

# GAO

## Highlights

Highlights of [GAO-25-107153](#), a report to congressional committees

### Why GAO Did This Study

In addition to rising drug prices, the U.S. has experienced ongoing drug shortages. Understanding the role that nonprofit drug companies could have in addressing these issues is an interest of Congress and researchers.

The Consolidated Appropriations Act, 2023, includes a provision for GAO to review what is known about nonprofit drug companies. This report describes (1) their missions, funding sources, and drug types; (2) challenges they reported; and (3) reported effect of their efforts.

GAO defined a nonprofit drug company as an entity that primarily operates to develop, manufacture, and distribute drugs for the U.S. market and that has a federal tax-exempt status. GAO identified seven companies that met its definition.

To describe their missions, drugs, challenges, and effect, GAO interviewed representatives from all seven companies and reviewed company documents and studies. GAO interviewed three hospitals, one distributor, and one health center that purchase drugs from the companies about their experiences. GAO selected them based on recommendations from nonprofit drug company representatives and research. GAO interviewed Department of the Treasury and IRS officials about a reported tax-exempt status challenge.

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May 2025

## NONPROFIT DRUG COMPANIES

### Information on Funding, Drug Types, Challenges, and Reported Effect

#### What GAO Found

Nonprofit drug companies have more recently emerged as an alternative model to for-profit drug companies. While both bring brand-name and generic drugs to market in the U.S., nonprofit drug companies do not focus on achieving certain profit margins, and their drug development efforts are funded in large part by donations, which are not taxed, unlike for-profit companies. In this report, GAO describes seven nonprofit drug companies.

- Five focused their missions on lowering drug prices or making drugs available for specific patients (such as uninsured women), or both. Two focused their missions on ensuring a steady supply of generic drugs.
- Three received funding only from their company founders to support their efforts, two received funding only from organizations, and two received funding from both sources.
- All three companies with drugs on the market—Civica, Medicines360, and Harm Reduction Therapeutics—received funding in the form of grants or loans from organizations to support their drug development and other related work. These organizations included hospitals, charitable organizations, and a for-profit drug company.
- The companies' current and planned drugs varied and included drugs with a variety of clinical uses.

Company representatives described challenges obtaining funding and expressed concerns about maintaining their tax-exempt status. Representatives from six companies described challenges obtaining enough funding for drug development. For example, representatives from one company described challenges obtaining enough funding from charitable organizations able to donate grants large enough to develop a drug, which the representatives attributed to the limited availability of large grants. Representatives from five companies expressed concerns about maintaining their tax-exempt status when using revenue from their drug sales to support their operations. One drug company reported a concern that revenue from its drug sales could be considered business income unrelated to the company's charitable purpose by the Internal Revenue Service (IRS) and thus taxable. IRS officials told GAO the agency has not taken a position on whether the sale of lower-priced drugs or the sale of drugs to specific patients, for example, serves a charitable purpose. Further, they told GAO that the agency has no set percentage or threshold amount of unrelated business taxable income that would result in the loss of an organization's tax-exempt status.

Representatives from the three companies with drugs on the market described the effect of their ongoing efforts. For example, one company sold a new drug-device combination product at a discounted price to certain hospitals and health centers, and another one provided a steadier supply of generic injectable drugs in shortage to hospitals compared to other manufacturers, according to representatives from the two companies. Representatives from some of the hospitals and the health center GAO spoke with generally agreed with the drug companies' assessments of their effect.