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

My name is Ralph Ives. I am the Executive Vice President for Global Strategy and Analysis at the Advanced Medical Technology Association (AdvaMed).

AdvaMed is the world's largest medical technology association. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. By medical technology, I am referring to medical devices, like catheters, pacemakers and orthopedic implants; imaging equipment, such as MRI, CAT scan and X-ray machines; and *in vitro* diagnostics, including tests for conditions like diabetes, cervical cancer and HIV. While our membership includes large multinational companies, about 75 percent of our membership comprises small and medium-size enterprises.

The U.S. medical technology industry is the most innovative and competitive in the world. Americans invented this industry. The United States has consistently enjoyed a trade surplus in medical technology. Our industry employs about two million Americans, directly or indirectly, in well-paying jobs. When I was recruited from the Office of the U.S. Trade Representative for my position at AdvaMed, I was told that this is an industry of which I could always be proud.

I am in charge of AdvaMed's overseas advocacy. In that capacity, my job is to seek fair, reasonable and non-discriminatory foreign government policies on regulatory, payment and other market access programs affecting our members' ability to provide patients the best medical technology available for their respective needs.

China Medical Technology Market

China has become one of our members' largest and fastest growing markets, though the total size of the medical technology market there remains much smaller than that of either the U.S., Europe or Japan. To put the roughly $12 billion Chinese market for medical technology in perspective, the approximate market sizes elsewhere for medical technology in 2013 were, respectively: over $115 billion in the United States; about $70 billion in Western Europe; and over $30 billion in Japan (our largest overseas market for a single country). However, estimating the exact size of these markets is difficult because of the variety and complexity of medical technology, with estimates of the number of products in the hundreds of thousands.

The medical technology market in China has grown rapidly – consistently by double digits for the past decade or so – and it is projected to continue to do so. For example, the medical technology market in 2006 was about one-third the size of today's market in China, and it could expand by 40% over the next three years.

U.S. bilateral trade with China has increased along with China's demand. In 2012 our exports from the U.S. to China were estimated at roughly $1.7 billion, with strong growth projected to continue for the foreseeable future. The USITC has estimated that orthopedics, cardiovascular and imaging sectors are the largest drivers, accounting for roughly 25% of the growth in U.S. exports to China.

These exceptional growth rates – in Chinese demand for medical technology and our bilateral trade – are due to several factors. Of course, the most obvious contributor is China's rapid economic growth and burgeoning middle class. Various estimates put the Chinese middle class at over a quarter billion people. When people have more income and wealth, they want better health care.

Another important stimulus for the demand for medical technology is the Chinese government's focus on improving the health care of its people and commitment of funds to do so. In April 2009, China announced an ambitious health care reform plan of comprehensive measures to increase access to health care – including broadening insurance coverage, building new health care facilities, increasing government spending, training medical personnel and increasing the role of information technology. This overarching health care reform plan has been implemented to rebuild in China a social safety net for medical services. Under this plan, all citizens have been promised access to basic health care services by 2020, and some reports indicate this goal is close to being achieved. The Chinese government pledged to spend $125 million over three years. A high-level of spending continued after 2011 to help meet the 2020 goal.

A third factor is China's aging population. By 2020, the country's population will actually start to decline. As some have observed, the trend for the population to age and decline before the nation as a whole is wealthy has many implications for China and the world. Just as health care needs tend to rise with age, so does the demand for innovative and high-quality medical technology. This provides an important opportunity for the medical technology industry.

AdvaMed members also invest in China. They build manufacturing plants, establish R&D facilities and purchase Chinese companies. The Chinese market is important because of its size, of course, but also because it can serve as an export platform to other markets, especially in Asia, and as a source of components.

Policy Challenges

Regulatory

As China's medical technology market has grown, so has the sophistication of its regulatory system. China, like the United States, wants to ensure that the medical devices reaching its patients are safe (they won't hurt people) and effective (they perform as intended). These are essentially the same fundamental criteria used by the FDA in the United States.

AdvaMed and its member companies have developed a cooperative relationship with what was, until last year, called the State Food and Drug Administration in China; it is now the Chinese Food and Drug Administration (CFDA). We have been working with CFDA officials to urge their use of internationally recognized, best regulatory practices in their pre-market approval and post-market surveillance systems. In addition, we have pressed for the transparent development and implementation of new regulations; that is, we have been asking for advance publication of proposed regulations, adequate time to provide comments, and reasonable transition periods before the regulations go into effect. We believe we are making progress on most of these issues.

The next few years will be pivotal in China's regulatory system. China has just approved a major revision to its medical device law (previously called Order 276) and we are awaiting the public release of this law. This revision creates a significant opportunity, and also significant risk for our industry.

It is expected that the revision to this law will impact all aspects of China's regulatory system (clinical trials, testing, inspections, evaluations, re-registration, post-market surveillance, etc.). We have already seen more than 20 new requirements with significant impact to our industry over the past year, and expect to see hundreds more as the revision is implemented. So far, China has been receptive to industry suggestions and proposals on these draft requirements and we hope that the revision of China's medical device law continues to be used to modernize the registration procedures, making them more efficient and effective.

An example of a new requirement that is "in play" in China is China's implementation of Unique Device Identifiers (UDI) for medical devices. In simple terms, this is a bar code that will be required on all medical technology products. The purpose of UDI is patient safety – to allow regulators to identify devices throughout distribution and use. For this system to function on a global basis, we need those countries that plan to adopt a UDI system to embrace a common approach. The U.S. FDA recently implemented a UDI rule in the U.S. with estimated costs to AdvaMed members in the millions of dollars.

Fortunately, the U.S. rule is based on international standards – in conjunction with the International Medical Devices Regulators' Forum (IMDRF). The EU is developing similar requirements which would also be based on international standards. We are concerned that China is contemplating a "home grown" UDI system that would not be consistent with the global approach, and that would require our companies to employ china-specific approaches throughout the supply chain. This would be very costly – not only for our firms but also for Chinese companies. More importantly this would undermine patient safety.

We have asked the U.S. government to work through the Joint Commission on Commerce and Trade, the IMDRF (of which China is a member) and other mechanisms to encourage China to make a commitment that its future UDI system will be based on international standards. We believe it is in China's interest, as well as our industry's interest, to do so.

Payment

As in many countries, there are a variety of ways medical technology manufacturers are paid for their products. Most medical technology is sold either directly or indirectly to hospitals and clinics. These providers may, in turn, be reimbursed by the patient, private insurance or the government. Different countries use varying mixes of these basic systems.

In China, the vast majority of health care has always been delivered through public (government-owned) hospitals and clinics, and the government has always been the primary stakeholder in the payment system. As in many countries around the world, the Chinese government is highly focused on controlling government health care costs. To this end, China has instituted requirements that hospitals and clinics must acquire most of the medical devices they use through consolidated tendering – which is often conducted at the provincial level.

We are increasingly seeing policies that are troubling for imported medical devices. For example, some provinces are requiring foreign manufactures to provide the import price of the product as a condition for entering the tender, and these prices create a ceiling price. There is no such limitation placed on the prices of domestic medical technology, which can be sold at lower prices because of lower costs – including manufacturing, transportation, research and development expenses – and a lack of service.

In some other cases, provincial officials are banning competition by foreign manufacturers for certain product lines. This policy obviously places U.S. medical technology at a disadvantage to domestic firms.

We have raised our concerns with provincial tendering officials, stressing that these practices will limit patient access to the best available medical technology. We have also alerted the U.S. government – the U.S. Trade Representative, Department of Commerce and U.S. Embassy – which is assisting us in our efforts. We hope we can change China's direction on this issue.

Intellectual Property

The protection of intellectual property is important to our industry, which spends an estimated 11% of revenue on R&D – second only to the pharmaceutical industry. Our industry is highly innovative, with the lifecycle of a medical device averaging about 18 months, which is similar to that of a smartphone.

The complexity of medical technology and the relatively rapid innovation cycle offer some degree of protection. Also, the good reputation of U.S. medical devices and diagnostics companies creates an obstacle to piracy. However, as Chinese manufacturers move up the value chain and export more of these products overseas, our members' concerns will intensify.

Our members' IP concerns primarily fall into three main categories. First, Chinese products appear to make use of our members' IP. Such products can sell at a lower price, since they did not entail the same level of R&D costs. This can be a problem in China and in other countries – mainly other emerging markets.

Second, we are seeing Chinese products that look like U.S. products but that do not function like U.S. products. When these make it to market in China, the U.S. or other global markets it creates a threat to public health, and a threat to our members' global reputations.

Third, in the regulatory/registration process in China, our companies are required to submit much more proprietary data to government and government-affiliated organizations than is required in other major markets. We hope to gain greater clarity into the policies governing the collection and protection of this data.

Ethical Business Practices

A fourth area of focus for us in China is business ethics, with the aim of ensuring that health care decisions are always made in the best interests of patients. AdvaMed has had a voluntary Code of Ethics for many years, and our members also abide by a range of anti-corruption laws including the U.S. Foreign Corrupt Practices Act and similar laws of trading partner nations. However, increased cross-border harmonization of business ethics and compliance efforts is essential to creating a level playing field for our industry in China and around the world.

We are working with our members in China on compliance and ensuring that our Code reflects Chinese laws and practices. We also have a memorandum of understanding with the Chinese Medical Device Industry Association to work together on a China-specific code. This effort will help promote practices that assure that the choice of one medical treatment or medical technology over another is made strictly with the interest of the patient in mind, and will also help ensure our industry's long-term reputation and success in China. Our work in China is part of a global effort to see a convergence of codes in the Asia-Pacific region and Latin America.

Conclusion

Our members have experienced rapid sales growth in China. We see opportunities for more. However, we are concerned about a possible move toward more protectionist policies for "indigenous" medical technology companies. AdvaMed remains highly committed to China, and we hope that the U.S. government also continues its high degree of engagement to support our industry in China – ensuring that China lives up to its global trade commitments and pressing for a level playing field for U.S. companies in this critical market. That would be our main messages to this Commission.