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BJC Health System

Via Electronic Submission (www.regulations.gov)

May 7, 2025

Mr. Jeffrey Kessler
Under Secretary
Bureau of Industry and Security
United States Department of Commerce

RE: XRIN 0694-XC120—Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Under Secretary Kessler,

I write you today on behalf of BJC Health System ("BJC"), a multistate integrated health system providing hospital, post-acute and professional medical services throughout the Kansas City and St. Louis metropolitan areas, eastern Kansas, and southwest Illinois. Due to its size and scope, BJC possesses an expansive view of the potential impacts of prospective changes to health policy, including those that affect the availability of essential medicines critical to the provision of world-class medical care provided by BJC clinicians at BJC-member institutions. **We thank the Trump Administration and the Bureau of Industry and Security at the Department of Commerce ("the Bureau") for its timely attention to a significant challenge facing the healthcare industry and our nation via this Request for Public Comments ("the Request").**[1] We offer below a review of recent commentary by BJC related to the domestic development, production, and distribution of pharmaceuticals and then focus on the specific questions raised in the Request regarding the influence of foreign producers and their governments on the domestic availability of Key Starting Materials ("KSM"), Active Pharmaceutical Ingredients ("API"), and Essential Medicines ("EM"). **We strongly recommend the Administration balance any system of penalties, import restrictions, or other deterrents against foreign producers with commensurate public support for domestic manufacturers, while maintaining or strengthening existing public support for healthcare providers and patients.**

BJC directs the Bureau to related commentary submitted by our healthcare supply chain partners at the Healthcare Industry Resilience Collaborative ("HIRC"), our academic physician partners at the Washington University School of Medicine ("WUSM"), the Association of American Medical Colleges ("AAMC"), the American Hospital Association ("AHA"), and the Missouri, Kansas, and Illinois Hospital Associations ("MHA," "KHA," and "IHA").

We thank the Bureau in advance for its consideration and look forward to continued collaboration advancing the health and wellbeing of our patients and the United States of America.

Review of prior Executive Branch policymaking and related BJC commentary

BJC first addressed issues related to pharmaceutical development, production, and distribution in response to a 2018 Request for Information issued by the Department of Health and Human Services ("HHS") during the first Trump Administration.[2] Commentary focused primarily on domestic factors driving high drug prices and the related policies and programs intended to ameliorate the effects of high prices on providers and patients, e.g., the 340B drug discount program. **We urged the Agency to consider revisions to laws and regulations governing domestic producers to increase competition and incentivize innovation in those markets while protecting programs supporting providers.** We did not consider the role of foreign producers and their governments in domestic markets at that time.

In 2023 BJC submitted public comment again to HHS via the Centers for Medicare and Medicaid Services ("CMS") regarding a proposal in the Medicare 2024 Outpatient Prospective Payment System proposed rule to subsidize the

[1] "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients," Industry and Security Bureau, Department of Commerce, published April 16, 2025, at 90 FR 15951 and available here: https://www.federalregister.gov/d/2025-06587.
[2] "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," Health and Human Services Department, published May 16, 2018 at 83 FR 22692, and available here: https://www.federalregister.gov/d/2018-10435. See BJC's public comment letter available here: https://www.regulations.gov/comment/CMS-2018-0075-2902.

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stockpiling of Essential Medicines by certain hospitals.[3] We opposed that specific proposal on the grounds that an increase in demand (via subsidy) for drugs experiencing a shortage, without a commensurate increase in the supply of those drugs (i.e., resolving the shortage), would only increase prices for providers, payers, and patients. **We acknowledged the role that foreign producers and governments play in determining the prices and availability of essential medicines but demurred on addressing those aspects of the subject in our response, as matters of national security and geopolitics generally fall outside our expertise as providers of medical care.[4]** Consistent with our 2018 commentary, we urged various domestic policy solutions to help alleviate shortages and secure an adequate supply of pharmaceuticals and the supplies and capital necessary to produce them domestically.

In 2024 BJC submitted public comment to a consortium of federal agencies including HHS and the Federal Trade Commission ("FTC") regarding whether and how drug wholesalers and Group Purchasing Organizations ("GPO") contribute to or help mitigate drug shortages.[5] **The FTC and its partner agencies asserted that, "All players within the drug supply chain are intrinsically linked and thus the actions of any market participant can determine whether a drug experiences supply disruptions or shortages." BJC strongly agrees with this statement—the many interlocking policy threads of drug development, production, and distribution demand a multi-faceted approach to prevent shortages and reduce high prices—**but otherwise took issue with the FTC's implicit assertion that GPOs in particular deserve blame for shortages or high prices**.** Rather, in our experience, GPOs alleviate the worst possible effects of those phenomena and enable health systems like BJC to anticipate and plan for disruptions to healthcare supply chains, including the procurement of, e.g., Personal Protective Equipment ("PPE") during the public health emergency declared in response to the COVID-19 pandemic in 2020—2023. The 2024 FTC solicitation for public comment did not address the role of foreign producers and governments in creating domestic drug shortages, and BJC did not address it in our commentary.

In between and after these prior requests for public input, various government agencies have addressed different aspects of the domestic supply chain for KSMs, APIs, and EMs, including most notably a 2024 HHS white paper covering the size and scope, contributing factors, and possible solutions to the drug shortage crisis.[6] **The report recommended HHS agencies, including the FDA and CMS, develop and deploy policies and programs to (a) boost domestic production, particularly of generics, and (b) support hospitals and other safety net providers' access to essential medicines via financial and other backing. BJC supports these policies and advises the Bureau to consider supporting their pursuit as one necessary element of a broader strategy to address foreign influence on domestic pharmaceutical markets.** While the HHS report primarily addresses the domestic aspects of drug shortages, it does note the impact of foreign producers and their governments, and references a related paper issued by the Homeland Security and Governmental Affairs Committee ("HSGAC") of the United States Senate examining the national security risks associated with drug shortages.[7]

The HSGAC report identifies multiple cascading negative effects of drug shortages on the economic and national security objectives of American governmental and business interests, including healthcare providers, insurers, and the pharmaceutical industry, and, by extension, the health and wellbeing of individual Americans. This report helpfully identifies a number of challenges related specifically to KSM and API supply chains and their criticality to drug

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[3] "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems […]," Centers for Medicare and Medicaid Services, published July 31, 2023, at 88 FR 49552 and available here: https://www.federalregister.gov/d/2023-14768. BJC's public comment is available here: https://www.regulations.gov/comment/CMS-2023-0120-3723.

[4] We note that the 2023 RFI built upon a series of actions taken by the prior Administration that may provide useful resources for the Bureau in developing policies to address foreign producers and their governments, including a report commissioned by HHS to identify a list of 86 "essential medicines" and the various forces, including foreign influence, impeding a robust domestic supply chains for those drugs. That report is available here: https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.

[5] "Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages," Federal Trade Commission, published February 14, 2024, and available here: https://www.regulations.gov/document/FTC-2024-0018-0001. See BJC commentary here: https://www.regulations.gov/comment/FTC-2024-0018-5420.

[6] "Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States," Office of the Secretary, HHS, published April 2, 2024 and available here: https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.

[7] "Short Supply: The Health and National Security Risks of Drug Shortages," HSGAC Majority Staff Report, United States Senate, published March 2023 and available here: https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.

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production and distribution. **For example, the report notes that nearly eighty percent of API manufacturing facilities are located outside of the US, and that, per testimony from the Administration for Strategic Preparedness and Response ("ASPR"), roughly ninety percent of generic sterile injectable drugs rely on KSMs originating in India or China.** The report argues that a combination of economic pressures, domestic tax law incentives, and foreign government interventions of varying kinds (direct subsidies, workforce development, and related labor and environmental regulations) have combined to drive pharmaceutical production (including by US-based manufacturers), to foreign-based facilities over the last fifty-plus years, and recommends a suite of policies to reverse those drivers to facilitate increased domestic production to meet the nation's demand for essential medicines.

Reports by HHS, ASPR, HSGAC and myriad other government and quasi-governmental agencies seem to converge on a common set of domestic policies to enhance domestic production and manufacturing of KSMs, APIs, and MEs. Of those policies, **BJC strongly supports improved foreign and domestic supply chain transparency, direct government investment in and support of the pharmaceutical supply chain, and subsidies for safety-net providers and patients**. However, few if any of these reports directly address whether/how the US Government should engage with foreign governments and producers to protect or otherwise support domestic industries. **We again thank the Trump Administration and the Bureau for its attention to this aspect of the current predicament and turn our attention to the specific questions addressed in this RFI.**

Imports of Pharmaceuticals and Pharmaceutical Ingredients

The Bureau provides a series of discussion prompts, including current and prospective demand and supply of KSMs, APIs, and MEs; the role of foreign suppliers compared to domestic producers; the effects of domestic and foreign government policies, e.g., direct subsidies and import/export controls, and the relative vulnerability of US markets to related disruptions; and potential policy solutions to foster greater domestic supply chain resiliency.

Regarding supply and demand, we note that the projected demand for medications will continue rising as our population ages, and more Americans experience age-associated conditions like arthritis and Alzheimer's disease. Similarly, the increasing prevalence of chronic diseases such as diabetes, hypertension, oncology, and cardiovascular disease, including within younger segments of the population, will drive additional demand for related pharmaceutical interventions. The majority of other widespread health conditions, e.g., behavioral health maladies, and many preventative care services, also involve varying degrees of pharmaceutical intervention. These needs will become unmanageable at the population level absent an adequate supply of a pharmaceuticals critical to supporting patient care, which in turn relies upon a secure supply chain of KSMs, APIs, and EMs. **The United States' overreliance on foreign sources for pharmaceutical production appears indisputable, as evidenced by the various sources cited above. BJC's continuous dialog with manufactures, distributors, trade organizations, and GPOs corroborates government agencies' findings that, while significant US-based production capacity exists, domestic producers struggle to compete with foreign government subsidized manufacturers, in part because US production remains heavily reliant on foreign-sourced KSMs and APIs.** This dependency represents the single greatest challenge to national security in terms of ensuring adequate domestic pharmaceutical production and access.

Based on our review of current literature and dialog with industry colleagues, we believe foreign governments pursue several core tactics to undermine and inhibit domestic pharmaceutical production. First, foreign governments subsidize production by their native manufacturers, enabling them to sell products at prices below their actual costs of production. Second, foreign governments incentivize their manufacturers to overproduce essential medicines, thereby flooding international markets, including the US domestic market, with extremely low-cost products, undercutting domestic competitors. Third, foreign governments restrict the quantity of KSMs and APIs available to U.S. domestic manufacturers and thereby limit the ability of domestic manufacturers to produce at the level necessary to recoup the marginal costs of production. **Combined, these foreign government tactics severely restrict the profitability of domestic production, which deters private investment, further undermining the competitiveness of domestic industry and forcing domestic firms to exit the market entirely. The loss of capacity through market exits in turn strengthens the deleterious effects of these foreign trade practices and further cements our dependence on foreign sources.** Any overreliance on foreign sources of critical inputs creates a condition of dependency that hostile foreign governments could leverage against the Unites States to achieve their adverse foreign policy objectives.

The ability of any foreign entity to restrict or otherwise control American access to life saving therapies poses significant threats to patient care, and BJC welcomes any/all government interventions to protect our ability to provide that care. Fortunately, increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce

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import reliance appears highly feasible with the right mix of policy interventions. **BJC strongly supports the expansion of domestic production of KSMs, APIs, and EMs through leveraging existing idle US drug production capacity, expanding the role of non-traditional entities like CIVICA RX in manufacturing and distributing generic drugs in particular, and investing in new and promising API development and advanced manufacturing capabilities.** Combined, these policy initiatives will significantly reduce US reliance on foreign drugs and ingredients while driving innovation in drug and ingredient production and in the pharmaceutical supply chain more broadly.

The Bureau also references possible additional measures, including tariffs or import/export quotas, necessary to protect national security interests in drug production. BJC lacks the expertise and experience necessary to evaluate or such policies generally, but we note that the current set of tariffs from which the Administration has presently exempted pharmaceuticals will nonetheless place increasing cost pressures on healthcare providers, threatening the financial viability of smaller and more rural hospitals in particular, to say nothing of possible shortages of essential equipment and supplies resulting from tariffs and other barriers to international trade fundamental to healthcare supply chains. **We strongly recommend the Administration focus its efforts first on enhancing domestic production before penalizing foreign producers or otherwise limiting foreign supplies of KSMs, APIs, or EMs.** We acknowledge that tariffs or quotas may prove useful to achieving our shared goals of ensuring adequate domestic supply, but caution that applying those remedies before achieving the required increase in domestic supply will necessarily increase the costs pharmaceuticals and their inputs and potentially exacerbate existing shortages of both.

Conclusion

BJC greatly appreciates the Trump Administration's attention to this critical issue. Drug shortages threaten the ability of US health care providers to meet the needs of American patients. These shortages arise through a mix of domestic policy shortcomings and foreign government interventions in pharmaceutical markets, including the domestic US market. Fortunately, this matter is well-studied, and several promising solutions await testing by resolute policy makers. **We strongly recommend the Administration balance any system of tariffs, import restrictions, or other deterrents against foreign producers with commensurate public support for domestic manufacturers, while maintaining or strengthening existing public support for healthcare providers and patients.** Together we can ensure world-class health care for all Americans.

Sincerely,

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