

United States Senate

WASHINGTON, DC 20510

June 11, 2025

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Dodaro:

To better understand the extent of excess or underutilized domestic manufacturing capacity and ensure efforts to invest in advanced domestic manufacturing are strategic and cost-effective, we request that GAO evaluate federal efforts related to current domestic manufacturing capabilities and capacity for critical drug products that have a high risk of shortage. Specifically, GAO's evaluation should:

- (1) examine, such as through a survey or other means, excess or underutilized domestic manufacturing capacity for critical drugs and active pharmaceutical ingredients of such drugs, including capacity to manufacture different dosage forms, such as oral tablets and sterile injectable drugs, and the capacity to manufacture drugs with various characteristics, such as cytotoxic drugs and drugs requiring lyophilization;
- (2) assess the types of costs associated with utilizing and expanding existing domestic manufacturing capabilities and federal policies, as of the date of the report, that may help establish or strengthen domestic manufacturing capacity for key starting materials, excipients, active pharmaceutical ingredients, and finished dosage manufacturing establishments; and
- (3) evaluate federal policies designed to invest in advanced domestic manufacturing capabilities and capacity for critical active pharmaceutical ingredients and drug products.

To the extent necessary, GAO's report may include a classified annex containing any information that the Comptroller General determines to be sensitive.

Please provide regular updates on the status of this GAO request. Thank you for your prompt attention to this important matter.

Sincerely,



Senator Gary C. Peters
Ranking Member
Committee on Homeland Security
& Governmental Affairs



Marsha Blackburn
United States Senator



Ted Budd
United States Senator



Tim Kaine
United States Senator