

# United States Senate

WASHINGTON, DC 20510

March 18, 2024

The Honorable Lloyd J. Austin III  
Secretary  
U.S. Department of Defense  
1000 Defense Pentagon  
Washington, D.C. 20301

Dear Secretary Austin:

We write with regard to the efforts by the U.S. Department of Defense (DoD or the Department) to implement Section 860 of the Fiscal Year 2023 (FY23) National Defense Authorization Act (NDAA), a provision that stemmed from the *Strengthening Supply Chains for Servicemembers and Security Act*, to address risks to the military pharmaceutical supply chain. Section 860 directed DoD to develop guidance for risk management of the Department's pharmaceutical supply chain, report on supply chain vulnerabilities, and establish a working group to develop policies for allocating scarce pharmaceutical resources.<sup>1</sup>

In 2023, drug shortages reached their highest levels since 2014,<sup>2</sup> including more than 300 drugs last year. Many of the drug shortages were for generics.<sup>3</sup> These shortages can have profound consequences for patients, leading them to delay or forego necessary care.<sup>4</sup> While there are several causes of drug shortages, supply chain disruptions due to quality failures are a growing concern.<sup>5</sup> In many cases, only a handful of pharmaceutical companies manufacture a particular generic drug. When these companies experience quality concerns or manufacturing challenges, there is enormous strain placed on the supply chain, leading to widespread disruptions.<sup>6</sup>

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<sup>1</sup> Office of Senator Elizabeth Warren, "Warren Announces Legislation Included in National Defense Authorization Act," press release, December 12, 2022, <https://www.warren.senate.gov/newsroom/press-releases/warren-announces-legislation-included-in-national-defense-authorization-act>.

<sup>2</sup> American Society of Health-System Pharmacists, "Drug Shortages Statistics," <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>.

<sup>3</sup> Axios, "America's drug shortages reach new heights," Tina Reed, May 22, 2023, <https://www.axios.com/2023/05/22/americas-drug-shortages-reach-new-heights>; NPR, "Many generic drugs are in short supply," Yuki Noguchi, <https://www.npr.org/2023/11/11/1212465756/many-generic-drugs-are-in-short-supply>

<sup>4</sup> NBC News, "1 in 3 U.S. hospitals severely affected by drug shortages, survey finds," August 10, 2023, <https://www.nbcnews.com/health/health-news/drug-shortages-causing-hospitals-skip-delay-ration-care-survey-finds-rcna99007>; The New York Times, "How the Shortage of a \$15 Cancer Drug Is Upending Treatment," Christina Jewett, June 26, 2023, <https://www.nytimes.com/2023/06/26/health/cancer-drugs-shortage.html>

<sup>5</sup> The New York Times, "Drug Shortages Near an All-Time High, Leading to Rationing," Christina Jewett, May 17, 2023, <https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html>.

<sup>6</sup> U.S. Committee on Homeland Security and Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages," March 2023, p. 13, <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf>.

In addition, 58 percent of drug manufacturers supplying the U.S. market were based overseas in 2022.<sup>7</sup> This exposes the drug supply chain to potential safety risks, as federal regulators have a reduced ability to conduct oversight in India, China, and other foreign countries. This reality makes it difficult for Americans to ensure the quality of products and inputs through the entire supply chain.<sup>8</sup>

The military is not immune to these challenges. For example, a recent report revealed that “some generic versions of [tacrolimus, an immune suppressant given to prevent organ rejection], given to soldiers who have lost limbs in combat, might not work.”<sup>9</sup> Intas Pharmaceuticals, an Indian manufacturer that produced the faulty tacrolimus, was also responsible for widespread and damaging shortages of oncology drugs, after an investigation by the Food and Drug Administration (FDA) revealed alarming deficiencies, forcing the plant to shut down.<sup>10</sup> For these reasons, we followed with great interest the announcement last August that DoD intended to enter into a cooperative agreement with the independent laboratory Valisure to conduct a pilot study to “generate objective drug quality data” for twelve common drugs<sup>11</sup> – from blood pressure medicine to antidepressants – “through independent sourcing and testing.”<sup>12</sup> According to Valisure’s announcement, DoD leadership “determined that the working group shall perform a logistical risk assessment and a quality risk assessment,” and that “[s]ome logistical [i]nformation may be produced through the operation of this study,” but “the primary purpose of this Research Project is to assess quality.”<sup>13</sup> In a statement, Valisure shared that its testing could help DoD and other federal agencies “differentiate the quality of available manufacturers” and “reward good manufacturers and exclude substandard medicines from being consumed.”<sup>14</sup>

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<sup>7</sup> Government Accountability Office, “DRUG SAFETY FDA Has Faced Persistent Challenges Overseeing Foreign Drug Manufacturing,” Tuesday, February 6, 2024, p.1, <https://www.gao.gov/assets/d24107359.pdf>.

<sup>8</sup> Bloomberg, “US Military Is So Worried About Drug Safety It Wants to Test Widely Used Medicines,” Anna Edney and Riley Griffin, June 7, 2023, <https://www.bloomberg.com/news/articles/2023-06-07/drug-safety-fears-spur-pentagon-plan-to-test-widely-used-meds>.

<sup>9</sup> Bloomberg, “The Pentagon Wants to Root Out Shoddy Drugs. The FDA Is In Its Way.” Anna Edney and Riley Griffin, December 4, 2023, <https://www.bloomberg.com/news/features/2023-12-05/pentagon-is-skeptical-of-cheap-generic-drugs-approved-by-the-fda>; Government Accountability Office, “DRUG SAFETY FDA Has Faced Persistent Challenges Overseeing Foreign Drug Manufacturing,” Tuesday, February 6, 2024, p. 3, <https://www.gao.gov/assets/d24107359.pdf>.

<sup>10</sup> The New York Times, “How the Shortage of a \$15 Cancer Drug Is Upending Treatment,” Christina Jewett, June 26, 2023, <https://www.nytimes.com/2023/06/26/health/cancer-drugs-shortage.html>; The Washington Post, “How troubles at a factory in India led to a U.S. cancer-drug shortage,” Daniel Gilbert, June 27, 2023, <https://www.washingtonpost.com/business/2023/06/27/cancer-drug-shortage-generics/>.

<sup>11</sup> Bloomberg, “The Pentagon Wants to Root Out Shoddy Drugs. The FDA Is In Its Way.” Anna Edney and Riley Griffin, December 4, 2023, <https://www.bloomberg.com/news/features/2023-12-05/pentagon-is-skeptical-of-cheap-generic-drugs-approved-by-the-fda>; Valisure, “Pharmaceutical Quality Risk Assessment Pilot Study By The Department of Defense & Valisure,” <https://www.valisure.com/dod-drug-testing-study>

<sup>12</sup> Valisure, “Pharmaceutical Quality Risk Assessment Pilot Study By The Department of Defense & Valisure,” <https://www.valisure.com/dod-drug-testing-study>; PR Newswire, “VALISURE SIGNS AGREEMENT WITH DEPARTMENT OF DEFENSE TO INDEPENDENTLY TEST & QUALITY SCORE DRUGS,” press release, August 8, 2023, <https://www.prnewswire.com/news-releases/valisure-signs-agreement-with-department-of-defense-to-independently-test-quality-score-drugs-301895301.html>.

<sup>13</sup> Valisure, “Pharmaceutical Quality Risk Assessment Pilot Study By The Department of Defense & Valisure,” <https://www.valisure.com/dod-drug-testing-study>

<sup>14</sup> Valisure, “Pharmaceutical Quality Risk Assessment Pilot Study By The Department of Defense & Valisure,” <https://www.valisure.com/dod-drug-testing-study>; PR Newswire, “VALISURE SIGNS AGREEMENT WITH

As required by Section 860 of the FY23 NDAA, the report revealed that 27 percent of the drugs on the FDA’s Essential Medicines List were categorized by the Defense Logistics Agency (DLA) as “Very High Risk” because they are either “dependen[t] on Chinese manufacturers using Chinese [active pharmaceutical ingredients (APIs)]” or “drugs with Unknown sources.”<sup>15</sup> The report further found that, out of the 211 drugs DLA examined, 46 were sourced from China and 126 had API sourced from India in 2022.<sup>16</sup> These findings underscore the urgency of strengthening and securing the Department’s pharmaceutical supply chains.

We appreciate DoD’s attention to these important matters and look forward to strengthening the resilience of our pharmaceutical supply chain. To that end, we ask that you provide answers to the following questions no later than April 1, 2024:

1. Please describe the steps DoD has taken to implement Section 860 of the FY23 NDAA.<sup>17</sup>
  - a. What is the status of the working group intended to assess risks to the pharmaceutical supply chain, identify the pharmaceuticals most critical to beneficiary care at military treatment facilities, and establish policies to allocate scarce drugs during supply disruptions?
    - i. Who are the members of the working group?
    - ii. Has the working group convened?
    - iii. What are the working group’s deliverables?
    - iv. When should we expect the first products from the working group to be shared with Congress?
2. Please provide a comprehensive list of all DoD pharmaceutical supply chain disruptions, including:
  - a. The source of such disruption;
  - b. Whether such disruption resulted in a drug shortage;
  - c. Whether the shortage has been resolved;
  - d. The actions DoD took to resolve such shortage; and
  - e. The impact of such disruptions and/or shortages on service members and military readiness.
3. Does DoD intend to share the results of the Report on the Department of Defense Pharmaceutical Supply Chain Risks with the agency’s health care providers and those who prescribe or administer these drugs?<sup>18</sup>

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DEPARTMENT OF DEFENSE TO INDEPENDENTLY TEST & QUALITY SCORE DRUGS,” press release, August 8, 2023, <https://www.prnewswire.com/news-releases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs-301895301.html>.

<sup>15</sup> U.S. Department of Defense, Office of the Under Secretary of Defense for Acquisition and Sustainment, “Report on the Department of Defense Pharmaceutical Supply Chain Risks,” November 2023, pp. 9-10, <https://www.warren.senate.gov/download/03/18/2024/fy23-ndaa-sec-860-risk-management-for-dod-pharmaceuticals>. Five percent of pharmaceuticals with an API sourced from China and 22 percent of pharmaceuticals with an Unknown for its API country of origin.

<sup>16</sup> *Id.*, pp. 11-12.

<sup>17</sup>The White House, “FACT SHEET: President Biden Announces New Actions to Strengthen America’s Supply Chains, Lower Costs for Families, and Secure Key Sectors,” November 27, 2023, <https://www.whitehouse.gov/briefing-room/statements-releases/2023/11/27/fact-sheet-president-biden-announces-new-actions-to-strengthen-americas-supply-chains-lower-costs-for-families-and-secure-key-sectors/>.

<sup>18</sup> U.S. Department of Defense, Office of the Under Secretary of Defense for Acquisition and

4. DoD IG's 2021 report recommended that the Defense Logistics Agency (DLA) Troop Support coordinate with Military Service customers to conduct responsiveness testing of the DLA's contingency contracts for pharmaceuticals and include testing results in the Warstopper Program annual reports.<sup>19</sup>
  - a. Please provide an update on the Department's implementation of this recommendation.

Sincerely,



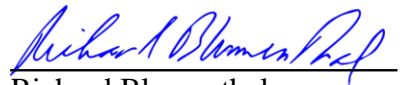
Elizabeth Warren  
United States Senator



Marco Rubio United  
States Senator



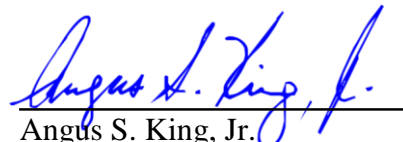
Joni K. Ernst  
United States Senator



Richard Blumenthal  
United States Senator



Mazie K. Hirono  
United States Senator




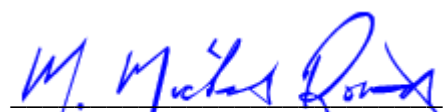
Angus S. King, Jr.  
United States Senator

Sustainment, "Report on the Department of Defense Pharmaceutical Supply Chain Risks," November 2023, <https://www.warren.senate.gov/download/03/18/2024/fy23-ndaa-sec-860-risk-management-for-dod-pharmaceuticals>.

<sup>19</sup> U.S. Department of Defense Inspector General, "Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain," September 20, 2021, p. ii, [https://media.defense.gov/2021/Sep/22/2002859154/-1/-1/1/DODIG-2021-126\\_REDACTED.PDF](https://media.defense.gov/2021/Sep/22/2002859154/-1/-1/1/DODIG-2021-126_REDACTED.PDF).

  
Kevin Cramer  
United States Senator

  
Eric Schmitt  
United States Senator

  
M. Michael Rounds  
United States Senator