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May 7, 2025

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

Re: BIS-2025-0022, XRIN 0694-XC120; Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Deputy Assistant Secretary Longnecker,

SCHOTT Pharma USA, Inc. and its affiliate sites around the globe (**"SCHOTT Pharma"**), appreciates the opportunity to submit comments to the Bureau of Industry and Security's Request for Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. SCHOTT Pharma is a global leader in drug containment and delivery systems for the pharmaceutical industry and is committed to supporting the U.S. healthcare sector by providing high-quality glass and polymer products essential for the safe and effective delivery of medications. Our commitment to excellence ensures that healthcare providers can rely on our products to maintain the highest standards of patient care, thereby safeguarding the health, welfare, and security of all Americans. In this comment, SCHOTT Pharma provides background on the critical role it and the Schott AG group of companies ("SCHOTT Group") play in contributing to a secure supply chain in the U.S. for medical products and medical countermeasures, followed by information responsive to your request on the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, including medical countermeasures.

I. Background Information on SCHOTT Group in North America

With over 130 years of experience delivering innovative, high-quality products, SCHOTT Group is the global leader in specialty glass, glass ceramics, and through SCHOTT Pharma, high-performance pharmaceutical containers and systems. SCHOTT Pharma is headquartered in Lebanon, Pennsylvania and proudly supports more than 200 jobs in the United States. In

March 2024, SCHOTT Pharma announced plans for a new manufacturing facility in Wilson, North Carolina for prefillable glass and polymer syringes uniquely suited to contemporary and future needs for critical medicines in the United States. The new facility will add 401 jobs to the region and include a total investment of more than $350 million, with groundbreaking expected within the next two years. SCHOTT Pharma also has a strong global presence in Europe, Asia, and South America, the operations of which work in concert with SCHOTT Pharma's operations in the U.S. As a result of their demonstrated superior performance, SCHOTT Pharma products are selected for approximately two-thirds of all new injectable biologics approved by the FDA each year, as the properties of these containers meet the challenges presented by complex, sensitive drugs. SCHOTT Group containers and systems are utilized to support injectables in a wide variety of therapeutic classes, including vaccines, monoclonal antibodies, cancer treatments, cardiovascular and diabetes care, antibiotics, and hospital drugs used in intensive care units, emergency rooms, and surgical suites.

II. Importance of SCHOTT Pharma Products to Health Care in the U.S.

SCHOTT Pharma's products, including vials, syringes, and ampoules, are integral to the packaging and delivery of vaccines, biologics, and other pharmaceuticals. Quality pharmaceutical glass reliably prevents contamination and ensures the integrity of medications throughout their shelf life.

SCHOTT Pharma's products are essential for meeting the increasing demand for advanced medical treatments. Advanced therapies incorporating GLP-1 agonists stand as a sterling example of reliance on advanced manufacturing requiring critical industrial inputs and insufficient domestic supply capacity for drug delivery to meet domestic demand. The emergence of GLP-1 agonists is expected to push demand for specific drug delivery systems dramatically higher, as GLP-1 drugs have accepted indications for Type 2 diabetes and weight management. Given comparatively high rates of obesity and Type 2 diabetes in the U.S., the demand for polymer and glass syringes required to store and transport critical biologic therapies appears likely to persist. Federal authorities have noted a long-term shortage of injectables and GLP-1 injectable drugs treating diabetes and obesity. The pervasive and systemic effects of obesity and Type 2 diabetes mean that a significant portion of the U.S. will seek, or may be compelled to seek, treatment employing GLP-1 agonist therapies. These rely on specially-manufactured delivery systems, such as those produced by SCHOTT Pharma.

III. Impact of Potential Tariffs on the Pharmaceutical Glass Industry

Implementing tariffs on the material inputs necessary for the production of pharmaceutical glass, drug delivery systems, or medical countermeasures would have a detrimental impact on the domestic production of both. Diminished domestic production will lead to reduced access to critical health care. SCHOTT Pharma relies on a global supply chain to source high-quality raw materials and finished products. Tariffs would increase costs, potentially leading downstream to higher prices for medications and medical devices, adversely affecting patient access and affordability. Tariffs would undoubtedly disrupt the supply chain, causing delays in the delivery of critical medical supplies, and even shortages. This disruption could be

harmful during emergencies when timely access to medications is crucial. As domestic production is not sufficient to meet domestic demand, further restrictions to supply will likely impact accessibility, health, and national security.

III. Current and Projected Demand for Drug Delivery Systems and Medical Countermeasures in the United States

The demand for pharmaceuticals and pharmaceutical ingredients in the United States is substantial and continues to grow. This growth is driven by an aging population, increased prevalence of chronic diseases, and advancements in medical treatments. SCHOTT Pharma's pharmaceutical glass products, such as vials and syringes, are critical components in the packaging and delivery of these medications. As the demand for pharmaceuticals rises, the need for reliable and high-quality packaging solutions becomes even more crucial. Ensuring that supply can meet this growing demand is essential for maintaining the integrity and safety of medical interventions.

IV. Extent to Which Domestic Production of Drug Delivery Systems and Medical Countermeasures Can Meet Domestic Demand

The domestic production of pharmaceuticals and pharmaceutical ingredients faces significant challenges in meeting the full scope of domestic demand. While SCHOTT Pharma is committed to expanding its production capabilities and has demonstrated so, the current industry-wide infrastructure and workforce in the U.S. are not sufficient to address demand. Investments in manufacturing facilities and workforce development are necessary to enhance domestic production capacity. Federal engagement with industry leaders, like SCHOTT Pharma, can help to bridge the gap between domestic production and demand through targeted direct investment.

V. Role of International Supply Chains in Meeting United States Demand for Critical Inputs

Non-domestic supply chains, originating in and spanning allied nations, play a vital role in delivering critical inputs to meet domestic demand for drug delivery systems and medical countermeasures. SCHOTT Pharma relies on global suppliers for raw materials and components essential to the production of pharmaceutical glass. FIOLAX® glass, for example, is the most widely used formulation in the world for glass containers and systems, and it is not available in the United States. International partnerships ensure a steady supply of high-quality materials, which are critical for maintaining the standards required for pharmaceutical packaging.

VI. Measures to Enhance Domestic Capacity and Reduce Import Reliance

Increasing domestic capacity for drug delivery systems and medical countermeasures is feasible but will require substantial joint investment by industry and government stakeholders. SCHOTT Pharma has demonstrated its commitment to expanding domestic production

capabilities through investments in manufacturing facilities and workforce development. Government could demonstrate its commitment to fostering specialized domestic advanced medical manufacturing by enacting tax incentives related to capital investments and further targeted enhancements to the tax code. Government could adopt a more effective and direct approach by partnering with industry stakeholders through targeted grants and cooperative agreements to develop the industrial base necessary to meet domestic demand.

SCHOTT Pharma appreciates the opportunity to provide input into the Section 232 investigation. We look forward to working with the Department of Commerce to inform policies that ensure access to critical inputs for drug delivery systems and medical countermeasures remains uninterrupted.

Sincerely,

Christopher Cassidy
President
SCHOTT Pharma USA, Inc. / SCHOTT North America, Inc.