November 3, 2022

The Honorable Gina M. Raimondo
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

Re: Comments to the International Trade Administration on "Draft Harmonized System Code List of Critical Supply Chains" (ITA-2022-0010)

Dear Secretary Raimondo,

We appreciate the opportunity to respond to the Commerce Department RFI on critical supply chains. The RFI requests suggestions for additions to the list, which we commend because the existing Food and Drug Administration (FDA) Essential Medicines, Medical Countermeasures and Critical Inputs list (FDA list) is not fully aligned with intent of Executive Order 14017.

In this comment letter, we explain why the criteria used in creation of the FDA list differ from the goals of EO 14017 that followed, provide examples of how the Commerce list moved in the right direction to close the gap, and provide specific examples and a general framework for further expanding the list to advance the intent of EO 14017.

The existing FDA list was created in response to President Trump's August 2020 Executive Order 13944, which directed the FDA to develop a list in face of "outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats." In turn, the February 2021 Executive Order 14017 issued by President Biden took the supply chain resilience efforts further by expanding the criteria to account for supply disruptions due to "extreme weather events, terrorist attacks, geopolitical and economic competition, and other conditions."

Despite the broader mandate to include many forms of supply shocks, the ***existing*** FDA list appears to have remained the starting point for the supply chain resilience assessments that the U.S. Department of Health and Human Services conducted to fulfill E.O. 14017. But without an update to the FDA list, the U.S. government would only be focusing on supply chains for drugs needed ***in face of*** an emergency caused by a pandemic or CBRN threats and not on drugs ***without which*** we would have a public emergency.

We therefore praise the Commerce Department for extending the FDA list to incorporate drugs and drug components without which we may have public health crises. For example, the Commerce Department list does include estrogen and progestin on its critical supply chain list, whereas the FDA list does not. These two compounds are used jointly or separately as active pharmaceutical ingredients (APIs) in oral birth control products taken by 14% of U.S. women of childbearing age. A shortage in their supply could cause major disruption in care for up to 10 million women. It is also constructive that the Commerce Department list goes beyond finished drug products and APIs, into excipients (inactive ingredients). For example, the Commerce Department list includes chemicals like Potassium Sorbate or Cellulose Ethers.

However, many common excipients are not listed on the Commerce Department list—possibly because the Commerce list of excipients is limited to excipients for drugs on the existing FDA list. One such prominent excipient is Magnesium Stearate, which according to NIH DailyMed is an inactive ingredient in 32,060 human drug products—many of them common drugs for treating high cholesterol, high blood pressure, diabetes, or bacterial infections. Other examples of common excipients not included on the Commerce list are Titanium Oxide, Lactose and Polysorbate. A severe disruption in the supply of any these and many other common excipients could potentially simultaneously disrupt the care of millions of patients.

The above examples are not exhaustive, so we urge the Commerce Department to reassesses the FDA list systematically. As the Commerce RFI notes, the list of critical goods and materials will facilitate ongoing targeted analysis of trade data and the evaluation of policies to strengthen these supply chains and therefore getting that list right is of utmost importance.

As the Commerce Department considers how to expand the list, we propose to use the 2022 National Academies model (NASEM model) for selecting products for resilience building initiatives. That model considers three elements: (1) the expected harm that a given product user might suffer from a shortage, (2) the magnitude of a potential shortage, and (3) the risk that a product may go into shortage. The first two elements are what we would consider for updating the list, with the third criterion assessed through an analysis of vulnerability. A multidisciplinary committee comprising of private and government experts would be well suited for updating the list under the broader mandate to include products without which we would face a public health crisis.

We have ongoing work that might inform such efforts. As part of the National Network for Critical Technology Assessment, funded by the National Science Foundation Technology Innovation and Partnerships Directorate, we are currently applying the NASEM model to not only finished dosage form drugs, but also their APIs and excipients. Our empirical findings are not available at that point, but we assume that the Commerce list of critical supply chains will be a living document and hope our work may inform future iterations of it.

Again, we appreciate the Commerce Department's efforts on this front and look forward to the continued improvements in supply chain resilience across the economy.

Sincerely,

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