ASPE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE OF SCIENCE & DATA POLICY

REPORT
JULY 2024

# The Potential Role of the Nonprofit Pharmaceutical Industry in Addressing Shortages and Increasing Access to Essential Medicines and Low-Cost Medicines

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## Key Points

- We identified 11 nonprofit pharmaceutical companies that launched between 2000 and 2022 with mission statements aimed to enhance access to affordable and essential drugs or resiliency in the supply chains of medical products.
- Some of these nonprofit pharmaceutical companies owned for-profit subsidiaries as a strategy to navigate a complex tax system; the majority did not have any medical products in the domestic pharmaceutical marketplace, none of them owned their own manufacturing facilities, and their financial statements suggested these tax-exempt companies were comparable in scale to for-profit small businesses and start-up companies.
- Two nonprofit pharmaceutical companies that have successfully launched medical products in the United States used different strategies for commercialization, including using contract manufacturing organizations for labeling and distribution and entering into a licensing agreement with a for-profit pharmaceutical company.
- Findings suggest that while nonprofit pharmaceutical companies hold promise in addressing drug shortages and enhancing access, their capacity and sustainability may be limited due to low production volumes, uncertainties about funding, and inexperience navigating complex tax, regulatory, and reimbursement systems.

## Introduction

Americans rely on medical products, such as prescription drugs, to prevent or treat acute and chronic diseases. However, persistent high prices and shortages threaten access to lifesaving therapeutics and pose a risk to the capacity of America's health system to effectively mitigate and respond to public health emergencies and ongoing public health issues.[1,2] These market gaps in the pharmaceutical industry have prompted a number of companies with alternative business models to enter the market, including nonprofit pharmaceutical companies, which are launched with any specified purpose other than making a profit.

The prevailing business model in the pharmaceutical industry is oriented toward the pursuit of the next blockbuster drug, defined as a drug with $1 billion or more in annual global sales.[3] For-profit companies may utilize their profits to reinvest in research and development (R&D) or deliver a high return on investment to shareholders. However, critics argue that the blockbuster model in the pharmaceutical market incentivizes a non-innovative culture that results in duplicative and nonproductive ventures targeted to populations where high revenues are guaranteed.[4] Further, some researchers have indicated that prioritizing the development of blockbuster drugs contributes to higher prices and unmet public health needs, such as shortages of older

generics and underinvestment in R&D for new antibiotics and drugs for certain rare diseases.[3-6] Researchers have proposed alternative business models to promote growth in the nonprofit pharmaceutical sector and address some of the existing market gaps.[7-10] These alternative business models include nonprofit collaborations with for-profit companies to increase manufacturing and distribution capacity, creation of nonprofit manufacturing and distribution companies, and partnering with other stakeholders to strengthen existing capability and expertise. (See Appendix A for a detailed summary of the alternative economic models that have been proposed in the literature.)

While the emergence of nonprofit companies to address market failures is not a new phenomenon in non-pharmaceutical markets,[11] there has been growing interest, including from Congress,[12] in understanding whether nonprofit pharmaceutical companies could offer solutions to the challenges of drug access and affordability.[8] Drawing from an environmental scan of the literature and key stakeholder interviews, this report examines the ways in which nonprofit pharmaceutical companies can address a number of existing gaps, including their potential role in reducing drug shortages, increasing access to essential medicines, and providing low-cost alternatives to expensive medications.

## Methodology

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) used a qualitative methods approach that included both an environmental scan and key stakeholder interviews. NORC, under contract with ASPE, conducted the preliminary searches and key stakeholder interviews.

### Defining Nonprofit Pharmaceutical Companies

Nonprofit pharmaceutical companies are tax-exempt entities that have an established presence in the pharmaceutical industry, typically pursuing R&D activities and licensing new drugs to for-profit companies. In this report, we define a nonprofit pharmaceutical company as a tax-exempt entity with a publicly disclosed goal of pursuing market authorization and commercialization of drugs to deliver low-cost medicines, including essential drugs and drugs in shortage, and broadening access to medical products. This excludes nonprofit companies that may invest in drug development to secure licensing agreements with for-profit companies and nonprofit companies that provide contract services (e.g., contract development manufacturing organizations [CDMOs]).

### Environmental Scan

The environmental scan used a list of primary and secondary search terms to identify peer-reviewed and grey literature relevant to the topic areas of interest: the nonprofit pharmaceutical sector, low-cost alternatives to expensive medications, drug shortages, and access to essential medicines. The initial search terms included keywords such as (“nonprofit pharmaceutical company” OR “nonprofit biopharmaceutical sector”) AND (“generic drugs” OR “low-cost alternatives”). Appendix B lists the search terms used for the preliminary searches conducted by NORC. The inclusion criteria included materials published in English between 2000 and January 2023. In addition, ASPE supplemented the preliminary searches conducted by NORC using a “snowball” approach to identify other relevant information.

Further, we cross-referenced the list of nonprofit pharmaceutical companies generated from the environmental scan with the IQVIA National Sales Perspective (NSP) dataset to gather market information such as the number of products and total sales from January 2017 to December 2022. For the identified products sold by nonprofit pharmaceutical companies in the IQVIA NSP dataset, we compared the sales volume of those products sold by the nonprofit pharmaceutical sector with the for-profit pharmaceutical sector. We note that this search resulted in the identification of one nonprofit pharmaceutical company, Civica, which indicates that

this is the only nonprofit pharmaceutical company marketing products in the United States during the period of analysis.

### Key Stakeholder Interviews

To supplement the environmental scan, NORC facilitated nine (9) interviews with key informants with expertise in addressing drug shortages, increasing access to essential medicines, or providing low-cost alternatives to expensive medications. Key informants were affiliated with nonprofit and for-profit pharmaceutical companies, academic institutions, and hospitals.

## Background

### Brief History of Nonprofit Companies in the Pharmaceutical Industry

Nonprofit companies are tax-exempt[i] economic entities organized around missions or objectives intended to further a social cause or provide a public benefit. Nonprofit companies differ from the traditional for-profit business model, which aims to maximize profit for investors. Nonprofit companies are restricted from distributing profits to any private shareholder or individual.[13] They leverage their social mission to attract donations from private entities or funding from public entities to finance the provision of their goods and services. Many sectors, such as pharmacies, hospitals, hospices, nursing homes, and home health care, are structured with a mix of nonprofit and for-profit companies. The literature examining non-pharmaceutical sectors suggests that the co-existence of nonprofit and for-profit companies can promote competition and increase access to services for consumers.[14-16] However, little is known about the benefits and implications of these two models in the pharmaceutical industry.

Although the pharmaceutical industry is dominated by for-profit companies, nonprofit companies have a long history of advancing innovation in this industry.[17-20] The majority of their contributions have occurred through R&D activities,[21,22] sponsored by funding from public and private entities. Some nonprofit companies independently conduct R&D with their endowments, royalties, donations, or other funding, while others partner with outside entities leading these activities. Philanthropic nonprofits,[ii] such as the Bill & Melinda Gates Foundation and CureDuchenne, may also fund sponsored targeted R&D projects with nonprofit and for-profit companies.

Typically, nonprofit companies have not pursued commercialization activities, such as obtaining market authorization from the U.S. Food and Drug Administration (FDA) and manufacturing and distributing pharmaceutical products.[8,17,23] The dominant approach has been for nonprofit companies to license new drugs from their R&D pipeline to for-profit companies.[8] Some experts have pointed out that this approach can result in negative consequences: nonprofit companies lose the right to manufacture their drugs exclusively, and for-profit companies launch new drugs with the goal of maximizing profits, which may result in high prices for consumers. For example, the Cystic Fibrosis Foundation (CFF), a philanthropic nonprofit organization, invested $150 million in a for-profit company to develop ivacaftor, the first drug to address the underlying cause of cystic fibrosis.[24] CFF then sold the royalty rights to ivacaftor for $3.3 billion to a different for-profit company.[25] The list price for ivacaftor when it was licensed in 2012 was $294,000 per patient per year.[26] In 2019, a new combination product, Trikafta (elexacaftor/ivacaftor/tezacaftor), was released with an average list price of $322,000 per patient per year.[27] Other examples of innovative and expensive drugs that were initially developed or financed by nonprofit companies and then were licensed to for-profits for commercialization

[i] In some circumstances, nonprofit companies are subject to taxes, such as taxes on unrelated business taxable income (UBTI).
[ii] Philanthropic nonprofits may invest in R&D with for-profit pharmaceutical companies.

include voretigene neparvovec for congenital blindness, tisagenlecleucel for leukemia, and bexarotene for lymphoma.[8,20] While non-exclusive licenses have been cited as an alternative, it is worth noting that licensors must also weigh factors such as costs or profitability to determine the terms of the license. For-profit pharmaceutical companies have also used business strategies such as licensing, mergers, and acquisitions to obtain access to new drugs. Researchers have reported that the share of revenues coming from innovations sourced outside of for-profit companies has grown from 25 percent in 2001 to about 50 percent in 2016.[28,29]

In this report, we focus on nonprofit companies that are pursuing commercialization activities in the pharmaceutical industry.

## Profile of Nonprofit Pharmaceutical Companies, 2000–2022

Table 1 provides a profile of nonprofit pharmaceutical companies that entered the market between 2000 and 2022. The information in the table points to a sector that is largely fragmented. The environmental scan conducted for this report identified 11 nonprofit pharmaceutical companies in the U.S. market that met our definition. Their specific mission statements ranged from providing affordable medications to enhancing access to essential medicines or those in shortage, though each mission statement identified product commercialization as one of the company's goals. Further, the environmental scan revealed variation with respect to the types and number of products nonprofit pharmaceutical companies provide—some focus on a specific treatment area with a handful of products, while others provide dozens of products across multiple therapeutic areas.

The nonprofit pharmaceutical companies also differ in their operations. Some engage in R&D for product development and commercialization. For example, Medicines360 engaged in R&D and commercialization of its hormonal intrauterine device (IUD), which is accessible to low-income women in public clinics across the United States.[10] (This case is discussed in more detail in *Access to Essential* .) In other cases, nonprofit pharmaceutical companies focus only on commercialization activities, such as manufacturing, distribution, and relabeling. For example, Drew Quality Group launched in 2014 with the mission to become a supplier of high-quality generic drugs that are manufactured in the United States.[30] As of March 2023, the environmental scan and key stakeholder interviewers suggest that Drew Quality Group has not yet achieved this objective. Another example is Civica, which entered the market in 2018 with a focus on relabeling and distribution of generic sterile injectables.[31] While there is no one-size-fits-all approach, a common theme is the expressed desire to promote the affordability of drugs and broaden access to pharmaceutical products by engaging in commercialization activities.

All the nonprofit pharmaceutical companies we identified have an Internal Revenue Service (IRS) tax-exempt status as either a 501(c)(3) charitable organization[32] or a 501(c)(4)[iii] social welfare organization.[33] Among the 501(c)(3) charitable organizations, some are designated as public charities rather than as private foundations.[iv] We examined the most recent IRS form 990 for each of the nonprofit pharmaceutical companies[34] and found that all of them reported annual revenues below $20 million, with the majority reporting annual revenues below $2 million. All the nonprofit pharmaceutical companies also reported negative annual net income, indicating expenses exceeded revenues. In contrast, research suggests that from 2000 to 2018, 35 large for-profit pharmaceutical companies reported median annual revenue of $10.6 billion and median net income of $1.1 billion.[35] While nonprofit pharmaceutical companies tend to be comparable to small businesses based on

[iii] 501(c)(4) social welfare organizations differ from 501(c)(3) charitable organizations in that donations or contributions to a 501(c)(4) organization are not tax-deductible on federal tax returns for the entity making the donation.

[iv] Private foundations have lower levels of public involvement and scrutiny in their activities than public charities. While public charities typically receive a greater portion of their funding from public sources, private foundations are typically controlled by small groups of individuals, such as family members.

their revenues or number of employees, the literature and many stakeholders noted that their tax-exempt status does not make them eligible for certain types of funding, such as Small Business Innovation Research grants from the National Institutes of Health (NIH), Small Business Administration (SBA) loans, or even bank loans that require some expected level of revenue.

**Table 1. Nonprofit Pharmaceutical Companies in the United States, 2000–2022**

| Name (Year Founded) | Total Revenue (Year) | Mission Statement | Conditions or Drugs Targeted | Current Drugs in U.S. Market | Associated Companies |
|---|---|---|---|---|---|
| **Civica Inc. (2018)** | $16,726,911, as of 2019 | Provide quality generic medicines that are available and affordable to everyone. | Various conditions requiring generic sterile injectables; insulin for diabetes | Civica Rx is involved in private labeling and distribution of 60 generic sterile injectables; CivicaScript is distributing abiraterone—used to treat prostate cancer—and plans to distribute three low-priced generic insulin products by 2024. | Civica Rx, CivicaScript, and Civica Foundation. While Civica Rx focuses on generic drugs used in the hospital setting, CivicaScript, a public benefit company (PBC),[v] works with pharmacy benefits managers (PBMs) and insurers to bring low-cost generics to outpatient and retail pharmacies. The Civica Foundation is a 501(c)(3) organization that provides philanthropic support to manufacture and distribute generic medications. |
| **Drew Quality Group (2014)** | less than $50,000, as of 2021 | Improve society's health by being a supplier of high-quality generic drugs, manufactured in the United States. | Generic drugs | None | N/A |
| **Fair Access Medicines (2015)** | less than $50,000, as of 2021 | Identify, develop, and deliver life-saving medicines to poorly served patients in the United States and worldwide at the lowest cost possible. | Insulin for diabetes | None | N/A |
| **Harm Reduction Therapeutics (2017)** | $1,550,000, as of 2019 | Make naloxone more accessible for everyday people by combining increased funding, generating more interest in public health, and building on our years of expertise. | Naloxone for opioid overdose | None. Over-the-counter naloxone product approved in July 2023, with an expected launch date in early 2024. | N/A |

[v] Public benefit companies are for-profit entities that maintain profit and public benefit objectives.

| Name (Year Founded) | Total Revenue (Year) | Mission Statement | Conditions or Drugs Targeted | Current Drugs in U.S. Market | Associated Companies |
|---|---|---|---|---|---|
| **Institute for Pediatric Innovation (2006)** | $34,443, as of 2020 | Research and develop innovative products that will improve the health of children and support those who provide care for them. | Pediatric conditions | None. Mission focus has evolved to focus on digital health. | N/A |
| **Medicines360 (2009)** | $17,400,453, as of 2019 | Catalyze equitable access to medicines and devices through product development, policy advocacy, and collaboration with U.S. and global partners. | Contraception, such as hormonal IUDs | One branded hormonal IUD, Liletta, through Actavis; over-the-counter emergency contraceptive through Curae Pharma360. | Medicines360's subsidiary is Curae Pharma360 Inc. which is a for-profit organization focused on improving the availability of quality generic drugs and other medicines that are in short supply. Medicines360 selected Actavis (formerly Watson Women's Health, then Allergan, and now AbbVie) as its for-profit commercial partner for a hormonal IUD. |
| **NP2 (2019)** | $340,500, as of 2020 | Promote public health by developing, manufacturing, and distributing medicines for the treatment of life-threatening diseases in underserved populations. | Generic drugs for cancer | None | N/A |
| **Odylia (2018)** | $60,528, as of 2020 | Accelerate the development of gene therapies for people with rare disease, changing the way treatments are brought from the lab to the clinic…to bring life-changing treatments to people with genetic disease regardless of prevalence or commercial interest. | Gene therapies for rare genetic disorders | None | Odylia has partnered with Cloves Syndrome Community, SATB2 Gene Foundation, Usher 2020 Foundation, RDH12 Fund for Sight, and PTC Therapeutics. |
| **Institute for One World Health \| PATH Drug Solutions (2000)** | $2,972,163, as of 2018 | Develop and deliver lifesaving medicines to women, children, and communities around the globe. | Drugs and vaccines for various infectious diseases, contraception, and maternal and child health | An injectable contraception, subcutaneous depot medroxyprogesterone acetate (DMPA-SC), through Pfizer. | PATH selected Pfizer as its for-profit commercial partner for an injectable contraception. |

| Name (Year Founded) | Total Revenue (Year) | Mission Statement | Conditions or Drugs Targeted | Current Drugs in U.S. Market | Associated Companies |
|---|---|---|---|---|---|
| **Remedy Alliance Inc. (2012)** | $95,600, as of 2021 | Ensure harm reduction programs have sustainable & equitable access to low-cost naloxone for distribution in their communities. | Naloxone for opioid overdose | Remedy Alliance is involved in the distribution of generic naloxone. | N/A |
| **Tutela Pharmaceutical (2020)** | Less than $50,000, as of 2021 | Ensure continued and affordable access of single-source medications to patients. | Single-source medications subject to discontinuation or divestiture by their manufacturers | None. Acquired license from Astellas Pharma Inc. for active ingredient of a medication previously tested for COVID-19. | Collaborators include Zensights, Pharmafusion, Tucker Ellis, LLP, Incubate IP, and Godfrey & Kahn, SC. |

*Note: All general information obtained from company websites; financial information was obtained through IRS.gov.*

Table 2 presents the number of products, sales, and units sold for the only nonprofit pharmaceutical company, Civica, identified in IQVIA's NSP dataset from 2020 to 2022, as well as the corresponding statistics for for-profit companies showing sales and units sold for the same products. The data show that Civica sold 350 million units of 64 products for $256 million in sales. We identified 88 for-profit companies with a total of 20.2 billion units sold and $13.9 billion in sales for the same products, suggesting that sales for the one nonprofit pharmaceutical company represents about 2 percent of total sales and volume for these products.

**Table 2. Descriptive Statistics by Pharmaceutical Sector, United States, 2020–2022**

| Description | Nonprofit | For-profit |
|---|---|---|
| Number of companies | 1 | 88 |
| Number of products | 64 | 64 |
| Total units sold | 350.2 million | 20.2 billion |
| Total sales | $255.9 million | $13.9 billion |

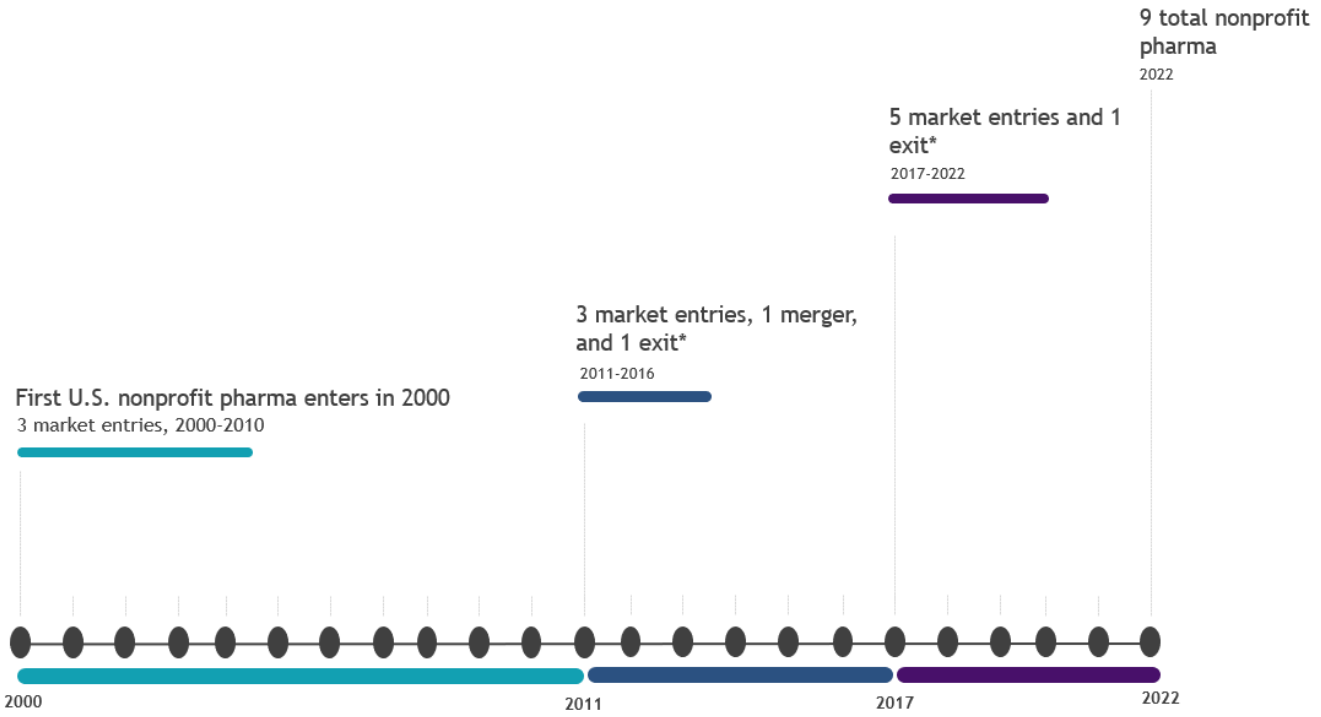
*Note: A product is defined as a molecule-form-strength combination.*
*Source: ASPE analysis of IQVIA National Sales Perspective data.*

## Market Growth

Growth in the nonprofit pharmaceutical sector was slow between 2000 and 2016 with one firm entering the market every three years, on average. Most of the growth in this sector occurred over the five years that followed; on average, one nonprofit pharmaceutical company entered the market each year during 2017–2021. Out of the 11 identified companies, two are no longer operating as originally envisioned (we consider these market exits), and one merged with a global nonprofit company in 2011 (Figure 1). As of August 2023, five of the 11 nonprofit pharmaceutical companies had either received FDA marketing authorization or were distributing medical products in the United States.

The majority of nonprofit pharmaceutical companies were either in the R&D phase of medical product development or looking to secure start-up capital. As discussed above, most nonprofit pharmaceutical companies have historically outsourced the manufacturing, packaging, and labeling of their medical products to contract manufacturers. However, one nonprofit pharmaceutical company, Civica, has exhibited noticeable growth since its creation in 2018. Civica offers over 60 generic sterile injectable medications to over 1,500 hospitals through Civica Rx.[36] Further, in 2021, Civica created CivicaScript, a PBC, to offer generic drugs used in the outpatient and retail settings.[37] The Civica Foundation was also established to provide philanthropic support to manufacture and distribute generics. Civica's rapid growth has been credited to its ability to leverage the long-term commitments of its hospital and health system members to secure long-term supply contracts.[38] These supply contracts have incentivized the reentry of numerous contract manufacturing organizations (CMOs) that had excess capacity and held many of the Abbreviated New Drug Applications (ANDAs) for generic drugs that Civica now labels and distributes to its members.

**Figure 1. Market Growth Timeline, Nonprofit Pharmaceutical Industry, United States, 2000–2022**




**Market exit refers to a shift in mission or operations that no longer covers commercialization activities.*

## Market Entry Strategies

Nonprofit pharmaceutical companies generally begin operations with funding from philanthropic entities or individuals, including crowdsourcing, that support their mission statement. In contrast, for-profit companies depend on raising funds through investors who expect a return on their capital. Without the expectation to sell pharmaceutical products that generate high profit, nonprofit pharmaceutical companies have a different risk tolerance and may be able to provide products with low or negative profit. However, both for-profit and nonprofit pharmaceutical companies face similar costs, timelines, and regulatory oversight when developing and bringing products to market, and both generate revenue from selling drug products and services.

Typically, nonprofit pharmaceutical companies focus on a single product when entering the market. Since they must demonstrate that their mission is compelling enough to motivate access to philanthropic funding, nonprofit pharmaceutical companies tend to be organized around addressing intractable market gaps to improve social welfare—for example, by increasing access to medicines at affordable prices, mitigating drug shortages, or developing new drugs for rare or tropical diseases.

When selecting their target drugs, nonprofit pharmaceutical companies, like their for-profit counterparts, consider multiple factors, such as the target market size, start-up costs, regulatory requirements, and the sustainability of their business model. In interviews, stakeholders noted that nonprofit pharmaceutical companies may prefer to focus on niche drugs such as those with low start-up costs, low margins, or high volumes. Some niche markets that nonprofit pharmaceutical companies have entered are:

- **Essential drugs or drugs in shortage:** Enhancing access to affordable medications, essential or lifesaving medications, and medications that experience persistent shortages is part of the mission of many nonprofit pharmaceutical organizations. This mission can also engender trust in the market as nonprofit

pharmaceutical companies begin to be recognized for filling gaps in market demand and meeting unmet medical needs.

- **Generics:** By targeting off-patent drugs, nonprofit pharmaceutical companies can focus on products that are typically associated with low margins, as well as lower start-up, development, and regulatory costs and lower litigation risks. These products are generally not attractive to for-profit companies due to the low margins and intense pressure to keep prices down via competition.
- **Discontinued drugs:** Nonprofit pharmaceutical companies can fill treatment gaps by focusing on medical products that have been discontinued or abandoned by for-profit companies due to low volume and profitability. These drugs represent opportunities for nonprofit pharmaceutical companies to enter the market.
- **High-volume drugs:** By targeting high-volume products like insulin, nonprofit pharmaceutical companies ensure the market can facilitate competition and business sustainability. Some of these high-volume drugs have experienced persistently high prices, despite being off patent.

## Results

### Low-Cost Alternatives to Expensive Drugs

Many life-saving drugs do not have low-cost alternatives, despite being off patent for an extended period. As a result, patients may incur debt or ration their medications, which leads to medication nonadherence and worse health outcomes.[39] In interviews, stakeholders shared that drug prices are set by for-profit companies to create shareholder value, which is typically achieved by maximizing profit. In contrast, many nonprofit pharmaceutical companies promote the affordability of medical products as a goal in their mission and vision statements. In practice, nonprofit pharmaceutical companies offer a cost-plus model that prices drugs at the level of margins that ensure their sustainability, adding a fixed percentage to the unit cost of each product.

Insulin is an example of a drug for which nonprofit pharmaceutical companies want to provide more alternatives. The global market for insulin is currently dominated by three manufacturers.[39,40] Almost a year after a nonprofit pharmaceutical company announced its two-year plan to enter the insulin market with prices set at $35 per vial, all three of the for-profit companies cut the out-of-pocket cost to a maximum of $35 per vial.[41-43] However, the entry of a nonprofit pharmaceutical company into the market was not the only source of competitive pressure. The decision by the for-profit companies to lower insulin prices followed announcements by the state of California that it was going to manufacture its own insulin in partnership with a PBC that operates a cost-plus model. In addition, the Inflation Reduction Act, signed into law in August 2022, capped out-of-pocket costs for insulin at $35 per monthly prescription for Medicare enrollees beginning January 1, 2023.[39,44]

The entry of nonprofit pharmaceutical companies into markets characterized by expensive generic drugs, few manufacturers, and high volume of sales may increase the competitive pressure for all companies to lower their prices. However, drug prices are driven not only by the pricing structures of manufacturers, who seek to capture the cost of R&D, but also by the markups of intermediaries, such as PBMs, wholesalers, and pharmacies. Drug pricing transparency, particularly around negotiated rebates and discounts, has been a topic of debate to increase the public's understanding of the financial arrangements that affect the profits of stakeholders in the pharmaceutical supply chain. Stakeholders shared that nonprofit pharmaceutical companies are attempting to disrupt persistently high prices for expensive medications by adopting transparency in their financial arrangements as one of their core business strategies. Efforts at providing transparency include disclosing the price and charging the same price for all members, without volume discounts.

Another strategy that nonprofit pharmaceutical companies are adopting to increase competitive pressure is to bring to market over-the-counter (OTC) alternatives to expensive prescription drugs. OTC drugs are typically sold at lower prices than drugs that require a prescription or that are administered in hospitals or physician offices. An example of a nonprofit pharmaceutical company that used this strategy is Harm Reduction Therapeutics, which was inspired to offer an OTC version of naloxone, a life-saving drug used to reverse an opioid overdose, as a way of counteracting price hikes.[45] Although FDA had encouraged sponsor applications for OTC naloxone products in 2019,[46] no existing for-profit company had submitted a New Drug Application (NDA) for OTC naloxone until two months after the nonprofit pharmaceutical company submitted its NDA in late 2022.[47,48] On March 29, 2023, FDA approved the first OTC naloxone product, developed by a for-profit company, and sales began in the summer 2023.[49] On July 28, 2023, FDA approved Harm Reduction Therapeutics' ReVIVE, with sales beginning in early 2024.[50]

*Challenges*

Nonprofit pharmaceutical companies have limited capacity to offer alternatives for expensive drugs that are not off-patent or are protected by a market exclusivity. While many nonprofit companies contribute to drug discovery and development, they typically leverage partnerships with for-profit pharmaceutical companies to commercialize their products, which creates uncertainties about the pricing model that will be used. For example, although Targretin (bexarotene), a cancer drug, was developed by nonprofit pharmaceutical companies and now has generic competitors available, it was commercialized in partnership with a for-profit company [22] and is sold for almost $30,000 for 100 capsules.[51] A related challenge is that the business structure of nonprofit pharmaceutical companies with wholly owned for-profit subsidiaries has the potential to undermine their credibility regarding transparency in drug pricing. One example is CivicaScript, a subsidiary of Civica that was established as a for-profit PBC, which focuses on generic drugs distributed via retail, mail, and outpatient channels for participating pharmacies.[38]

The low levels of therapeutic concentration and market share achieved to date by nonprofit pharmaceutical companies may not be sufficient to disrupt drug pricing in the pharmaceutical market, for multiple reasons. First, stakeholders we interviewed noted that prices of nonprofit pharmaceutical company drugs may not be the lowest in the market at any given time because their prices are designed to create stability in the market and to be the lowest sustainable price for nonprofit pharmaceutical companies (see *Drug Shortages* for additional discussion). Second, since list prices for drugs do not reflect markups along the pharmaceutical supply chain for each distribution channel, it is difficult to quantify the actual savings for payers and patients when there is a mix in business models. This is especially true for drugs that are administered in hospitals or physician offices because the reimbursements for those drugs are usually bundled with the reimbursements for other services.[52] Third, while OTC products tend to be low cost, OTC drugs are not covered by health insurance, which may limit patient savings as well as the number and types of patients that could benefit from these drugs.[53]

## Drug Shortages

According to FDA, the majority of drugs in shortage are sterile injectables and older generic drugs with a median time of 35 years since first approval.[54] Root causes of generic drug shortages are the low profitability of generic drugs and the lack of market rewards for generic manufacturers that invest in quality management maturity; shortages can also occur due to supply chain disruptions or increased demand.[vi]

[vi] Quality management maturity measures the consistency and reliability of business processes to assure and maintain the quality of products in the marketplace, including early signals to enable actions to prevent drug shortages triggered by quality issues.

The nonprofit funding model, which does not expect the same high rates of return for investors, suggests that nonprofit pharmaceutical companies may be able to sell drugs, such as generics, that are associated with low profits. However, just like any organization, nonprofit pharmaceutical companies need to balance their sustainability and cost goals. Some researchers have proposed using the Health Care Utility (HCU) model,[vii] a novel governance and financing structure, to address drug shortages and persistent price hikes of generic drugs.[55] The HCU model relies on member[viii] financing to provide products and services at the lowest sustainable price. Proponents of the HCU model argue that its core tenets address the factors and misaligned incentives that contribute to drug shortages.[6] The HCU model informed the business structure of Civica Rx, which provides same-price guarantees with no volume discounts, requires long-term commitments, and embeds a quality assurance process in its contracts with CMOs.[36,38] This pricing approach includes maintaining a six-month buffer supply of its products as a mitigation strategy against drug shortages or supply chain interruptions.[56] Further, Civica Rx limits its volume agreements to 50 percent of each member's total volume and establishes contracts with multiple CMOs in North America, Europe, and South Asia to increase the geographical diversity of its suppliers and mitigate supply chain risks.[36]

*Challenges*

In interviews, some stakeholders shared that the pricing of products by nonprofit pharmaceutical companies, like Civica Rx, may not be the cheapest on the market because their pricing may account for the cost of investments in quality management systems to mitigate shortages. Stakeholders pointed out that the HCU approach to addressing drug shortages is limited because it provides drugs for members only. The volume of drugs produced by nonprofit pharmaceutical companies may also be too low to have an impact in the broader market. Further, since many nonprofit pharmaceutical companies neither own the license to nor manufacture their own generic drugs, some function like a group purchasing organization (GPO), and as such, they have no control over the price that patients ultimately pay.

Some stakeholders have been skeptical about the feasibility of replicating or scaling up models like the one used by Civica Rx, for multiple reasons. First, long-term contracts may result in members paying a price that is higher than the lowest available market price in the short term, although the price would remain unchanged when there is a shortage. Another risk is the potential to further concentrate bargaining power in one entity and perpetuate the existing oligopoly in the pharmaceutical industry. Stakeholders shared lessons from the health care industry, which is dominated by nonprofit health systems, that suggest the nonprofit model may not always translate to maximizing social welfare. For example, research suggests that nonprofit hospitals are not more likely to provide charity care or unprofitable services than their for-profit counterparts.[57]

## Access to Essential Medicines

FDA, in collaboration with other federal agencies, began developing and publishing a list of essential medicines, medical countermeasures, and critical inputs in 2020 in response to President Trump's Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States.[58] FDA's list of essential medicines identifies those medical products that have the greatest potential impact on public health and are most needed by patients for acute and urgent medical conditions. The goal of FDA's essential medicines list is to ensure that the American public is protected against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear threats by ensuring sufficient and reliable long-term domestic production of these products.[59] Another list of essential medicines, managed by the World

[vii] Utility is a reference to commonly shared basic goods, such as electricity and gas.

[viii] Members are customers of the HCU; for example, health systems are the customers for hospital-based drugs and health insurance companies are customers for retail drugs. Some call the HCU a "closed-system" model because only members have access to the products and services.

Health Organization (WHO), identifies medications that may be critical to ensuring that a nation's health system can meet the health care needs of its population. The WHO list of essential medicines prioritizes disease prevalence, public health relevance, and evidence on efficacy, safety, and comparative cost-effectiveness. For this report, we examine the role of nonprofit pharmaceutical companies in addressing gaps in the provision of critical medicines for both chronic and acute health conditions.[60] For purposes of the stakeholder interviews, essential medicines were broadly defined to include those in the FDA list of essential medicines and others such as oncology drugs or sterile injectables.

In interviews, stakeholders shared that nonprofit pharmaceutical companies could increase access to essential medicines by leading R&D for low-volume medical products to address unmet health needs, such as products focused on rare diseases, neglected tropical diseases, and antimicrobial resistance. Examples of nonprofit pharmaceutical companies engaged in R&D to develop new technologies include Innovative Genomics Institute (IGI), which is working to develop and commercialize CRISPR gene-editing therapies to treat sickle cell disease.[61] Further, the environmental scan identified that R&D and commercialization for new antibiotics to combat antimicrobial resistance is another market gap that may be appropriate for nonprofit pharmaceutical companies.[62,63] In comparison to brand-name drugs in other therapeutic areas, new antimicrobials typically have very low volumes and low prices.[64]

Strategies to bring critical medical products to market at lower cost include identifying new uses and indications for approved and off-patent drugs, a strategy known as drug repurposing.[65] Since safety data exists for approved drugs, it has been estimated that nonprofit pharmaceutical companies can avoid approximately 40 percent of the costs for drug development by repurposing approved drugs.[66] This strategy can be effective for conditions that have few treatments available, such as rare and neglected diseases. For example, the Institute for One World Health repurposed paromomycin, an off-patent drug that is no longer used as an antibiotic, to cure visceral leishmaniasis, a neglected tropical disease.[ix]

A closely related strategy focuses on rescuing abandoned compounds. These are compounds that for-profit companies researched and developed safety and efficacy data for, but ultimately abandoned before completing development and attaining regulatory approval, typically due to concerns over low profitability. This market gap presents opportunities for nonprofit pharmaceutical companies. In one example, the nonprofit Tutela Pharmaceutical executed an exclusive license agreement for a compound that was abandoned by a for-profit company after the completion of phase 1 and 2 clinical trials.

Another market gap of interest to nonprofit pharmaceutical companies is increasing access to drugs for underserved populations by prioritizing diversity in clinical trials to ensure generalizability of evidence. For example, Medicines360 sponsored a phase 3 clinical trial for the first hormonal IUD that prioritized diversity in the enrollment of clinical trial participants. The company generated safety and efficacy evidence for women of all races, women who had never given birth, overweight or obese women, and women with sexually treated infections—something that wasn't done for hormonal IUDs that were available on the market at the time.[10] The environmental scan identified a study that concluded that patients at a Title X clinic experienced increased uptake and decreased average payments after the introduction of Medicines360's hormonal IUD.[67] This was the only example we identified of a nonprofit pharmaceutical company successfully developing and commercializing a branded medical product for the U.S. market. While this nonprofit pharmaceutical company retained ownership of the NDA, commercialization of the medical product occurred through a licensing agreement with a for-profit company. In exchange for licensing the intellectual property of the nonprofit

[ix] It is worth noting that NIH's National Center for Advancing Translational Sciences created a drug repurposing program intended to facilitate sharing of data and other resources for scientists and others interested in repurposing drugs. See https://sites.google.com/ncats.nih.gov/therapeutic-repurposing/home.

pharmaceutical company, the for-profit company committed to prioritizing commercialization of the hormonal IUD, paid an upfront payment and milestone payments, and paid continuous royalties on units sold, which are non-taxable because they are not classified as unrelated business income.[10] Retaining ownership of the license allowed Medicines360 to maintain ownership of the drug and reinvest in R&D to identify new indications. Stakeholders noted that entry by Medicines360 for an underserved market spurred additional investment and development of new products by for-profit companies. Other strategies that nonprofit pharmaceutical companies have adopted to launch their products include creating wholly owned for-profit subsidiaries, entering into partnerships with PBCs, or selling the license to a for-profit pharmaceutical company. However, as noted above, these types of partnerships or business structures have the potential to undermine their credibility regarding transparency in drug pricing.

*Challenges*

Nonprofit pharmaceutical companies face challenges with repurposing off-patent drugs and rescuing abandoned compounds, including difficulty raising capital to conduct expensive phase 3 clinical trials and aligning with donor priorities.[66] For example, disulfiram, a drug approved as an anti-alcoholism medication, has been proposed as a candidate to be repurposed to treat many diseases, including various cancers, Alzheimer's disease, and COVID-19.[66,68] However, in such circumstances, nonprofit pharmaceutical companies must consider the interests of their donors as they prioritize which potential new indications to pursue. While donors may prioritize public benefits, it is unclear that their priorities will always align with public health needs that maximize social welfare.

Further, the risk of donor fatigue undermines the long-term sustainability of the nonprofit model. Pull incentives, wherein the government aims to reward new drug development for underserved markets by reducing the risk of insufficient future revenue streams through higher reimbursement policies, have been successfully employed to develop new hospital-based antibiotics. For example, the Centers for Medicare & Medicaid Services (CMS) have paid new technology add-on payments for novel antibiotics used in the inpatient setting.[69] However, oftentimes sales revenue from antibiotics cannot sustain a company's infrastructure costs, so other investments unrelated to sales revenue would also be necessary to ensure the sustainability of the nonprofit model for companies developing antibiotics or other low-volume medical products.[64,69]

Beyond R&D costs, nonprofit pharmaceutical companies need to raise funds for complex commercialization activities, such as manufacturing, distribution, reimbursement, and post-marketing commitments. If a company's nonprofit tax-exempt status was obtained based on a mission to conduct research, then its sales revenue from commercialized medical products may be subject to business income taxes. In addition, stakeholders shared that commercial activity by nonprofit pharmaceutical companies may attract litigation and jeopardize tax-exempt status under the IRS "commerciality" doctrine.[x] Stakeholders also noted that FDA has limited experience working with nonprofit pharmaceutical companies, who may also not be aware of flexibilities available to them.

Nonprofit pharmaceutical companies adopt several strategies to navigate the complex pharmaceutical supply chains in the United States and retain tax-exempt status. However, some of these strategies may not be feasible for low-volume products. In one example, stakeholders shared that a nonprofit pharmaceutical company regained ownership of a gene therapy that was licensed to a for-profit company, likely because of claw-back clauses[xi] in the licensing agreement. For several years after gaining the license for the gene therapy,

[x] In its determination that a business entity did not qualify as a 501(c)(3) organization, IRS stated "factors courts have considered in assessing commerciality are competition with for-profit commercial entities; extent and degree of below cost services provided; pricing policies; and reasonableness of financial reserves."

[xi] Claw back is a contractual provision that allows an instance of recovering assets or benefits previously given out.

the for-profit company had been unable to meet the comparability[xii] requirement to scale it, and the company had ultimately terminated related development activities. While the gene therapy may be available to patients through the compassionate use program, shareholders stated that nonprofit pharmaceutical companies may not have the financial resources and expertise required to launch phase 3 trials, pay FDA user fees, maintain all of the regulatory requirements to obtain FDA approval, or meet manufacturing requirements for widespread distribution without a commercial for-profit partner.

## Limitations

This report has several limitations. First, the stakeholder interviews were limited to nine experts, and as such, the findings from this report may not be generalizable to all stakeholders impacted or involved. For example, the stakeholder interviews included a limited number of experts from the for-profit pharmaceutical industry. Further, although the environmental scan aimed to include broad terms, it is possible that our search terms and results did not capture other key topics or issues. Lastly, given the nascent nature of this sector, there was limited availability of data to quantitatively examine the role of the nonprofit pharmaceutical companies in increasing the supply of essential and affordable drugs.

## Discussion and Conclusion

The findings from this report suggest that nonprofit pharmaceutical companies have the potential to address drug shortages and enhance access to affordable and essential medicines. However, their sustainability and effectiveness may be limited due to low production volumes, a complex tax system, ineligibility for small business funding sources, and to some extent, lack of awareness of nonprofit pharmaceutical companies by the government and the public at large.

Although this report identified 11 companies in the nonprofit pharmaceutical sector, only one was captured in a database of drugs sold in the United States during 2020–2022. The data showed that the volume of sales for this nonprofit pharmaceutical company, which sells 60-plus generic sterile injectables, represented about 2 percent of the total sales volume for the same generics sold by for-profit companies. This finding aligns with stakeholder interviews that indicated that nonprofit pharmaceutical companies currently have limited ability to fill large gaps in the market or create pressure to bring prices down due to their low production volume.

Due to the lack of profit motive, nonprofit pharmaceutical companies have a different risk profile and set of strategies than their for-profit counterparts. Because of this, nonprofit pharmaceutical companies have the potential to increase access to essential and affordable medicines. For example, their strategies to repurpose generics, pick up abandoned products, or bring OTC products to market have partly contributed to pressure on the industry to increase access to low-cost insulin products and to bring OTC naloxone products to market. Further, the focus of nonprofit pharmaceutical companies on low-volume drugs necessitates the conduct of R&D or commercialization activities on essential medicines that for-profit companies may not deem commercially viable.

While nonprofit pharmaceutical companies are governed by a different set of tax laws than for-profit companies, they are subject to the same FDA regulatory requirements and R&D costs to bring products to market. This has led nonprofit pharmaceutical companies to target products that are relatively inexpensive to

[xii] Comparability requirement means demonstrating that phase 2 results are comparable to phase 3 results.

develop and that have a higher probability of success. Some industry experts do not see nonprofit pharmaceutical companies as disruptors to the industry or as a source of solutions to the issues at hand based on the fact that many of their activities involve relabeling approved products and have low sales volume.

Although nonprofit pharmaceutical companies can leverage their tax-exempt status to seek funding from diverse sources, the complex tax environment sometimes results in a mixed structure of nonprofit and for-profit companies operating under the same organizational umbrella, and this can blur efforts to increase transparency or ensure that drugs are affordable. Though the majority of nonprofit pharmaceutical companies have operational sizes comparable with small businesses, their tax-exempt status makes them ineligible for some types of funding, such as grants from the NIH Small Business Innovation Research program, SBA loans, or even bank loans that require some expected level of revenue. Further, reliance on diverse funding sources can create challenges for nonprofit pharmaceutical companies seeking to align their drug development and commercialization activities with public health priorities.

Through the literature search and stakeholder interviews, we identified a variety of approaches to addressing challenges that nonprofit pharmaceutical companies face. These approaches can be largely divided into financial and nonfinancial incentives. Financial incentives include the establishment of a federal program or set of initiatives that could fund or provide financial support for the development and manufacturing of drugs by nonprofit pharmaceutical companies at all stages of the product life cycle—from early discovery research activities to commercialization—and that could also provide financial support for capital investments. Stakeholders proposed a number of financial incentives tailored to the nonprofit pharmaceutical sector, such as interest-free loans, grants, cooperative agreements, loans not requiring repayment, and advanced purchasing agreements with the government (which would enhance the sustainability of nonprofit companies). Stakeholders and the literature also cited other existing tools that could be leveraged to expand eligibility to the nonprofit pharmaceutical sector, including NIH's Small Business Innovation Research grants, the Health Resources and Services Administration's (HRSA's) 340B Drug Pricing Program, and advanced purchasing commitments from the Strategic National Stockpile.

In addition to the proposed initiatives discussed above, several Congressional bills have been introduced in recent years aimed at the nonprofit pharmaceutical sector. These include Senate Bill 2257, the Expanding Access to Affordable Prescription Drugs and Medical Devices Act, introduced in 2021, which included provisions for funding and low-interest loans to support nonprofit drug development and required FDA user fee waivers. Financial initiatives such as the provisions included in this bill could align eligibility with certain criteria such as manufacturing drugs that are essential, in shortage, or fulfilling a public health need. As an example of the impact of federal funding, some stakeholders cited funding that allowed Civica to begin construction of a manufacturing facility in Virginia. This funding was awarded to Phlow Corporation, a U.S. drug manufacturing PBC, by the U.S. Administration for Strategic Preparedness and Response (ASPR) to build manufacturing capacity of essential medicines in shortage.[70,71] Stakeholders noted that federal support, in the form of funding or purchase agreements, would help ensure that nonprofit pharmaceutical companies achieve a production volume sufficient to exert pressure in the industry, increase their sustainability and financial stability, and also increase awareness of and trust in the nonprofit pharmaceutical sector. This support could promote market entry, competition, and expansion in this sector.

Existing literature and stakeholders have also proposed non-financial incentives to encourage growth in the nonprofit pharmaceutical sector. Specific examples include expediting FDA review of nonprofit applicant submissions or creating separate regulatory programs for nonprofit pharmaceutical companies. As noted above, regulatory challenges are not specific to the nonprofit pharmaceutical sector. Past studies focused on the for-profit sector have proposed similar solutions (i.e., reduced FDA timelines, simplification of clinical trial protocols, increased interactions with FDA, improved predictability of the review process) to reduce the cost of

bringing drugs to market.[72] FDA already uses existing tools to address drug shortages, including approaches that involve prioritizing and expediting review of certain applications and inspections, providing technical assistance and guidance for small companies,[73] and authorizing waivers, reductions, exemptions, or refunds of user fees when certain conditions are met.[74] However, further research is needed to understand how these existing tools can be leveraged to address issues that are specific to the nonprofit pharmaceutical sector.

Through the literature review and discussions with stakeholders, we also identified proposals for using changes to the tax code as a way to lower the entry barrier for nonprofit companies in the pharmaceutical sector. Policy proposals include creating tax incentives that can facilitate the transfer of patents of abandoned drugs, creating incentives for for-profit companies to partner with nonprofit pharmaceutical companies, clarifying the tax code to facilitate activities and funding mechanisms, creating a new tax-exempt designation for nonprofit pharmaceutical companies that are fulfilling a public health need, classifying drug sales of nonprofit pharmaceutical companies as non-taxable revenue, and creating protections to uphold the IRS nonprofit designation. However, stakeholders highlighted the risk of mission drift and oligopoly in the nonprofit pharmaceutical sector if regulations are not implemented to ensure accountability. Literature and stakeholders provided lessons learned from the health care industry, which is dominated by nonprofit health systems, that suggest that the nonprofit model may not always maximize social welfare.

To conclude, while the nonprofit pharmaceutical sector holds promise and can play a role in addressing drug shortages and enhancing access to affordable and essential medicines, more research is needed to understand the available or potential tools that can reduce existing barriers and challenges, as well as understand their implications on competition, drug pricing, and innovation in the pharmaceutical industry.

## Appendix A. Alternative Economic Models for Commercialization by Nonprofit Pharmaceutical Companies

Several alternative economic models have been proposed in the literature to promote market authorization and commercialization by nonprofit pharmaceutical companies in the marketplace. Three of them are summarized below.

### Nonprofit pharmaceutical companies as market authorization holders leveraging the manufacturing and distribution expertise of for-profit companies

Existing literature has proposed that nonprofit pharmaceutical companies could expand their organizational capacity to pursue market authorization of new products discovered through their R&D pipeline rather than license the intellectual property or engage in mergers and acquisitions.[8,9,23] In this model, nonprofit pharmaceutical companies would leverage the expertise of for-profit pharmaceutical companies to maximize efficiency in production and distribution.[8] For example, nonprofit pharmaceutical companies could license new products to multiple for-profit companies for manufacturing and distribution. Further, the partnership agreements could include clauses to ensure social welfare outcomes, such as affordability and access for underserved populations, and balance sustainability against the need to generate profits. Proponents of this model state that this strategy could ensure that pricing is guided by drug affordability goals.

An important challenge to scaling up this strategy is that nonprofit pharmaceutical companies may not have the expertise or financial resources to navigate clinical development activities, such as phase 3 clinical trials. Another challenge is ensuring that a nonprofit pharmaceutical company is accountable to its core mission and will not engage in misaligned actions, such as price-gouging. Participation on the board of trustees by major donors and patients, who have a financial interest in drug affordability and accessibility, may mitigate this risk.[6]

Medicines360 demonstrated the viability of this concept with the commercialization of its hormonal IUD in the United States.[10] The product was initially launched with an $82 million grant from a private philanthropic nonprofit. The total cost, including product liability insurance, of bringing the hormonal IUD to market was $73.4 million. Medicines360 partnered with Actavis, a for-profit company. However, Medicines360 retained its rights to market the hormonal IUD at a deeply discounted price to public clinics and hospitals, such as federally qualified health centers, throughout the United States. Similarly, Medicines360 retained marketing rights to sell the hormonal IUD in low- and middle-income countries.

### Nonprofit pharmaceutical companies as market authorization holders with in-house manufacturing and distribution expertise

In this model, nonprofit pharmaceutical companies would expand their organizational capacity to manage all commercialization activities, including manufacturing and distribution.[8,9] An important barrier to adopting this approach is the high start-up costs for new nonprofit pharmaceutical companies that do not have the ability to leverage the economies of scale of established for-profit companies. This is a particular problem for low-volume and new pharmaceutical products. One solution is for nonprofit pharmaceutical companies to modify this approach by outsourcing actual production to CMOs. Another solution would involve selling exclusive licensing of some products to raise start-up capital for internal commercialization of other products.[8]

Proponents state that this strategy could be appropriate for nonprofit pharmaceutical companies that want to target drugs that are not costly to bring to market, such as old generic drugs that have low profits and experience frequent shortages.[6] The ANDA process to obtain market authorization for old generic drugs is less expensive because some of the regulatory requirements can be fulfilled with existing data on efficacy and

safety. An ASPE analysis found that the average cost to develop a generic drug was $2.4 million ($3.2 million in 2022 dollars) and the time required to bring the product to market was just under five years.[75]

One example of a nonprofit pharmaceutical company demonstrating the viability of this model for old generic drugs is Civica.[38] As of March 2023, Civica Rx was distributing 60 generic sterile injectables to its members in the United States through its supply contracts with foreign and domestic CMOs. Civica is in the process of expanding to outpatient and retail pharmacies through CivicaScript. While Civica currently relies on ANDAs of its CMOs, it plans to obtain its own ANDAs for generic drugs, such as insulin, and is building a manufacturing facility in Virginia.[36,38]

### Nonprofit pharmaceutical companies leveraging product development partnerships

Nonprofit Product Development Partnerships (PDPs) are another model that has proven successful for launching affordable and accessible medical products. PDPs coordinate financial and development efforts for medical product development in partnership with for-profits, nonprofits, and public stakeholders. For example, the Global Alliance for TB Drug Development (TB Alliance) received FDA approval for pretomanid to treat extensively drug-resistant tuberculosis. TB Alliance negotiated license agreements to ensure access in low-income countries.[76] Nonprofit PDPs have succeeded in bringing many medical products to market that address unmet public health needs in low- and middle-income countries.[77] PATH, a U.S.-based nonprofit, obtained FDA approval and commercialized depot medroxyprogesterone acetate (DMPA-SC), an injectable contraceptive, for the domestic market through a PDP.[77,78] Joint academic-industry-government alliances to foster collaboration are also common in the United States and have similar objectives to those of PDPs.[79] However, they are not formally incorporated.

## Appendix B. Environmental Scan Search Terms

| Primary Search Terms | Secondary Search Terms |
|---|---|
| Nonprofit pharmaceutical company | **Cost/Costly/High Cost** |
| Pharmaceutical public benefit corporation | Price |
| Nonprofit pharmaceutical sector | Affordability |
| Nonprofit pharmaceutical market | Low-cost generic drugs |
| Nonprofit biopharmaceutical company | Low-cost alternatives |
| Biopharmaceutical public benefit corporation | Low-cost substitutes |
| Nonprofit biopharmaceutical sector | Low-cost biosimilars |
| Nonprofit biopharmaceutical market | Reimbursement |
| Biotechnology | Payers |
| Nongovernmental pharmaceutical company | **Access** |
| Charitable organizations | Drug shortage |
| Tax-exempt organizations | Essential drugs/medications |
| | Life-threatening disease/rare disease |
| | Life-saving medication |
| | Critical drugs |
| | Public health emergency |
| | Orphan drugs |
| | **Specific Drugs** |
| | Antibiotics/antibacterials/antimicrobials |
| | Saline |
| | CNS drugs |

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The authors gratefully acknowledge research support from NORC at the University of Chicago (NORC) under contract #HHSP233201500048I.

**SUGGESTED CITATION**
Adetunji, O., Oliver, J.F., Parasrampuria, S., Singson, G., and Beleche, T. “The Potential Role of the Nonprofit Pharmaceutical Industry in Addressing Shortages and Increasing Access to Essential Medicines and Low-Cost Medicines.” Washington, D.C.: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. July 2024.



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