Jeffrey I. Kessler
Under Secretary
Bureau of Industry and Security
14th and Constitution Avenue, NW, Room 3876
Washington, DC 20230

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Doctors for America thanks the U.S. Department of Commerce Bureau of Industry and Security for their draft guidance “Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients” issued on April 16th, 2025.

Doctors for America (DFA) is an independent organization of more than 27,000 physicians and trainees from across the country addressing access to affordable care, community health and prevention, and health justice and equity. DFA focuses solely on what is best for our patients, not on the business side of medicine, and does not accept any funding from pharmaceutical or medical device companies. This uniquely positions DFA as an organization that puts patients over politics and patients over profits. DFA also hosts the FDA Task Force, which is a group of physicians and trainees across specialties working together to advance policies and regulations that ensure patients have timely access to truly safe and effective medical products.

The manufacturing of pharmaceuticals and related medical products in the United States is subject to the highly complex, tenuous nature of global supply chains. According to a recent United States Pharmacopeia (USP) analysis of active pharmaceutical ingredient (API) Drug Master Files, a large majority of API manufacturing sites are not in the United States. In 2023, India accounted for 48% of the manufacturing sites, China accounted for 16%, and the European Union (EU) another 17%[1]. Oral solid dosage forms are primarily manufactured in India, while injectable formulations are more commonly produced domestically[2]. Other medical products that are frequently imported from other countries include personal protective equipment (PPE), diagnostic technologies, and medical devices[3]. In 2022, Canada alone exported C$3.08 billion in medical devices to the U.S. Healthcare supply chains rely upon multinational imports to support widespread access to essential health products[4].

Our organization affirms the importance of maintaining geographically diverse medical supply chains and supports exemptions to tariffs on pharmaceuticals, APIs, and medical devices. Maintaining variability and redundancy in medical supply chains generally mitigates risks posed by regional disruptions, geopolitical instability, or natural disasters[5]. Experts have warned that

imposing tariffs on medical goods will increase healthcare costs and exacerbate existing critical shortages that will negatively impact healthcare systems and patients[6-8]. Historically, even small shifts in supply chains had led to shortages, especially when emergency measures for rapid production scalability fail to meet demand. Recent examples include the national IV fluid shortage which occurred after Hurricane Helene damaged Baxter's North Cove manufacturing site that produces 60% of the US supply[10]. Other notable shortages of medications, medical devices, and supplies have occurred over the years, including the PPE shortage at the start of the COVID-19 pandemic, contrast media shortage in 2022, and persistent scarcity of life-saving chemotherapy drugs[11-13]. Our physicians have witnessed firsthand how shortages compromise delivery of timely, evidence-based care, create avoidable risks for patients, and most importantly, cost lives.

DFA Task Force member Dr. Shreya Mandava shares: "While on an overnight shift in the surgical ICU during residency, I was notified of an unexpected supply chain disruption that left our service unable to order continuous renal replacement therapy (CRRT) fluid bags for at least 12 hours. Our call team repeatedly asked ourselves which patients would or would not survive through the night as we allocated the remaining CRRT fluids among patients in renal failure. Even at a well-resourced academic medical center, my training has been impacted by several instances of shortages impacting patients, ranging from basic IV fluids to antibiotics to surgical equipment. " These shortages force healthcare providers to make impossible choices about rationing life-saving treatments.

The broad issue of national healthcare shortages is extremely complex and has been a focus of task forces in the U.S Department of Health and Human Services (HHS) and US Food and Drug Administration (FDA)[14,15]. The FDA has previously stated that the security of the nation's drug supply is affected by dependence on foreign sources of API, resilience of domestic manufacturing bases, and reliability of U.S. manufacturing facilities[15]. Doctors for America supports investment in the expansion of domestic manufacturing capacity for medical products. However, it is essential to recognize that building and certifying new manufacturing facilities may require five to ten years[16]. While tariffs may provide economic incentives for companies to strengthen domestic supply chains, they risk destabilizing the markets in the short-term without expanding production capacity. Numerous experts have proposed alternative long-term solutions for expanding U.S. manufacturing capacity such as direct federal investment in emergency manufacturing infrastructure, targeted tax incentives for pharmaceutical companies, and quality metric based manufacturing incentives[14,15,17]. The FDA has also been investigating advanced manufacturing technologies as a multifaceted solution to improve supply chain resilience and public health emergency preparedness[3]. Should the administration instead pursue broad tariffs on pharmaceutical and API imports, it will be critical to implement national supply chain vulnerability assessments and share actionable information with stakeholders to alleviate healthcare constraints[5,18].

Lastly, Doctors for America acknowledges concerns regarding the impact of pharmaceutical imports on public safety. Illegal fentanyl flow into the U.S. is largely driven by trafficking from China, India, and Mexico, although new transit countries have been rapidly emerging[19]. Several

of our physicians have dedicated their lives to helping patients struggling with addiction and we appreciate the administration's consideration of the devastating impact of the opioid crisis on American communities. However, there is a lack of evidence supporting economic policies such as tariffs as effective tools for disrupting fentanyl trafficking networks. These organizations are highly adaptive and capable of circumventing traditional enforcement mechanisms[20,21].

There has also been notable concern regarding pharmaceutical recalls due to API quality concerns. Ensuring the safety and quality of imported medical products is a priority for our Doctors for America FDA Task Force. The FDA has a critical regulatory role in ensuring safety and quality of imported medical products. Enhancing inspection capacity, improving regulatory cooperation, and increasing transparency in FDA supply chain oversight are more likely to yield sustainable improvements compared to blunt trade policy instruments such as tariffs. The FDA has already invested considerable resources into developing a comprehensive approach to drug quality surveillance to inform risk-based inspection planning[22,23].

In conclusion, the complexities of pharmaceutical, API, and medical product manufacturing in the United States necessitate careful, strategic approaches to strengthen supply chain resiliency. Doctors for America supports efforts to grow domestic manufacturing capacity, particularly in the face of critical shortages. However, aggressive economic measures such as tariffs are unlikely to provide a viable long-term solution and may severely exacerbate health care shortages and compromise patient care in the interim. Doctors for America supports medical exemptions for tariffs on pharmaceuticals, APIs, and medical devices and instead affirms policies that balance domestic and global production, while also prioritizing the safety, quality, and reliability of the medical supply chain.

Please do not hesitate to contact our Task Force Chair Dr. Janet Krommes (janetkrommes@comcast.net) should there be any questions or concerns.

Respectfully submitted,

FDA Task Force, Doctors for America

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