



Press Release

Addressing U.S. Drug Shortages and Drug Recalls

PAULINA ENCK | APRIL 4, 2023

Even as the COVID-19 pandemic winds down, drug shortages persist for generic drugs with low-profit margins and significant manufacturing complexity. In a new insight, Director of Health Care Policy Laura Hobbs explores the causes of these shortages and discusses how the Food and Drug Administration (FDA) and Congress could address the issue.

Key points:

- FDA receives relevant information on the global drug supply chain and active pharmaceutical ingredients used to produce many essential medicines but lacks the capacity to properly analyze these data to mitigate or avoid potential drug shortages; industry, too, lacks critical visibility into these supply chains.
- A recent report from the Senate Committee on Homeland Security and Governmental Affairs emphasized, among other things, that drug shortages can occur due to limited manufacturer access to production materials, as well as quality issues or product contamination.
- To address these problems, FDA could standardize the submission of information manufacturers already provide on potential drug shortages; once that data is usable, Congress could allow public disclosure of shortage information to alert manufacturers and increase competition in specific drug markets.

[Read the analysis](#)