Prepared Statement

Of

Mr. Christopher Priest

Principal Deputy, Deputy Assistant Director, Healthcare Operations

Defense Health Agency

REGARDING

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

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

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

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

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

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

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

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

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

The Defense Logistics Agency (DLA)

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

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

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

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

Authorities and Regulatory Framework

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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