United States Senate
WASHINGTON, DC 20510

September 16, 2024

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

Dear Secretary Austin,

We write regarding the Department of Defense's (DOD's or the Department's) pharmaceutical acquisition strategy, including whether, and if so, how, such strategy has changed due to the February 2020 Circuit Court decision in *Acetris Health, LLC v. United States*,[1] which loosened Buy American requirements for federal agencies purchasing pharmaceuticals.[2] We are concerned that the decision may be exacerbating the Department's reliance on foreign pharmaceutical products, increasing national security risks and potentially compromising military readiness.

Historically, federal agencies have made pharmaceutical acquisition decisions based on the Federal Acquisition Regulations (FAR), which prohibits federal agencies from procuring products from a country that does not comply with the Trade Agreements Act (TAA).[3] Accordingly, prior to the *Acetris Health, LLC v. United States* decision, the Department of Veterans Affairs (VA) placed purchasing restrictions on drug manufacturers whose products were formed with active pharmaceutical ingredients (API) from TAA non-compliant countries, typically following Customs and Border Protection (CBP) country-of-origin determinations.

In *Acetris Health, LLC v. United States*, the U.S. Court of Appeals for the Federal Circuit (the Court) considered the VA's strategy, and specifically, the agency's purchasing restriction on a number of drugs manufactured by Acetris, a New Jersey-based pharmaceutical company. The VA contended that Acetris's drugs violated the FAR, given that the products were formed with a single API sourced from India – a TAA non-compliant country.[4] In defending its policy, the VA relied on CBP's country-of-origin determination, which found that "the manufacturing process at the [Acetris] New Jersey facility did not result in substantial transformation [of the API] in the

[1] Acetris Health, LLC v. United States, No. 2018-2399, slip. Op. (Fed. Cir. Feb. 10, 2020).

[2] Congressional Research Service, "The Buy American Act and Other Federal Procurement Domestic Content Restrictions," David Carpenter and Brandon Murrill, November 8, 2022, https://www.crs.gov/reports/pdf/R46748/R46748.pdf.

[3] *Id.*

[4] *Id.*; Steptoe, "Federal Circuit's Acetris Decision Addresses Rules for Determining TAA Compliance," Paul Hurst, Caitlin Conroy, Gregory McCue, Tom Barletta, February 26, 2020, https://www.steptoe.com/en/news-publications/federal-circuits-acetris-decision-addresses-rules-for-determining-taa-compliance.html.

US and that the tablets were a product of India for purposes of US government procurement under relevant CBP precedent."[5]

Despite this evidence, the Court found that Acetris's drugs were in compliance with the FAR, thereby rendering the VA's restriction improper. At a hearing of the U.S. Senate Committee on Armed Services' Personnel Subcommittee in April, Col(ret) Victor Suarez explained the ramifications of the decision: "Today, a Chinese firm could make all the API and precursor materials for a medicine, ship it to a U.S. subsidiary that does packaging and final labeling, and still be able to label it as American made. This would be considered an American-made drug and principally illustrates this loophole."[6]

This decision poses significant risks to the military's drug supply chain, which is already over-reliant on foreign sourced pharmaceuticals. For example, in the DOD's interim report on Pharmaceutical Supply Chain Risks, the Department revealed that "54% of the DoD pharmaceutical supply chain is considered either high or very high risk, with dependency on non-[TAA] compliant suppliers, sourcing from China and India, or unknown."[7] As witnessed by the Covid-19 pandemic, an over-reliance on foreign countries for critical materials, including pharmaceuticals, leaves the U.S. vulnerable to international supply shocks.

To better understand how the *Acetris* decision has affected DOD's pharmaceutical acquisition strategy, we respectfully request answers to the following questions by September 30, 2024:

1. In his testimony, Col(ret) Victor Suarez noted that, as a result of the 2020 *Acetris Health, LLC v. United States* decision, a drug product that is packaged and labeled in the United States would be in compliance with Buy American requirements, even if the components of that product were manufactured overseas. Is this consistent with the Federal Circuit Court of Appeals' interpretation of the *Acetris Health, LLC v. United States* decision?
2. Has DoD changed how it interprets Buy American requirements following the *Acetris* decision?
    a. Are there changes to the *Buy American Act* or the TAA that would strengthen the resilience of DOD's pharmaceutical supply chain?
3. How many drugs did DOD consider to be in compliance with Buy America requirements before and after the *Acetris* decision?
    a. Please provide a list of the drugs that were previously out of compliance pre-decision, but in compliance post-decision.

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[5] *Id.*

[6] United States Senate Committee on Armed Services, Subcommittee on Personnel, "Hearing to Receive Testimony on the Department of Defense's Efforts to Ensure Servicemembers' Access to Safe, High-Quality Pharmaceuticals," April 30, 2024, p. 58, https://www.armed-services.senate.gov/imo/media/doc/043024personneltranscript.pdf.

[7] Statement of Col(Ret) Victor A. Suarez, U.S. Senate Committee on Armed Services, Subcommittee on Personnel, "To Receive Testimony on the Department of Defense's Efforts to Ensure Servicemembers' Access to Safe, High-Quality Pharmaceuticals," April 17, 2024, https://www.armed-services.senate.gov/imo/media/doc/suarez_statement.pdf.

   b. Please provide a list of the contractors and subcontractors producing these drugs.
4. How, if at all, has the *Acetris* case affected DOD's acquisition strategy for drugs?
   a. Has the Court's decision increased or decreased concerns about purchasing safe and high-quality drugs while maintaining supply requirements?
5. Has there been an increase in protests from domestic manufacturers that have had bids rejected due to the use of foreign-sourced API?
6. Does DOD track the number of drugs purchased by the Department that contain APIs or key starting materials manufactured in or sourced from China or other non-TAA compliant countries?
   a. If yes, please provide, for the last five years, the number of drugs purchased by DOD that meet this description.
   b. If not, please explain why not.
7. What policies, if any, does DOD have in place to prioritize the acquisition of generic drugs with components from TAA-compliant countries?
   a. Please provide a list of any statutes, regulations, or other DOD policies that prevent the Department from establishing or otherwise strengthening policies that prioritize the acquisition of generic drugs with components from TAA-compliant countries
8. At a hearing of the U.S. Senate Committee on Armed Services Subcommittee on Personnel in April 2024, Dr. Martinez Lopez agreed to consult health care stakeholders, including domestic generic manufacturers, to understand what barriers prevent manufacturers from developing or sourcing APIs and other components domestically. What progress has DOD made since the hearing toward this goal?

Thank you for your attention to this important matter.

Sincerely,

Elizabeth Warren
United States Senator

Rick Scott
United States Senator

Marco Rubio
U.S. Senator

Joni K. Ernst
United States Senator

Christopher S. Murphy
United States Senator

M. Michael Rounds
United States Senator