United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

September 2, 2026

The Honorable Orice Williams Brown
Acting Comptroller General of the United States
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Acting Comptroller General Brown:

We write to request that the Government Accountability Office (GAO) conduct a study examining the relationship between the country of pharmaceutical manufacturing origin and drug recall patterns in the United States, as well as the Food and Drug Administration's (FDA) exercise of enforcement discretion with respect to foreign manufacturing facilities whose products appear on the FDA drug shortage list.

Over the past three decades, the United States has ceded an alarming share of its pharmaceutical manufacturing capacity to foreign nations. Since 2000, this trend has accelerated significantly, with active pharmaceutical ingredients (APIs), key starting materials (KSMs), and finished dosage forms increasingly sourced from China and from countries where pharmaceutical manufacturing sectors are substantially dependent on APIs or KSMs sourced from China. This concentration of production in foreign supply chains poses serious risks to American patients, national security, and the integrity of the U.S. drug supply.

FDA's recall data and foreign facility inspection records offer a window into the public health consequences of this dependency. However, no comprehensive, systematic analysis has examined recall rates, recall severity classifications, and inspection outcomes disaggregated by country of manufacture over time. Separately, reporting suggests that FDA has exercised enforcement discretion to defer or deprioritize action against foreign manufacturing facilities with significant compliance deficiencies when those facilities produce drugs listed on the FDA shortage list. The scope, frequency, and downstream public health consequences of such enforcement decisions have not been independently evaluated.

Accordingly, we request that GAO conduct a study comprising the following three components:

Component One: Recall Analysis by Country of Manufacture

GAO should analyze FDA recall data linked to foreign facility registration records to assess recall frequency, classification by severity (Class I, II, and III), and trends by country of manufacture from 2000 to present. The analysis should include, at minimum:

- Recall rates disaggregated by country of manufacture, with particular attention to China and countries whose pharmaceutical sectors are substantially dependent on Chinese-origin APIs and/or KSMs;
- Trends in recall volume and severity classification, including an integrated risk analysis by country, over the study period;
- Comparison of recall rates and severity between domestically manufactured and foreign-manufactured drug products; and
- An assessment of any data gaps or limitations in FDA's recall and facility registration systems that constrain country-of-origin analysis.

Component Two: FDA Enforcement Discretion and the Drug Shortage List

GAO should review FDA's exercise of enforcement discretion with respect to foreign manufacturing facilities subject to Warning Letters, Official Action Indicated (OAI), or Voluntary Action Indicated (VAI) inspection classifications whose drug products appear on the FDA drug shortage list. The review should include, at minimum:

- The frequency and duration of instances in which FDA deferred or deprioritized
- enforcement action against a foreign facility with an active Warning Letter, OAI classification, or VAI classification due to that facility's role in supplying a drug on the drug shortage list;
- The countries of manufacture associated with such facilities;
- Any documented downstream public health outcomes associated with continued market access for products from facilities under deferred enforcement; and
- An assessment of whether FDA has established formal or informal policies governing such enforcement discretion decisions, and whether those policies are applied consistently across inspection classification levels and countries of manufacture.

Component Three: Analysis of FDA's Disclosure of Recalls to Patients

GAO should conduct an analysis of FDA's process for disseminating information on drug product recalls to patients. This analysis should examine, at minimum:

- FDA's processes for informing patients about recalls, including the stakeholders FDA engages with, the sequence and timing of those engagements, and the criteria FDA uses to determine the scope and urgency of patient-facing communications in the event of a recall;
- The relationship between recall classification level (Class I, II, and III) and the extent, timing, and modality of FDA's patient-facing communications, including whether FDA's communication practices are applied consistently across classification levels;
- The extent to which FDA's recall communication processes account for drugs dispensed through mail-order pharmacy and pharmacy benefit managers, including whether patients receiving medications through these channels receive timely and adequate notice of recalls relative to patients served by retail pharmacy;
- FDA's ability to track whether patients are receiving information on recalls, including whether FDA has any systematic mechanism to confirm patient-level receipt of recall notifications, and any gaps that exist in FDA's ability to inform patients and stakeholders during recalls; and
- The degree to which FDA's patient recall communication processes adequately reach older Americans, including seniors who rely on mail-order pharmacy, caregivers managing medications on behalf of older patients, and Medicare beneficiaries for whom generic drug recalls may present heightened disruption risk given limited therapeutic substitution options.

We appreciate your attention to this request. Should you have questions or need additional information, please contact Chairman Scott's staff with the Senate Special Committee on Aging at 202-224-5364 or Ranking Member Gillibrand's staff at 202-224-0185.

Sincerely,

Rick Scott
Chairman
Senate Special Committee on Aging

Kirsten E. Gillibrand
Ranking Member
Senate Special Committee on Aging