

Congress of the United States
Washington, DC 20510

July 26, 2021

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

Dear Secretary Austin:

We write today to request information on the Department of Defense's (DOD or "the Department") efforts to implement congressional directives from the *National Defense Authorization Act for Fiscal Year 2018 Report* (FY18 NDAA Report) requiring the Department to reduce the prices of DOD-funded drugs, vaccines, and medical equipment. The report directed DOD to "authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged" in comparable countries.¹ It is unclear, however, whether and to what extent DOD has complied with this report language.

Americans spend more on drugs than people in any comparable country, and over the past 10 years, spending on retail prescriptions has increased by almost \$100 billion.² The average American spends \$1,229 per year on prescription drugs, sometimes paying up to two to four times more than they would elsewhere.³ As drug companies hike prices, patients bear the costs and are forced to make dangerous choices. According to a Kaiser Family Foundation poll, at least three in ten adults reported skipping drug doses, delaying prescriptions, or taking less of a drug than prescribed in order to save money.⁴ Despite the financial and medical hardship for patients, drug companies continue to raise prices, and they do so even though they rely on

¹ Congress.gov, "National Defense Authorization Act for Fiscal Year 2018 Report," July 10, 2017, <https://www.congress.gov/115/crpt/srpt125/CRPT-115srpt125.pdf>, p. 173.

² Centers for Medicare & Medicaid Services, "National Health Expenditure Fact Sheet," April 26, 2019, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>.

³ Organisation for Economic Co-operation and Development, "Pharmaceutical spending," 2019, <https://data.oecd.org/healthres/pharmaceutical-development.htm#indicator-chart>, Government Accountability Office, "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France," April 28, 2021, <https://www.gao.gov/products/gao-21-282>.

⁴ Kaiser Family Foundation, "KFF Health Tracking Poll – February 2019: Prescription Drugs," Ashley Kirzinger et al., March 1, 2019, <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>; Stat, "One-quarter of people with disabilities in the U.S. are rationing their insulin," Ed Silverman, June 18, 2019, <https://www.statnews.com/pharmalot/2019/06/18/one-quarter-of-people-with-diabetes-in-the-u-s-are-rationing-their-insulin/>.

American taxpayers to fund billions of dollars-worth of drug and device development and research each year.⁵

Access to lifesaving drugs, devices, and other medical products should not be limited to only those that can afford them. Fortunately, the federal government has the authority under the *Bayh-Dole Act* to make certain medical products more affordable.⁶ Specifically, the law grants the federal government the authority to retain “nonexclusive, nontransferable, irrevocable, paid-up” licenses for drugs, devices, and vaccines developed with government funding. In certain situations, such as when necessary to “alleviate health or safety needs” that have not been “reasonably satisfied” by the licensee, the federal government can “march-in” and direct other licensees to produce the desired product or contract with third parties for manufacturing at a reasonable price.⁷ Over the past two decades, DOD has contributed more than \$15 billion to support medical research and of the almost 20,000 projects the drugs and other medical products that benefited funding could be subject to march-in rights.⁸

Recognizing the high prices of medical products developed, in part, with DOD funding, the Senate Armed Services Committee directed DOD to utilize march-in rights to lower prices. Specifically, the Committee’s FY18 NDAA report directed the Department:

“to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.”⁹

It is unclear what steps, if any, DOD has taken to comply with this report language. To better help us understand what steps DOD has taken since the NDAA directions in 2017, we request answers to the following questions no later than August 9:

1. What steps, if any, has DOD taken steps to implement the FY18 NDAA Report language?

⁵ Center for American Progress, “How Big Pharma Reaps Profits While Hurting Everyday Americans,” Abbey Meller and Hauwa Ahmed, August 30, 2019, <https://www.americanprogress.org/issues/democracy/reports/2019/08/30/473911/big-pharma-reaps-profits-hurting-everyday-americans/>.

⁶ Congressional Research Service, “March-In Rights Under Bayh-Dole Act.” John R. Thomas, August 22, 2016, <https://fas.org/sgp/crs/misc/R44597.pdf>.

⁷ 35 U.S.C. Ch. 18. Patient Rights In Inventions Made With Federal Assistance, Public Law 94-517. <https://uscode.house.gov/view.xhtml?path=/prelim@title35/part2/chapter18&edition=prelim>; NIH Grants & Funding, “Bayh-Dole Regulations,” https://grants.nih.gov/grants/bayh-dole.htm#se37.1.401_16.

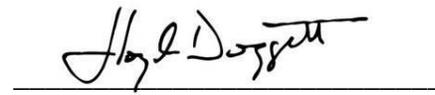
⁸ Center for American Progress, “How the Next Administration Can Lower Drug Prices,” Maura Calsyn and Thomas Waldrop, September 17, 2020, <https://www.americanprogress.org/issues/healthcare/reports/2020/09/17/490140/next-administration-can-lower-drug-prices/>.

⁹ Congress.gov, “National Defense Authorization Act for Fiscal Year 2018 Report,” July 10, 2017, <https://www.congress.gov/115/crpt/srpt125/CRPT-115srpt125.pdf>, p. 173.

2. Please provide a complete list of the drugs, vaccines, and medical technologies that have “benefitted from DOD funding” and have a price that “is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.”
3. For each of the drugs, vaccines, and medical technologies identified in (2):
 - a. Has DOD considered using its authorities under 35 U.S.C. 209(d)(1) or 203 to authorize a third party to produce a lower-cost product? If not, why not?
 - b. Does DOD have plans to use its authorities to expand access to a lower-cost product? If not, why not?
4. What barriers, if any, has DOD faced in implementing the FY18 NDAA Report language?

Sincerely,


Elizabeth Warren
United States Senator


Lloyd Doggett
Member of Congress