduce the number of items subject to "approval" ("hezhun") and/or "filing" ("beian") at the central authority level, and simplify the process.

### 2. Clean Energy Vehicles

- Postpone the NEV mandate<sup>31</sup> until 2019 and incorporate flexibility into the mandate's credit system.

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<sup>31</sup> Tentative Administrative Rules on Enterprises Average Fuel Consumption and New Energy Vehicle Credits (G/TBT/N/CHN/1187) and the latest draft published by Ministry of Industry and Information Technology, June 13th 2017.

- Secure a commitment from China to remove explicit and implicit requirements for participation in the new energy vehicle (NEV) industry that mandate technology “mastery” and creation of new, indigenous brands.
- Secure a commitment from China not to expand restrictive requirements to other participants in the NEV industry.
- Ensure that all qualifying vehicles, regardless of brand or place of manufacture, are afforded equal treatment in awarding of energy saving and other incentives.
- Remove the 50% ownership cap on manufacturing of key components of NEVs, such as high energy power batteries.
- Secure a commitment from China to allow foreign-invested entities, including automotive JVs, to compete for R&D funding, and to conduct one or more workshops on how foreign-invested entities can apply for and participate in R&D funding opportunities for China-based research.

### 3. Automotive Emissions Standards

- Secure a commitment from China to expand capability at national, provincial, and local levels to enforce environmental and emissions standards consistently.
- Secure a commitment from China to confirm, apply, and implement truck emissions standards on time and in a manner consistent with global practices.
- Secure a commitment from China to adopt, apply, and implement auto safety, emissions and fuel regulations in a manner that is consistent with global practices.

### 4. Automotive Financing

- Consistent with China’s 2012 S&ED commitment to allow foreign and domestic auto financing companies to issue bonds regularly, including issuing securitized bonds, ensure equal access to capital market funding options, such as corporate bonds and asset backed programs, for automotive finance companies through published rules and less restrictive qualifications.

### 5. Government Procurement

- Secure a commitment from China, consistent with the high-level commitments of national treatment for foreign investors by Chinese leaders in the S&ED and other fora, to limit the procurement criteria to attributes of the vehicle by removing or revising the IP ownership and R&D spending requirements.
  - Following up on China’s 2013 JCCT commitment to not publish the *Draft Party and Government Organ Official Use Vehicle Selection Catalogue*, seek confirmation from China that it will comply with this commitment at all levels of the government.

- China should agree to revise the Ministry of Information and Industry Technology's (MIIT) eligibility criteria for government procurement of vehicles to ensure that U.S. auto companies invested in China are able to participate in vehicle procurement opportunities on the same footing as their domestic counterparts.

## **BANKING AND NONBANKING FINANCIAL SERVICES**

- Secure a commitment that China will stay all regulations requiring “secure and controllable” products until these regulations are consistent with WTO agreements/rules (including but not limited to those in the TBT Agreement), are narrowly tailored, take into account international norms, are nondiscriminatory, and do not impose nationality-based conditions or restrictions, on the purchase, sale, or use of ICT products by commercial enterprises unnecessarily—per commitments made at the Presidential bilateral in September 2015.
- Building on the 2016 S&ED and past commitments of the Chinese government to increase foreign ownership levels for securities firms, futures companies and fund management firms, secure a commitment from China to permit foreign financial services firms to own 100% of the operations in which they invest and to establish themselves in a juridical form that best suits their business model (branch, subsidiary, JV).
- Continue to streamline the approval process of foreign bank subsidiaries in terms of location selection.
- Allow foreign banks to submit multiple network expansion applications simultaneously.
- Secure commitment from China to put in place a precise and transparent roadmap that would permit foreign securities firms to engage in a full range of securities activities as domestic securities firms and eliminate the need for a “seasoning” period.
- Allow foreign banks to offer a full line of products and services, such as online banking and credit and debit cards supported by payment brands and issued on networks of their choice.
- Urge China to continue the process of rapid liberalization of the current Qualified Foreign Institutional Investor (QFII) restrictions on an agreed transition schedule.
- Permit underwriting by locally incorporated banks of foreign banks of Commercial Paper (CP), short-term notes (STNs)/medium-term notes (MTNs) and improve upon the application review criteria.
- Secure commitments from China that provide for equal access to regulatory proposals; require public availability of proposed regulations; provide an adequate public comment period (of no less than 30 days) on new regulations; and mandate the enforcement of regulations in a non-discriminatory manner. Encourage strengthened coordination of different regulators as well as between central and local level regulators to reduce reporting requirements.

## **CHEMICALS**

### **1. Chloroform Import**

- Secure commitments from China to issue import/distribution licenses to large chloroform suppliers.

### **2. Soda Ash**

- Secure a commitment from China to eliminate the 9% value-added tax (VAT) rebate provided to Chinese soda ash exports, which creates an un-level playing field for soda ash exporters competing with China in third markets. At the 2014 S&ED, China committed to “improve its Value Added Tax rebate system, including actively studying international best practices, and to deepen communication with the United States on this matter, including regarding its impact on trade.” While the Chamber recognizes this commitment as an accomplishment, we would encourage China to adopt changes to its rebate system to reflect its efforts to meet international best practices.
- We further request that the U.S. Government, in the context of this year’s JCCT, add soda ash to the ongoing discussions with the Chinese government over excess capacity in its industrial sectors. China’s growing soda ash overproduction is contributing to falling soda ash prices and is causing harm to U.S. exports. The U.S. government should encourage China to discontinue industrial policies that promote soda ash excess capacity.

### **3. Coal**

- Secure a commitment from China to allow foreign companies to establish wholly foreign-owned enterprises (WFOEs) in large-scale coal and chemical product manufacturing and ethane manufacturing with annual production of 800,000 tons or more.

### **4. Chemical Waste Handling**

- Secure a commitment from China to speed up the approval of qualified waste handlers in order to reduce compliance and costs burdens of chemical manufacturers.

## **CIVIL AVIATION**

- Secure a commitment from China at senior, political levels to move toward a more flexible and open airspace and airway structure in support of economic development, reform, and opening up.
- Encourage the Chinese government to rebate the VAT assessed on freighter conversion services conducted on both domestic and foreign airliners by maintenance, repair and overhaul (MRO) companies.
- Secure a commitment from China to reduce the high VAT and import duty for regional and general aviation (GA) aircraft.

- Secure a commitment from China to streamline and expedite review procedures for foreign investment in commercial aviation and related ventures.

## ELECTRONIC PAYMENT SERVICES

- China's WTO commitments require it to open its domestic market to U.S. suppliers of electronic payment services (EPS), but China still has not implemented its commitments. Pursuant to the U.S.-China 100-Day Action Plan, China committed: "By July 16, 2017, to issue any further necessary guidelines and allow wholly U.S.-owned suppliers of EPS to begin the licensing process. This should lead to full and prompt market access."
  - **Approvals:** The People's Bank of China (PBoC) should accept license applications submitted by U.S. EPS suppliers that results in full and prompt market access. *Applications to Prepare* should be processed and completed as expeditiously as possible.
  - **National Security Reviews:** If U.S. EPS companies' BCCI license applications are required to undergo a potential National Security Review (NSR) at any stage in the process, the NSR should be transparent, time-bound, and narrowly-tailored to consider only legitimate national security factors. Similar to the U.S. CFIUS process, greenfield investments should not be subject to the NSR and/or the NSR should favorably recommend companies that have been processing cross border-transactions.
    - China should provide a detailed list of any and all Chinese government and non-governmental entities involved in the NSR process and a full description of the sequence and timeframe by which the NSR will occur.
    - China should clarify the NSR process including a time-bound schedule for final decisions on NSR-reviewed transactions, not to exceed 90 calendar days in total. Clarifications should confirm that greenfield investments are not subject to the NSR and/or that any BCCI application submitted by a U.S. company with at least 3 years of experience processing cross border transactions should receive a favorable NSR recommendation.
  - **Card Issuance:** issues formal guidance (e.g., a normative document) reiterating that Chinese banks may continue to issue dual brand-dual currency bankcards that allow U.S. EPS suppliers to process foreign currency payment card transactions and that international routing of such transactions will continue to follow commercially-agreed terms.
- **Standards:** To meet national information security level protection, foreign EPS providers are required to use products that are certified by the national encryption authority and in line with China's national and industry standards. However, the PBOC 3.0 standard differs from the universally accepted EMV chip standard which is used globally by all major EPS suppliers including China UnionPay to ensure interoperability and consumer convenience for cross-border payments. Compliance with PBOC 3.0 by foreign EPS suppliers would significantly increase operational costs at no additional benefit to Chinese consumers; as such, the PBOC 3.0 standard should be voluntary rather than required for card issuance.

- **Local Entity Requirement and Data Localization:** The new Measures require, under certain conditions, foreign EPS providers to discontinue processing of cross-border transactions using off-shore facilities, and instead process such transactions on-shore in China. Moreover, when domestically issued bank cards are used domestically, the transaction processing must be completed on-shore, through domestic bank card clearing operators' infrastructure. Given the long history of EPS suppliers providing foreign currency transactions on a cross-border basis in China, such processing should be allowed to continue and not be required to be transferred on-shore. Moreover, free cross-border data flow for EPS should be allowed, as strict in-country requirements for servers and data storage will not resolve security and privacy concerns; instead, they will result in higher costs to consumers and an inability to take advantage of the best available technology.
- Secure a commitment that the final issuance of the regulation will result in foreign EPS providers being granted full market access to domestic RMB processing in accordance with the WTO ruling on the EPS case in 2012.

## ENERGY/ENVIRONMENT

### 1. National Treatment

- Secure a commitment from China to provide equal treatment to foreign or foreign-invested companies and not favor locally owned manufacturers through government/SOE procurement preferences, de jure and de facto localization requirements, and product standards.
- Request that China provide foreign-invested companies equal treatment with regard to Strategic Emerging Industries (SEIs) related policies and incentives, such as in energy saving & environmental protection, new energy, new energy vehicle, and high end equipment manufacturing.
- Secure a commitment from China to remove requirements for applicants to have indigenous intellectual property when applying for relevant SEI incentives at local levels (in Shanghai, Jiangsu, Sichuan). Such requirements discriminate against foreign-invested companies, which do not have locally-owned intellectual property.
- Ensure full implementation of China's JCCT commitments regarding wind turbine market access and local content requirements.

### 2. Standards

- Urge China to increase engagement with and participation of foreign invested enterprises in the development of laws, regulations, standards, pilot programs and financial incentive programs relating to clean technology.
- Secure commitment from China to develop new clean energy standards that build on existing international standards so as to reduce duplications and improve effectiveness.

- Secure from China a commitment for full implementation of the JCCT<sup>1</sup> commitment to ensure that the processes for developing standards of smart grid products and technologies are open and transparent, allow foreign stakeholders to participate in the development of standards, technical regulations and conformity assessment procedures on no less favorable terms than it affords domestic stakeholders.
- Secure from a China a commitment to ensure that high-quality, practical, internationally harmonized standards are in place for all sectors of the clean technology industry, and that they are effectively implemented and enforced.
- Encourage government agencies to share best practices related to standards enforcement, including applicable penalties for violations, in order to further ensure a fair, competitive playing field.

### 3. Bidding Criteria

- Secure a commitment from China to amend government and SOE procurement practices to adopt full life cycle assessments in the evaluation of clean technology products/projects. Ensure China commits to adopting international standard bidding processes in which China's local public tender and bidding processes and terms and conditions for clean energy infrastructure projects are based on the quality, rates of return, and long-term viability of projects, rather than primarily on price alone.

### 5. Equity and Other Restrictions

- Secure commitments from China to:
  - remove restrictions that limit foreign investment to 50% or less in high-energy propulsion batteries for new energy vehicles,
  - lift equity restriction on foreign investment in liquid natural gas which would allow foreign companies greater flexibility to structure their operations and bring technology and expertise to the Chinese market more rapidly, and
  - lift restrictions on foreign firms investing in cogeneration plants, which limit operational bandwidth and hinder their ability to compete on a level playing field with Chinese domestic competitors.

### 6. Oil and Gas

- Secure from the Chinese government a commitment to initiate comprehensive oil and gas legislation, to include the designation of a specific regulator for the oil and gas sector, and to accelerate market-oriented pricing reforms of domestic natural gas and petroleum products.
- Encourage China to develop a clear regulatory framework for shale gas production sharing contracts that addresses the unique aspects of shale gas exploration, development, and production, as well as investor concerns such as the mandatory JV requirement.



## 7. Heavy Duty Commercial Emission Enforcement and Fuel Economy

- Encourage China to meet its commitment for nationwide availability of low-sulfur diesel fuel beginning Jan. 1st, 2015. It is also important that Diesel Emission Fluid (DEF or Urea) is available. Application of urea into the exhaust stream is necessary to achieve NSIV emission requirements. If the requirement for using urea is not enforced, vehicle operators will operate without it, resulting in higher emissions. It will also drive down demand for urea resulting in urea providers no longer investing in developing nationwide urea infrastructure. Enforcing the use of urea and requiring diesel stations to stock urea will ensure that it is available for all.
- Secure a commitment from China to engage bilaterally with the United States to share best practices on achieving measurable fuel economy gains from commercial vehicles.

## 8. Transportation of Dangerous Goods

- Secure the following commitment related to harmonization of dangerous goods regulations for ground transportation to ensure an uninterrupted supply chain for consumer products with equitable market access as experienced in other global venues.
  - China should reaffirm its commitment to harmonize its dangerous goods regulations with the UN Model Regulations by adopting full implementation of GB 28644.2-2012 & GB28644.1-2012 nationwide and in multiple transport modes including parcel post services. These regulations follow the UN Model regulations and allow for the transportation of low risk products known as Limited Quantity/Excepted Quantity for transportation by ground as it already does for air and vessel shipments.

## **EXPRESS DELIVERY SERVICES (EDS)**

### 1. Customs and Trade

China's WTO GATS schedule indicates that it does not have any limitations specified under courier services (CPC 75121), except for those specifically reserved to Chinese postal authorities by law at the time of accession. The Courier Services classified under CPC 75121 include "services consisting of pick-up, transport and delivery services, whether for domestic or foreign destinations, of letters, parcels and packages, rendered by courier and using one or more modes of transport, other than by the national postal administration."

- Secure a commitment from China to remove this segment from its investment restrictions negative list.

Further, China has applied overly burdensome regulatory approaches in China's domestic express delivery market. For example, the requirement for 100-percent open box inspection, x-ray inspection, and shipper identification checks for all express shipments. Additionally, express operators must be licensed at the local city level, which is a burden given the network model of our business, and number of cities for which we must be licensed.

China's current import clearance regime is supported by three channels which unnecessarily complicates trade and restricts low-value shipments, including shipments from U.S. small e-commerce businesses. These complications prevent companies from benefitting from expedited shipments, which was envisioned by the WTO Trade Facilitation Agreement.

China's import clearance procedures are complex and supported by highly calibrated import duty and tax structures. Imports can be cleared through a choice of three channels: 1) Normal Channel; 2) E-Commerce Channel (GAC 26); and 3) Postal/Personal Shipments Channel. Due to the burdensome requirements to utilize the e-commerce channel, including retailer commercial presence and registration that is limited to companies with Chinese affiliates, the Chamber recommends

- Secure a commitment to streamline and facilitate measures for shipments under the Normal Channel, based on the World Customs Organization's Immediate Release guidelines.
- Secure a commitment that clearance of goods should be based on value, rather than based on the various channels, which discriminate between e-commerce and non-e-commerce goods, which would simplify documentation and applicable taxes, enhance clearance times, and facilitate returns.

China Customs adopted a series of measures, including efforts to reduce or cancel electronic declaration data transmission and inspection fees at different ports. While China Customs has made great strides in eliminating or reducing fees in some ports, additional trade costs can be eliminated by other border agencies at each port.

- Call on China to eliminate user fees charged by all agencies at each port.
- Secure a commitment from China to establish a U.S.-China government-industry customs dialogue to address customs bottlenecks in the supply chain, which, among other things, hamper the growth of U.S. exports to China. Customs and industry share a common goal of safe, efficient clearance, and an open dialogue could help both parties move toward that goal. Many issues could be addressed through the dialogue, but top priorities for U.S. industry would be the issues noted below.
- Secure and commitment to work with the General Administration of Customs (GAC) to build on recent progress that has been made to simplify bonded transfer procedures so that goods to and from locations that are not international gateways can flow smoothly through China's gateway airports into international trade networks. This will help China achieve its goals of developing second-tier cities and expanding foreign trade and help EDS providers with hubs in China operate those hubs more efficiently. Current customs procedures create perverse incentives to operate hubs outside of China, which damage the interests of firms and local governments who have invested in hubs in China.
- Secure a commitment from China to establish low value and *de minimis* customs clearance levels, consistent with U.S. levels and with China's position as one of the world's largest participants in global trade.

- Secure a commitment to remove the GAC's four-hour prior to loading advanced commercial information requirement for export goods and standardize China's export requirements with international norms and industry practices.
- Encourage China to establish a 24-7 customs handling system similar to that in other advanced trading economies. Customs and other border crossing agencies, such as AQSIQ, should commit to building and maintaining IT systems that are available for trade 24-7 with a high degree of reliability. When systems go down, agencies should be encouraged to communicate clearly with traders the reason for the outage, to provide back-up solutions, and to make allowances for delays due to system failures.
- Secure a commitment from China that any change in tariff codes will follow the World Customs Organization rules and standards and to release draft annual Harmonized System changes at least three months before the legal effective date to allow sufficient time for companies to implement.
- Secure a commitment from China to eliminate ancillary charges levied by local customs or port/airport operators or concessionaires for services such as connection to the customs network, customs forms and access to customs facilities. Whenever possible, such as when filing declarations through the on-line customs system, firms should be able to choose to provide such services for themselves or from a number of qualified vendors. Where sole-source charges are necessary, they should be levied strictly on a cost-recovery basis.
- Secure a commitment that China will clearly define the parameters for export and import controls criteria so that the application of compliance requirements is consistent.
- Increase transparency and consistency of customs enforcement across all ports.

## 2. Logistics

- Secure a commitment that that any licensing or permitting regulated at the national level remains at the national level such that market players do not face more onerous province-by-province or even city-by-city licensing or permitting requirements. For example, Articles 52 and 53 of the SPB's Postal Law of the People's Republic of China (PRC) are inconsistent with the "Business Scope of Express Business Operation Permits." The Chamber recommends that the SPB clarify the difference and support the broadest possible business scope, aligned with the national network business model of EDS providers and the interests of consumers.
- Secure a commitment that China will provide greater transparency, including the ability for public comment, in the drafting of the Express Ordinance currently under review by the State Council Legislative Affairs Office. This draft is based on iterative drafts from the State Post Bureau (SPB) and the Ministry of Transportation, and will be of great significance to the EDS industry. Industry looks forward to the opportunity to submit comments and recommendations to ensure a framework that drives healthy growth and competition in the interest of consumers.
- Secure a commitment from SPB that all proposed regulations must be published for comment, that interested parties must be provided with at least forty-five (45) days within which to provide

comments, and that SPB must respond in detail regarding whether the recommendations are being adopted and, if not, the reasons they are being rejected.

- Secure a commitment that China's 2011 Express Service National Standards and subsequent express standards that are recommended industrial standards according to China's Standards Law will not be cited in any postal regulation with compulsory enforcement.
- Secure a commitment to enable EDS providers to contract with Chinese domestic delivery permit holders to provide local pick-up and delivery, trucking and other services related to express delivery.
- Secure a commitment from China to remove restrictions in China's Postal Law that prevent foreign EDS providers from providing their Chinese customers with domestic document delivery services.
- Secure a commitment from China to simplify SPB's current permitting processes and re-evaluate its security measures, in line with China's central government's call for comprehensive governance reforms and to conform such measures to a balanced, risk-based, strategic approach relative to the need for fast and efficient trade.
- Secure a commitment that security measures and requests for information and access to company IT and other systems be, not only balanced, risk-based and strategic, but also implemented uniformly. Provincial and local agencies are increasingly requiring companies to provide information and access that is inconsistent, overly burdensome and that raises business confidentiality concerns.
- Secure a further commitment that any requests for new data reporting will be posted for public comment in advance of implementation and that firms will be given sufficient time (at least six months) to prepare for implementation. SPB currently collects substantial data from firms on shipments, facilities, vehicles and staff. Secure a commitment that other agencies, including local agencies, seeking the same data will obtain that data through the existing SPB reporting systems.
- Ensure coordinated and consistent security measures between the SPB and Ministry of Public Security at all levels, national, provincial and local.

### 3. Aviation

- Urge China to live up to its commitments under the U.S.-China air transport agreement, and remove CAAC restrictions on change-of-gauge operations and co-terminalized flights between Beijing, Guangzhou, Shenzhen and Shanghai.
- Urge China to provide transparency and improved certainty for slot coordinators and carriers by committing to reform its slot allocation procedures to meet the International Air Transport Association (IATA) Worldwide Scheduling Guidelines, and to ensure fair and equal rights for airlines to compete in the international air services market.

- Encourage China to increase airport and airspace capacity by: opening significantly more of China's airspace to civilian air operations; improving coordination between civilian and military airspace authorities; appropriately prioritizing resources to expand airports and other infrastructure in China's highest demand markets rather than directing resources first to lower demand markets; and improve air traffic control capacity, capabilities and flexibility to meet ever increasing demand in China's airspace.

## **INSURANCE, PENSIONS, AND ASSET MANAGEMENT**

### **1. Equity Restrictions on Foreign Investment**

- Secure a commitment from China to relax the 50% equity restrictions on foreign investment and allow foreign insurers to own up to 100% of a life insurer in China, and allow foreign insurers their choice of juridical form: branch, wholly-owned subsidiary or JV. The 50% equity cap, imposed by China to protect its nascent insurance industry from foreign competition since China's WTO accession, is unnecessary in present-day China. It hinders insurance penetration and deprives consumers of best in class financial products and services. Lifting the cap will help China achieve its objectives to deepen financial reforms and promote financial inclusion.

### **2. Online Insurance Distribution**

- The Chamber recommends further opening the Internet channel by allowing more types of products to be sold online nationwide, to include critical illness products, based on the draft regulation on Internet insurance issued by China Insurance Regulatory Commission (CIRC) in December 2014. These regulations allowed certain products to be sold online without geographic restrictions under certain conditions. Lifting the branching restriction will tap the enormous potential of online insurance sales, provide more options for consumers and contribute to China's ambitious goals of reforming the financial sector and enhancing financial inclusion.

### **3. Foreign Currency Denominated Products**

- The Chamber recommends CIRC and Central SAFE approve the sales of long-term foreign currency denominated life insurance products (FCDP). FCDP are already available in other markets in Asia (e.g. Japan). Access to FCPD would provide Chinese consumers with improved diversification to manage risk, particularly in the face of volatile equity markets, and offer Chinese consumers with foreign currency savings in China an alternative to low-interest bank deposits. FCDP would help to support China's drive towards more innovation in the financial services sector.

### **4. Secure and Controllable**

- Secure a commitment that China will stay all regulations—including the China Insurance Regulatory Commission (CIRC) *Insurance System Informatization Regulatory Requirements* (draft)—requiring “secure and controllable” products until these regulations are consistent with WTO agreements/rules (including but not limited to those in the TBT Agreement), are narrowly tailored, take into account international norms, are nondiscriminatory, and do not impose nationality-based conditions or restrictions, on the purchase, sale, or use of ICT products by

commercial enterprises unnecessarily—per commitments made at the presidential bilateral in September 2015.

## 5. Branches, Subsidiaries

- Secure national treatment for foreign insurers in branch licensing and request CIRC to issue an administrative notice to clarify and implement in practice that all insurers, both foreign-invested and domestically-owned, are authorized to submit multiple concurrent applications for branch approval, which, if approved, will be granted concurrently within a reasonable timeframe. Although current branch application procedures have formally leveled the playing field between foreign-invested insurers with respect to branch as well as sub-branch approvals, foreign insurers still suffer stricter and lengthier approval procedures in comparison to domestic entities and the *de facto* refusal to concurrent branch applications.
- The abilities to expand geographically and diversify risk portfolios are basic, fundamentally important insurance principles which allow insurance companies to avoid concentration of risk and unbalanced, over-exposed books of business.
- In support of China's commitment to address the moratorium on new licenses for regional sales offices, amend the regulations for the three structures that perform functions comparable to regional sales offices, i.e., sub-branches, central sub-branches and departments, to allow foreign-invested insurers to apply directly to the local CIRC office under the same procedures as domestically-owned insurers and not through the International Department of central CIRC.
- Request CIRC to adopt global best practices in terms of branch requirements, regulatory maintenance and compliance costs in order to reduce the burdensome costs for foreign insurers to operate in China. The cost of operating in China is very high compared to most other markets. Administrative burdens and compliance are particularly onerous, including CIRC's I/T requirements and rules regarding claims, finance and compliance personnel for new branches.

## 6. Liability Insurance

- Request CIRC to help advance an understanding of the Tort Liability Law and its relevance to the insurance sector, in line with the State Council's explicit goal to build a liability culture and improve food and product safety. To shift financial burdens away from the state, it is essential that Chinese companies purchase liability insurance to protect their balance sheets. In particular, product liability insurance should be required for companies bidding on government contracts.

## 7. Enterprise Annuities (EA)

- Establish a transparent and public procedure for formulating CIRC recommendations to Ministry of Human Resources and Social Security (MOHRSS) as part of the ongoing licensing process for EA providers where the licensing authority is held by MOHRSS in consultation with CIRC, the China Banking Regulatory Commission (CBRC) and the China Securities Regulatory Commission (CSRC).

- End the informal moratorium on EA licensing (last batch of licenses were awarded in November 2007) and publish the necessary process for companies to apply for EA authorization on an ongoing basis.
- Allow 100% foreign equity ownership in EA-related companies.

#### 8. Insurance Brokerage

- Allow international and regional brokers to service Chinese small and medium enterprises (SMEs). If approved, this development would lead to a better understanding of loss control and risk-management techniques among companies currently not being served by foreign brokers.
- Liberalize the rules for setting up brokerages and allow captive agents to convert to brokers which would broaden market access for insurers.

#### 9. Investment of Assets

- Recognize the global experience, capital, and organizational resources for all seasoning or staffing requirements for Insurance Asset Management Companies (IAMC) and/or other investment requirements, focusing on the desired risk management standards, rather than the number of bodies necessary to guide each type of investment class.
- Allow foreign invested insurers the option to work with mutual fund companies (several of which have foreign partners) to leverage their extensive experience and global best practice on fund management.

#### 10. Remuneration

- Allow foreign-invested insurers to use the "Rules and Guidelines for the Management of Remuneration of Insurance Companies" issued by CIRC in July 2012 for consideration and reference only. The rigid remuneration standards set by the Guidelines are likely to lead to obstacles in the competition for talent and also unfairly handicaps foreign-invested insurers whose management remuneration structure is inherently different because foreign insurers operate globally and generally from their home offices.

### **MEDIA/ENTERTAINMENT/ACADEMIC JOURNALS**

#### 1. Filmed Entertainment

- Complete the U.S.-China Film Agreement “MOU” review, consistent with shared commitments that an updated MOU will enhance opportunities and access for foreign revenue sharing films, including by increasing the revenue share in line with international norms, increasing the number of revenue sharing movies allowed into China, promoting and approving additional companies to engage in distribution, eliminating black-out periods for foreign films, allowing film producers to determine release dates, and formally allow film producers to engage in marketing.

- Allow foreign enterprises to hold a majority share in entities engaged in the production, distribution, and publication of audiovisual products and games in all formats, including new media.
- Enforce a ban on the sale of audiovisual media by street vendors.
- Increase steps to curtail online piracy, including unauthorized streaming of U.S. television programming and other audio-visual content from sites in China.
- Ensure that the censorship process for audiovisual works is transparent and is conducted in a timely fashion, and work to establish a transparent and consistent film ratings system. Specifically, eliminate the two-window and entire series requirements for approval of OTT content and replace it with a rolling approval process, subject to the same levels of transparency and timeliness as domestic content.
- Broaden the carriage of foreign TV content beyond hotels and foreign compounds, and eliminate foreign content restrictions on Chinese TV channels, including the limit on foreign-produced animation during primetime.

## 2. Sound Recordings

- Secure a commitment from China to allow the U.S. sound recording industry to invest and operate in China in all facets of the music business, in the same manner as Chinese record companies. This would include the right/ability to sign artists, record, produce, market, and distribute recorded music in physical form as well as over Internet and mobile platforms.
- Secure a commitment from China to allow U.S. record companies to acquire or establish foreign-invested enterprises (which can be wholly foreign-owned, majority foreign-owned or controlled, or minority foreign-owned or controlled, at the election of the U.S. company) for the purpose of engaging in the above full range of activities.
- Secure a commitment from China, consistent with the recent WTO decision on trading rights, to ensure that any entity may freely import sound recordings into China, invest in and operate companies involved in the digital distribution of music, and enjoy the same rights and privileges as their Chinese counterparts.
- Secure a commitment from China to terminate the discriminatory censorship regime that it maintains with respect to foreign music for physical release. Chinese censorship restrictions delay or prevent U.S. copyright owners from providing legitimate products to the market in a timely fashion. For example, PRC government censors are required to review any sound recording containing foreign repertoire before its physical release, while domestically produced Chinese repertoire is only recorded, not censored (and, of course, pirated product is wholly uncensored and is the dominant form of music accessed by Chinese society).
- Regarding online distribution of foreign-produced sound recordings, it is noted that a trial period for 1 year for the licensed platforms to self-censor the sound recordings was started in



late 2013. This self-censorship scheme should be maintained after the trial period. Up to now, the aforesaid pilot project is still on-going and no progress or problem is reported.

- Secure a commitment from China to abolish the requirement for foreign music producers to have exclusive licensee for the purpose of content self-censorship for online distribution of foreign-produced music. There is no written confirmation from Ministry of Culture (MOC) regarding the abolishment of the requirement for exclusive licensee.
- Push for the early adoption of the Copyright Amendment Bill which includes the introduction of rights for producers to collect royalty for the use of sound recordings in public performance and broadcast programs.
- Secure a commitment from China to extend the term of protection for sound recordings to at least 70 years as soon as possible.
- Encourage the Chinese government to introduce additional regulation, supervision and control over the collecting societies so that right owners can be adequately and properly compensated for the uses of their works.

### 3. Cable Television

- Secure commitment from China to revise the catalogue for foreign investment to allow foreign enterprises to set up companies to produce and distribute TV programs, own TV channels and provide telecom valued-added services over China's cable TV networks.
- Eliminate the ban on foreign animation during primetime television.

### 4. Academic Journals

- Fully implement the 2009 *Notice on Strengthening Library Protection of Copyright* commitments by the National Copyright Administration (NCAC), MOC, Ministry of Education (MOE) and National "Anti-pornography" Office to strengthen copyright protection in libraries in all provinces, autonomous regions and municipalities through:
  - adoption of model inspection guidelines;
  - regular inspections;
  - development and adoption of individual library copyright protection plans;
  - regular progress reports from provincial authorities about enforcement of the library directive; and
  - a library roundtable on copyright in the educational and research setting.
- Ensure timely conclusion of long-delayed administrative case involving KJMed, an unauthorized provider of online journals. Ensure that the outcome provides effective deterrence against similar services that have emerged while this case has stalled.
- Investigate and pursue swift enforcement against new unauthorized online journal access providers, including copycat sites to KJMed and document sharing sites.

- Reconvene interagency meetings with the NCAC, MOE, MOC, and libraries, as a follow up on the 2009 library directive that resulted in a voluntary inspection campaign targeting online journal piracy. Create an enforcement hotline, where libraries/publishers can report infringing sites directly.
- Address the increased unauthorized dissemination of copyrighted material through personal cloud storage services (e.g. Baidu Cloud, Aliyun, Weiyun).

## **MEDICAL TECHNOLOGY/HEALTH CARE**

### **1. Market-Based Health Care Reform**

- The Chamber welcomes the 2017 update to the National Drug Reimbursement List (NDRL)—the first update since 2009—which will improve the access and affordability of innovative medicines for patients in China. In many developed markets, new medicines are reimbursed shortly after receiving regulatory approval. However, reimbursement of innovative medicines added to the 2017 NDRL was delayed on average by nearly six years.
- We encourage the Chinese government to shift towards a more timely, transparent and predictable reimbursement system, in which manufacturers may apply for reimbursement at any time, drug clinical assessment is completed within a pre-defined period following the application (e.g., within 90 days), and negotiations between manufacturers and the responsible government agency take place periodically (e.g., semi-annually). The drug clinical assessment should be transparent, evidence-based, focused on clinical benefits and independent from economic considerations. Following the clinical assessment, a fair negotiation based on clear conditions and open communication should be conducted between the national reimbursement authority and the manufacturer. These reimbursement system reforms would provide U.S. companies increased market access and significantly improve patient access to innovative medicines.
- Lower the tax rate for private hospitals. Healthcare remains excluded from the list of “encouraged” industries in the Guiding Catalogue on Foreign Investment and therefore does not enjoy a reduced corporate rate of 15% as many other encouraged industries do. Private healthcare enterprises continue to pay the standard maximum rate of 25%. Moreover, due to the inability of foreign-invested healthcare providers to consolidate accounts of their facilities (including those in the same city), this could lead to an exponentially higher effective tax rate for the company as a whole.
- Secure a commitment by China to further encourage private investment in healthcare by fully implementing the initiatives in Document 58 at all government levels and add healthcare services to the encouraged category of the Catalogue Guiding Foreign Investment.
- Remove the caps on foreign ownership of private healthcare enterprises, which were moved into the restricted category in the revised 2015 Guiding Catalogue on Foreign Investment.
- As the PRC government continues to implement its healthcare reform plan, secure a pledge from the government to continue market economic reform in the healthcare sector and avoid

limiting patient choice through interference in the market, such as restrictions on healthcare services, preferential market access treatment for domestic products, inappropriately low reimbursement rates, or the introduction of price caps and markup limitations.

- Streamline and harmonize competitive, market-oriented bidding practices for medical devices and pharmaceuticals at the provincial level.
- Set up tiered product quality categories in the pharmaceutical tendering process that are based on scientific criteria and internationally accepted standards, including a category for originators/reference drugs with the highest price premium.

## 2. Medical Devices

China is the fourth largest medical device market after the U.S., Europe and Japan and continues to grow. For some U.S. manufacturers, China is their second largest market. The Chinese government is increasing healthcare spending as its people age and chronic diseases are on the rise. However, the government has been implementing payment and regulatory policies that impede the ability of U.S. firms to supply innovative medical technology and the situation continues to deteriorate.

An overarching concern is “Made in China 2025” which calls for 80 percent of core medical device components to be manufactured in China and 70 percent of county hospital high-end medical equipment to come from domestic producers by 2025. This initiative also envisages the Chinese industry making substantial inroads in international markets for high-end medical devices—in essence, moving up the value chain.

U.S. industry views features of China's regulatory system—especially clinical trial requirements and country of origin rules—to impose a greater burden on foreign suppliers and to be more burdensome than necessary to achieve China's own industrial and healthcare policy objectives.

In addition, the Chinese government continues to impose price cuts in public tenders that disadvantage high-value U.S. products. Some provinces have limited or even prevented foreign firms from bidding. In some cases, provinces are driving prices to such low levels that U.S. medical device companies (which devote up to 18% of revenue to R&D) cannot compete, as the value and quality of their products are not rewarded. As a result, some U.S. firms have begun withdrawing products, and the effects of limiting winners will likely cause more lost opportunities.

U.S. manufactures are likely to be more adversely effected by these policies than domestic firms, and are likely to have to withdraw their higher value products—or even be banned from the market by the government as noted above. The U.S. trade deficit with China in medical devices is likely to grow significantly as U.S. products are denied market access as a result of these policies.

- In September 2017, China's health ministry—the National Health and Family Planning Commission (NHFPC)—issued a notice to industry regarding national price negotiations for a series of medical devices, including drug coronary stent systems, artificial hip prostheses, implantable cardioverter defibrillators, and cardiac resynchronization therapy. The notice gave industry 11 days to provide to Chinese authorities clinical, production, and pricing information that is not readily available, proprietary, or not germane to policy. Failure to provide such

information in the dedicated timeframe was to result in device companies being shut out of Chinese public and military hospitals, which make up a majority of patients and medical device spending across the country's entire health system.

- While the deadline was extended to submit this information, the NHFPC system should be substantially modified if it is to avoid unintended consequences of substantially delaying or denying patient access, devastating the market for the selected products (and more if the program is extended). The requirements are confusing, contradictory and do not recognize the many specific types of medical devices sold in even the initial four categories.
- The NHFPC documents provide no indication of how products will be evaluated, whether volume will be a consideration, or how services will be taken into account.
- The NHFPC program appears to be based on the pharmaceutical model, without appreciating the many clinical and economic differences between pharmaceuticals and devices – e.g., medical devices have an 18-24 month innovation cycle and require installation, training, repair and service.
- Regarding CFDA registration fees, foreign firms must pay significantly higher fees than domestic firms. While discriminatory, industry accepted the increase as long as the additional resources were used to pursue important improvements. The U.S. Food and Drug Administration (FDA) and U.S. industry engaged in a collaborative process on user fees that have led to significant improvements at the Agency. CFDA should commit to a similar dialogue with industry to wisely invest these resources in areas that will streamline the regulatory approval process.
- In order to improve medical device tendering, secure commitments adhering to these general principles:
  - recognize the unique differences between pharmaceuticals and medical devices, utilize a more integrated evaluation of product quality, price, service, and innovation;
  - do not artificially limit the number of products, brands, companies, or distributors participating in tenders;
  - increase industry engagement in the development of transparent and procedurally-fair tendering policies; and
  - conduct tenders in accordance with transparent and standardized procedures, guided by clear rules and criteria developed in consultation with industry, and carried out in a consistent, unified approach that protects the confidentiality of data submitted by bidders.
- In order to improve patient access to medical devices in China, secure a commitment by China to fairness and transparency in the implementation of quota and related licensing requirements, including establishing and making public the timeframes within which quota and related licensing decisions are to be made.
- Encourage the CFDA to continue its constructive engagement with the medical device industry and other stakeholders as it pertains to the ongoing implementation of medical device regulations Order 850 (previously 650).

- Help address the regulatory approval backlog by improving CFDA performance reports to better identify challenges and opportunities that will expedite the review process, these include:
  - taking a systemic approach to performance reports by providing a complete picture of the registration process from time of accepting an application to time of receiving license;
  - including data points on the total time an application is in review and the number of days actually spent reviewing the application as well as broken down by review phase, e.g. administrative review, technical review and CMDE management review, and CFDA final approval review; and
  - including data points on when and how often the review of an application is stopped, the amount of stoppage time used by CFDA and by applicants, as well as the types of questions asked of applicants in these cases.

While CFDA has made laudable efforts to reduce the time to market for medical devices, they are also implementing burdensome regulations that pose serious challenges to U.S. firms – such as country of origin requirements and redundant and/or scientifically unnecessary clinical trials. Similarly, investment regulations are vague, including the definition of “Chinese” investment. Thus, even if U.S. firms invest in China and try to become “local,” Chinese agencies do not appear to consider them to be “Chinese” enough to receive favorable treatment.

Most of China’s regulatory policies are not explicitly created to discriminate against U.S. firms but have the effect of substantially impairing market access. The two biggest obstacles are obtaining country-of-origin (CoO) approval and conducting unnecessary clinical trials. The CoO forces U.S.-based companies to obtain U.S. FDA approval first, even if the company does not intend to sell the product in the U.S. The local clinical trial regulation requires U.S. companies to duplicate trials that have already been conducted elsewhere in China or conduct first ever clinical trials in China for medical devices that other regulatory authorities including U.S. FDA do not require.

As a result, market delay can be several years and cost millions of dollars per device. The innovation cycle for medical devices is typically under two-years, thus firms may no longer market or even manufacture the product by the time they receive Chinese approval. The long timelines and capital required to successfully navigate this process makes it nearly impossible for SMEs to enter the market, and larger firms do not even bother to try, i.e. unnecessarily burdensome regulations are hampering Chinese patient access to life-sustaining and life-saving medical technologies that are readily available to patients in other countries.

### 3. Clinical Trial Approval Processes and Local Participant Requirements

- China remains an outlier in the drug and medical device review and approval process, with new products typically taking four to six years longer to reach the China market than other major markets. Accelerating this timeline will improve the efficiency of global drug development and reduce the time it takes for innovative new products to reach Chinese patients.
- While there have been steps taken by CFDA to reduce the drug application backlog and streamline the review and approval system, the implementation of these commitments and

CFDA's ongoing reforms to the regulatory approval process are not fully transparent and consistent with international standards. Therefore, we recommend that the United States:

- Encourage China to provide equal treatment to all innovative products seeking registration and to ensure that the new product classification categories are not applied in a manner that discriminates against foreign manufacturers and are based on scientific principles.
- Encourage China to remove restrictions that require foreign medical device manufacturers to first obtain foreign marketing approval, e.g. U.S. FDA 510(k) or PMA; accept foreign clinical data; and remove requirements to conduct clinical trials in China.
- Encourage China to remove the requirement that foreign applicants submit a certificate of pharmaceutical product (CPP) showing foreign approval together with their registration application for an imported drug. Similarly, the CPP should not be a requirement to initiate the clinical trial application review process for imported vaccines. A similar requirement for medical devices, Certificate of Foreign Government (CFG), should be reformed as well.
- Ensure fair treatment for foreign and import medical devices. On average, reviews of imported devices are taking at least two months longer than domestic ones. That does not include Country of Origin requirements, which expands that gap another year or more. Also, provincial tendering is driving down prices so that high quality and innovative medical technology, which tends to come from American companies, is finding it increasingly difficult to compete.
- Encourage Chinese government departments to refrain from issuing further national policy documents with blanket preference for public hospitals to equip and utilize “domestic products,” or allowing hospitals to set specific requirements for the application rate of “domestic products” (which are often defined as “local brands”).
  - Starting in the spring of 2015, the Chinese government has issued policies to promote the purchase and use of “domestic” medical devices in hospitals and healthcare institutions. The stated intent is to develop domestic industry and lower healthcare costs. For example, the State Council Office Guiding Opinion on Promoting the Healthy Development of the Medical and Pharmaceutical Industry, released March 6, 2016, states, “Strictly implement the ‘Law on Government Procurement’ regulation, where domestically produced pharmaceuticals and medical devices can meet the required need, government procurement projects in principle should procure domestically produced products; gradually increase the level of domestically produced equipment in public healthcare institutions.”
  - By directing public hospitals to preferentially equip and utilize domestic medical equipment and apparatus, the NHFPC is adding extraneous considerations to a decision, which should be based on value and open market competition, the needs of healthcare providers and the best clinical outcomes for patients, whether the company is foreign or domestic.
- Direct local governments, including Bureaus of Health and Family Planning, to avoid any preferential treatment based on country of origin or country of brand in procurement practices.
  - On May 21, 2015, the National Health and Family Planning Commission issued the first batch of the “Outstanding Domestic Equipment Catalogue,” covering digital X-ray, color ultrasound, and fully automatic biochemical analyzer machines. Of the 218 products submitted for consideration by 57 companies, 95 products from 27 companies were selected.

Despite many applications for products made in China by the local factories of multinational companies, all of the products selected were from Chinese-owned brands. On Feb 21, 2016 the NHFPC issued the second batch of product selection, including MRI, CT, automatic blood cell analyzer, respirators, anesthesia machines, blood dialysis machines, and automatic medicine dispensing machines. Of the 209 applications submitted, 153 products were approved, once again with no domestically produced equipment made by a foreign-invested enterprise approved. The NHFPC has communicated to industry that the Catalogue is for domestic brands only, is designed to assist these companies in promoting their products to hospitals, and is not meant to have any direct link to procurement practices.

- The Catalogue of Outstanding Domestic Equipment should be eliminated outright as it is overtly discriminatory and violates the principle of equal treatment for all companies registered in China regardless of ownership. This catalogue serves to hinder China's own healthcare objectives by reducing patient access to devices that sustain and save lives.
- Encourage China to implement its draft policies (May 2017 Circulars) to shorten the clinical trial approval (CTA) review process timeline to 60-day reviews to foster simultaneous participation in global clinical trials, speed up drug and device development, and reduce the time it takes for innovative new products to reach the patient. Additionally, to further shorten the CTA review process for biologic CTAs, we recommend removal of the requirement to conduct analytical testing of the biologic test article, which is unique to China.
- Support China's work toward a well-resourced, well-funded regulatory agency that invests user fees in the latest technology, adequate staffing levels, scientific expertise, and adoption of international best practices—all of which have a direct impact on encouraging innovation, protecting public safety, and promoting good public health.
- Secure a commitment from China to harmonize process and regulatory requirements to international best practice in order to help build capabilities, enable participation in the global marketplace, and attract foreign and domestic investment in innovation.
- The China Pharmacopeia represents another key area for harmonization. There are several examples of China excipients with much stricter limits within China's Pharmacopeia than in the U.S. and European Pharmacopeias. As a result, these excipients can only be supplied by Chinese companies, which cause unnecessary disruptions in global product supply and patient access.
- In order to register a product in China, clinical trials for most products must be conducted in China. Requirements for the minimum number of Chinese patients recruited into clinical trials are predetermined, based on an opaque decision-making process, and do not take into account the rarity of disease or other science-based determinations. China should implement clinical trial data requirements that are science-based, and follow ICH guideline principles and practices so that China may be included in simultaneous global development programs.

#### 4. Conformity Assessment, Certification and Licensing Requirements

- Secure a commitment from China to ensure national treatment and to harmonize China's medical device pre- and post-market conformity assessment, registration and re-registration, and adverse event reporting/recall provisions with international practice as embodied by ISO 13485 and Global Harmonization Task Force guidance.
- Secure a commitment from China that continues the development and implementation of a Chinese Unique Device Identifier (UDI) system that is consistent with relevant international standards, including guidelines of the International Medical Device Regulators' Forum (IMDRF) and U.S. FDA. As part of this undertaking, China should commit to regular and open consultation with industry and U.S. FDA as it implements its UDI system.
- Secure a commitment from China to harmonize its regulatory framework with international regulatory standards and practices. China should commit to accept the Clinical Trial Approval (CTA) amendments after initial submission, to recognize and accept clinical trial data from patients in other countries (for biopharmaceuticals and medical devices), and to allow submission of the Certificate of Pharmaceutical Product (CPP) in parallel to the New Drug Application (NDA) process, or just prior to approval.
- Remove the prior country of original approval requirement for all drug and medical device products.
- Streamline and clarify China's labeling and Instructions for Use (IFU) requirements as outlined in the 3rd Edition of Decree 276.

### RETAIL AND DIRECT SALES

#### 1. Retail and E-Commerce

- Secure from China a commitment to revise the *Measures on the Administration of Foreign Investment in Commercial Sectors* and other related regulations in line with China's WTO commitments and common international practices.
- Secure a revision to the Tentative Regulations of SAIC on the Proportion of the Registered Capital to the Total Amount of Investment of Sino-Foreign Equity Joint Ventures to make minimum capital requirements consistent with the Company Law, and to ensure foreign and domestic retailers are treated equally in regard to the minimum registered capital requirements.
- Secure a commitment from China to eliminate restrictions on retail networks of foreign majority-owned companies with more than 30 stores that prohibit selling particular goods, including DVDs, CDs, books, petroleum, tobacco, and pharmaceuticals, or at a minimum, ensure that regulations on the distribution restrictions are applied equally to Chinese and foreign retailers.
- Issue guiding policies to provincial and municipal governments to standardize requirements of WFOE for foreign retailers.



- Secure a commitment from SAIC to publish clear guidance to all local AICs that channel fees should not be regarded as commercial bribery under Chinese law, thus ensuring national law will be implemented consistently nationwide.
- Secure a commitment from China to revise the Foreign Investment Catalogue to move e-commerce from the “restricted” to “encouraged” category and allow foreign telecommunications e-commerce companies to set up and operate open online marketplaces, including providing basic and value-added telecommunications services.

## 2. Direct Sales

- Secure commitments from China to review and revise the Direct Sales Regulations, the Regulations to Prohibit Multi-level Marketing, and their associated administrative directives, to bring them in line with China’s WTO commitments, standard international practices, and business reality in the China market.
- Secure a commitment from China to enhance market access and increase transparency by simplifying and increasing the speed of the license approval process according to the 90 day process in the direct selling regulations, and duly informing companies regarding their approval progress.
- Secure a commitment from China to simplify the approval process by requiring only provincial-level approval of service center establishment plans; eliminate multilevel government approvals and sales initiation approvals.
- Urge China to revise the requirement for having a service center in each district to one per city, and ensure that local requirements are consistent with national regulations.

## SOFTWARE

### 1. Software Legalization

- Press the Chinese government to fully implement its JCCT and S&ED commitments on government and SOE software legalization in a comprehensive and transparent manner. It is essential that software legalization encompass all types of software, not just select categories. China should commit not to influence, either formally or informally, the software purchasing decisions of SOEs in any way and to eliminate all explicit or *de facto* mandates or preferences for the procurement of domestic software brands by government agencies or SOEs, including measures such as price controls or preferences for certain types of licenses or licensing terms. In order to hold government and SOE officials accountable for these efforts, the Chinese government should develop performance indicators for government and SOE officials linked to measurable progress on software legalization.
  - For SOE legalization, China should develop a legalization program that encompasses all SOEs under the authority of CBRC or directly supervised by the State-owned Assets Supervision and Administration Commission (SASAC), including central, provincial and municipal-level SOEs, and requires SOEs to utilize software asset management (SAM) best

practices and third-party audits and certify annually that all their software is fully licensed. China should ensure that all government agencies tasked with overseeing SOE legalization are adequately resourced in terms of funding, manpower and appropriate audit tools, and ensure that SOE software procurement budgets are transparent and sufficient to meet software legalization needs.

- For government legalization, China should implement ongoing legalization programs for government agencies at all levels - central, provincial, municipal and county – and at all institutions that are funded by and report to these agencies. This includes providing sufficient and transparent budgets for software purchases and implementing SAM best practices.

## 2. Copyright, Criminal and Patent Law Reform

- Secure a commitment from the Chinese government to continue to consult closely with industry stakeholders and move the process forward to amend the Copyright Law, Criminal Code and related laws and judicial interpretations to include needed changes to facilitate civil and criminal enforcement against the unlicensed use of software by enterprises. This includes clearly establishing in the Copyright Law that unlicensed software use is an infringement of the right of reproduction (whether the unauthorized copy is a permanent or temporary reproduction), clarifying that enterprise use of unlicensed software and Hard-Disk Loading (HDL) may be subject to criminal penalties, strengthening rules related to evidence preservation orders, increasing statutory damages for copyright infringement, and providing for criminal liability for circumvention of technological protection measures (TPMs) as well as production and distribution of tools and methods to circumvent TPMs.
- In regards to Patent Law, press the Chinese government to remove the State Intellectual Property Office's (SIPO) proposed “ex officio” patent enforcement powers against ill-defined “market-disruptive” activities and permit broad patentability of graphical user interfaces (GUI) and computer programs that have a technical character.
- As mentioned in the IP section above, press SIPO to remain open to further comment and engagement on the draft *Service Invention Regulations* (SIR), in particular to ensure that employer-employee contracts or agreements supersede the provisions of the SIR regarding employee compensation.

## 3. Trade Secrets

- Press Chinese government to implement its Action Program on trade secrets protection and enforcement with effective enforcement actions and public awareness initiatives, and undertake necessary legal reforms.

## 4. Market Access

- **Software Procurement:** Revise new Ministry of Finance rules on software procurement to eliminate price controls and preferred licensing terms that have the effect of discriminating against or excluding foreign brands and broaden the definition of “standard configurations” of desktop software to include all types of software used by government agencies. Moreover, these rules should not be used to direct or influence procurement by SOEs.

- **Telecom Services Catalogue:** Eliminate from coverage under the Catalogue IT services offered by software companies that should not be considered telecom services, e.g., cloud computing, content delivery, information security services and call centers.
- **ICP, ISP and IDC Licenses:** Address restrictions that prevent foreign companies from obtaining internet content provider (ICP), internet service provider (ISP) and internet data center (IDC) licenses, which they need in order to offer cloud computing and other internet-based services.
- **MLPS:** Remove the restrictive provisions of the Multi-Level Protection Scheme (MLPS) requiring that information security and other IT products procured for a broad array of information systems be Chinese-owned products with Chinese-owned IP.
- **Encryption Products:** Push for a transparent revision process of China's current commercial encryption regulations that rescinds the ban on importing, distributing, and selling foreign commercial encryption products to domestic commercial organizations in China. Ensure the government of China is not informally requiring or pressuring companies to use indigenous encryption algorithms like ZUC through SOEs, unwritten and discriminatory incentives, or otherwise.
- **Standards-Setting Process:** Urge China to institute meaningful reforms in its standards-development processes to allow participation by both foreign and domestic companies on an equal footing, to encourage development and adoption of industry led standards and ensure that such standards efforts proceed in an open and transparent manner, and to adopt internationally accepted standards when available. Encourage China to avoid using the international standardization process to standardize prescriptive technologies, like the ZUC algorithm, so they can then mandate them domestically in a way that stifles innovation and competition, and is contrary to the spirit of the WTO Agreement on Technical Barriers to Trade.

## TAX

- **China “1000 Enterprises” Tax Initiative:** Secure commitment from Chinese Government to ensure confidentiality of data collected as part of the *China 1000 Enterprises Initiative*, and that information gathered is relevant and data formats are compatible with existing company systems. Secure a commitment that any data provided by companies remains secure and is not made available or leaked outside of SAT, or used for purposes other than the ones stated. In this regard, ‘data security’ encompasses the following aspects: the process of the data collection, transfer of the data as well as the subsequent storage of data.
- Provide greater clarity as to when exported services will qualify for VAT exemption.
- Provide greater clarity on tax treatment of outbound remittances by PRC subsidiaries of U.S. companies, which currently are being held up by the tax administration pending tax clearance.

- Devote additional resources to clear the backlog of Advance Pricing Arrangements applications to give greater tax certainty to U.S. companies which have transactions with their PRC subsidiaries such as licensing transactions or services or exports of manufactured goods.
- Obtain commitment to provide more preferential individual income tax treatment to foreign professionals working in China including expanding the scope of exempt benefits-in-kind, more favorable treatment of equity compensation, and eliminating the tax gross-up calculations where tax is borne by employers.
- Exempt from Circular 698 reporting requirements for genuine corporate restructuring taking place within a majority owned group, to encourage more efficient consolidation of Chinese subsidiaries by U.S. entities.
- Provide greater certainty regarding the commencement of business timing for tax loss carry forward rules by establishing an SAT advance ruling mechanism on the commencement of business date which will be binding on all levels of the tax administration.
- Introduce a tax consolidated filing regime for corporate income tax purposes. This would allow foreign investors with multiple legal entities in China to offset their tax losses from some of their legal entities against the taxable profits in other legal entities. Tax losses in China can only be carried forward for 5 years under China's Corporate Income Tax Law so there is a significant tax cost for large scale investment projects if tax losses cannot be recouped within the first 5 years of operations of the legal entity that incurred the tax losses. Tax consolidated filing is possible in many mature tax jurisdictions such as Australia, Japan and in the U.S. and helps attract more foreign investment.
- Permit settlement of salary cost reimbursements for foreign employees on secondment to China from overseas without the imposition of any taxes such as Business Tax or Value Added Tax. This is a problem faced by many U.S. MNC's in their efforts to have top executive talent work on their investments in China. Currently U.S. executives seconded to the China branch must continue to have employment with a U.S. entity to continue to participate in the U.S. retirement savings plan. However, when the U.S. payroll entity charges the salary costs to the Chinese subsidiary, these salary cost reimbursements are subjected to China's Business Tax unless certain strict requirements are satisfied. This has left many Chinese subsidiaries unable to remit the salary cost reimbursements to the U.S. payroll entity.

## **TELECOMMUNICATION SERVICES**

### **1. Value-Added Telecom Services Licenses**

- In 2013, MIIT issued for public comment proposed revisions to China's Telecom Services Catalogue (Catalogue). In December 2015, MIIT issued the final Catalogue, with an entry of force date of March 1, 2016. The revised Catalogue expands the scope of China's telecommunications regulatory regime to include many emerging ICT services such as cloud computing, internet data service centers, and content distribution network services. Companies in sectors falling under this regulatory regime will be required to obtain related licenses; for example, companies providing web- and cloud-based content services will need to obtain an

Internet content provider (ICP) license. Foreign companies, however, are not allowed to obtain an ICP license unless they establish an entity in which foreign equity is less than 50%. China's treatment of a number of sectors, including cloud computing, as VATS is not in line with international practice. We recommend that China remove investment and other restrictions (e.g. equity caps) that prevent foreign investment in areas such as cloud computing.

- China's deployment of cloud computing technologies will be better enhanced by adopting global standards and policies that reflect the international and borderless nature of this critical and strategic industry. Yet China remains largely off limits to foreign ICT companies due to equity caps, investment restrictions, in-country hosting requirements and a slew of market entry barriers.
- In December and January, MIIT proposed two draft notices – *Regulating Business Operation in Cloud Services Market* (2016) and *Cleaning up and Regulating the Internet Access Service Market* (2017). These measures, together with existing licensing and foreign direct investment restrictions on US CSPs operating in China under the *Classification Catalogue of Telecommunications Services* (2015) and the *Cybersecurity Law* (2016), would require US CSPs to turn over essentially all ownership and operations to a Chinese company, forcing the transfer of incredibly valuable intellectual property and know-how to China.
- China's increased controls over the Internet are creating barriers to the cross-border flow of data and the ability of companies to operate in China. In a globalized economy, companies across all sectors rely on the Internet to transmit and receive data to operate and serve their customers. A spate of recent regulatory rules in China are clamping down on Internet flows, making it difficult and unpredictable for companies that operate in the Chinese market.
- Secure a commitment from China to remove remaining caps to FDI in this sector and remove JV requirements. Eleven years after China's WTO accession, China continues to use its discretionary interpretational authority to limit the number of foreign invested telecom entities to only 20 to 30 and all in the VATs area.
- Secure a commitment to reconsider the capital structure required of service providers as defined in the *Resale Services Circular* so that both incumbent and new entrant carriers can acquire capacity at wholesale rates and interconnect their networks to deliver services to a broader customer base. The very narrow definition in the Circular means that foreign investors are essentially excluded from the market.

## 2. High Capitalization Requirements

- Secure a commitment from China to lower capitalization requirements for basic service licenses and allow foreign companies access to the market.

## 3. JV Partnership Requirement

- Secure a commitment from China to eliminate the requirement that a foreign company must select a state-owned and licensed telecom company as a JV partner.

#### 4. Independent and Impartial Regulator with Transparent Procedures

- Secure a commitment from China to establish a regulatory body that is separate from, and not accountable to, any basic telecom supplier, and that is capable of issuing impartial decisions and regulations through transparent procedures.

#### 5. Draft Telecom Law

- Secure a commitment from China to go beyond codifying existing rules in the draft Telecom Law by incorporating the above suggestions. Finalizing and adopting a market opening Telecom Law should be a top priority. Any revision of the Telecom Law should allow both foreign and domestic companies to provide cloud computing services in the China market.
- Urge China not to adopt unique indigenous technical standards for cloud computing that would create market access barriers for foreign firms operating in China.