Nonprofit Pharmaceutical Companies: Background, Challenges, and Policy Options

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Executive Summary

Over the past several years, high prescription drug prices have caught the attention of past and current administrations, Congress, the media, and the public. Driven by the need to generate value for shareholders and sustain profits, for-profit pharmaceutical companies are major contributors to this problem, imposing excessive launch prices for new drugs and annual price increases for existing ones that often outpace the inflation rate.[1]

To address high drug prices and the challenges they create for access to drugs, organizations have been exploring and working to create nonprofit pharmaceutical companies. These nonprofit companies prioritize drug access and affordability in the United States as core components of their mission. In the current federal policy landscape, however, there are specific incentives for the operation of for-profit pharmaceutical companies that do not similarly benefit their nonprofit counterparts, as well as several other barriers to sustainability for nonprofit companies.

Waxman Strategies sought to understand the existing policy landscape, including its challenges, and to identify potential policy solutions to ensure greater sustainability for nonprofit pharmaceutical models, with a broader goal of placing nonprofits on a level playing field with for-profit companies. Beginning in July 2019, this work proceeded in several stages, including a comprehensive literature review, semi-structured interviews with subject-matter experts, and a roundtable discussion among current and former leaders from nonprofit pharmaceutical companies.

This paper reviews the project's key findings, which can be roughly divided into five themes:

- **Tax code** issues, including the current federal requirements for charitable tax-exempt organizations, pose fundamental challenges to the work of nonprofit pharmaceutical companies in support of their mission to provide low-cost drug products.
- Absent venture capital's traditional role in **financing drug research and development**, nonprofit pharmaceutical companies face extraordinary difficulties in raising money for research and development, operations, and attracting talent.
- The **U.S. Food and Drug Administration (FDA) policies and practices**—particularly the extraction of large user fees from drug manufacturers regardless of their profitability or mission—pose obstacles to the sustainability of nonprofit companies.
- Nonprofit pharmaceutical companies lack **access to pharmaceutical supply chains and distribution channels**, which are dominated by large for-profit pharmaceutical companies and wholesalers.
- Nonprofit pharmaceutical companies also report that **federal health program reimbursement policies**—many of which are well-intentioned such as the Medicaid "best price" rules—present a challenge to nonprofit companies seeking to offer lower prices for all or select markets.

Based on these challenges, along with discussions with experts and nonprofit leaders, this paper concludes by proposing a potential menu of options that policymakers may consider in order to address barriers and design new incentives to encourage the nonprofit pharmaceutical model and ensure its sustainability in addressing the problem of high prescription drug prices.

Background

Beginning in July 2019, Waxman Strategies began examining the landscape, including the principal challenges confronting nonprofit pharmaceutical companies, and seeking to identify potential policy options to address those challenges. This project proceeded in several stages, including a comprehensive literature review, semi-structured interviews with subject-matter experts, and a roundtable discussion between leaders from nonprofit pharmaceutical companies.

Initial research revealed that, though the nonprofit pharmaceutical model has historically been focused on bringing affordable drugs to market in the developing world, a variety of nonprofit companies have more recently focused their efforts to provide products in the United States. These companies are at various stages of maturity, ranging from those at the earliest stages of establishing a nonprofit organization, to others with products that have been commercialized and are available on the market. They also differ in their specific objectives. For instance, some organizations focus on developing new drugs for conditions that have been neglected by for-profit companies due to the lack of revenue the products may generate or are on the FDA drug shortage list. Others seek to address unmet medical needs with novel products, such as over-the-counter versions or lower-priced competitors to existing products on the market. Still others aim to create generic versions of existing drugs to create price competition. Despite these differences, we found that nonprofit companies typically share in common a fundamental commitment to ensure access to affordable drugs that are currently not available on the market or are prohibitively expensive. By virtue of their nonprofit status, these organizations report that they are able to pursue research and development that traditional for-profit companies have avoided because of the latter's need to maximize their profits. The first stage of background research for this project also yielded preliminary insights into some of the policy barriers that nonprofit companies were thought likely to experience in the areas of the federal tax code, the FDA's policies and processes, and the pharmaceutical supply chain.[2]

Subject-matter interviews further illuminated the tensions between existing policies and the nonprofit model. Seventeen experts were interviewed, including academic researchers, lawyers with expertise in the pharmaceutical industry or nonprofit organizations, pharmaceutical industry consultants, and current and former leaders of nonprofit pharmaceutical or device companies. Discussions were guided by a series of questions intended to inquire about the principal challenges confronting nonprofit pharmaceutical companies and how they might be resolved through policy change. As themes emerged from these interviews, a framework of issues took shape. This framework divides nonprofit companies' challenges into roughly five areas corresponding to the successive stages of the nonprofit drug development and commercialization process: tax status; capital investment and funding; FDA issues; supply and distribution; and reimbursement.

After completing the subject-matter expert interviews, Waxman Strategies invited 12 individuals—most of whom are current or former leaders of nonprofit pharmaceutical companies—to participate in a roundtable discussion held in Washington, DC, on October 29, 2019. The purpose of the roundtable was to further clarify and refine the framework of issues that emerged from the preceding interviews and to identify the most promising policy

solutions. The balance of this paper is intended to summarize the highlights from this discussion. Roundtable participants included:

- Deborah Drew, Director, Founder, and Chairman, Drew Quality Group
- Autumn Ehnow, Vice President, Public Policy and Government Affairs, Medicines360
- Debbi Ford, Chief Communications and Public Affairs Officer, CivicaRx
- Jessica Grossman, MD, Chief Executive Officer, Medicines360
- Michael Hufford, PhD, Co-Founder and Chief Executive Officer, Harm Reduction Therapeutics
- Donald Joseph, JD, Director and former CEO, BIO Ventures for Global Health
- Carolyn Kahn, PhD, Vice President, Fair Access Medicines
- Regine Lanfranchi, RPh, PharmD, BCPS, Head of Medical Affairs, Drew Quality Group
- Joff Masukawa, President and Founder, Diligentia Strategy
- John Pinney, Co-Founder and Chairman of the Board, Harm Reduction Therapeutics
- Martin VanTrieste, President and Chief Executive Officer, CivicaRx
- Jim Wilkins, PhD, President and Founder, Fair Access Medicines

Challenges Faced by Nonprofit Pharmaceutical Companies

Nonprofit pharmaceutical companies report encountering multiple challenges in the current policy environment. This paper organizes the most salient of these challenges into five categories: (1) tax status, (2) capital investment and funding, (3) FDA issues, (4) supply chain and distribution systems, and (5) reimbursement in federal health programs.

TAX STATUS

The types of federal tax-exempt status that are currently available do not adequately reflect the activities a nonprofit pharmaceutical company must perform pursuant to their mission of commercializing a drug product. Nonprofit leaders attest to the struggle to obtain federal tax-exempt status and to maintain it over time because of their unique mission and sources of funding. They also report inconsistencies in U.S. Internal Revenue Service (IRS) decisions to confer, deny, or retract tax-exempt status.

Existing designations under Section 501(c)(3) of the Internal Revenue Code (26 U.S.C. § 501(c)(3)) include several constraints which make sustainable operation difficult for nonprofit pharmaceutical companies. For example, companies that register as "public charities" face considerable headwinds in meeting the requirements of the "public support test"—under which entities are generally expected to maintain diverse sources of funding—given the hefty upfront investment necessary to fund a pharmaceutical product through its development.[3] Though some nonprofit pharmaceutical companies have registered as "medical research organizations," these companies are required to continuously engage in active medical research and must therefore endure steep research and development expenditures even after product commercialization.[4] An

additional tax status-related challenge is the classification of the revenues from drug sales as "unrelated business income."[5] Such classification opens these entities up to tax liabilities which vitally challenge their ability to continue operating as low-cost drug manufacturers and, at worst, could threaten an organization's eligibility for tax-exempt status in the first place.[6]

For-profit pharmaceutical companies, unlike their nonprofit counterparts, have the benefit of myriad tax credits and other state and federal tax incentives for their operations. For example, for-profit companies that perform certain research and development-related activities may claim certain federal tax credits or deductions.[7] Even where nonprofit companies may technically be eligible for such tax incentives, they are not well-positioned to benefit from them due to nonprofit companies' comparatively lower revenues and limited tax liabilities.

CAPITAL INVESTMENT AND FUNDING

Nearly every nonprofit company we consulted reported that nonprofit pharmaceutical companies face extraordinary difficulties in raising money for drug research and development, as well as recruiting and compensating talent. Bringing a pharmaceutical product to market entails considerable expense and risk.[8] Nonprofit companies lack access to the most common means that for-profit companies employ to raise capital, such as investment by venture capital. Additionally, firms require significant resources in order to recruit and retain talented staff and leadership. Not only are nonprofit companies typically unable to compete with the salaries of their for-profit counterparts, they are also unable to offer stock options to employees, further limiting their ability to attract highly qualified staff.

Nonprofit companies' efforts to find alternatives to the dominant model of financing drug research and development have met with limited success. Although some nonprofit pharmaceutical companies have sought and obtained funding from philanthropies, others report that foundations and other large donors remain unaware of the nonprofit pharmaceutical model and are deterred by the high level of risk and expense involved in drug development and manufacturing. Nor do federal grant programs appear to be a viable alternative to venture capital for nonprofits. For example, eligibility for the federal Small Business Innovation Research (SBIR) grant program, which provides federal financial assistance to domestic small businesses for the purpose of research and development activities, is limited to for-profit entities.[9] According to some of the roundtable participants, nonprofit pharmaceutical companies are similarly ineligibile for state funding for research and development. And, despite the growing importance of corporate social responsibility (CSR) programs,[10] large for-profit pharmaceutical companies currently have little incentive—even disincentives, in some instances—to partner or share resources with nonprofit pharmaceutical companies (*e.g.*, compound libraries and analytical tools).

U.S. FOOD AND DRUG ADMINISTRATION (FDA) ISSUES

Nonprofit pharmaceutical companies identify certain FDA rules and practices as obstacles to their ability to fulfill their missions. For example, FDA user fees reportedly pose a significant financial challenge to nonprofit pharmaceutical companies. The FDA generally levies user fees—such as initial application fees and annual manufacturing facilities fees—on drug manufacturers.[11] User fee rates are established without regard to an entity's mission or sales. Because nonprofit pharmaceutical companies prioritize the availability of drugs that are a public health need instead of maximizing their sales revenue, having to pay the same user fees owed by large for-profit companies essentially functions as a regressive tax. Currently, fees can only be waived or reduced in narrow circumstances,[12] so nonprofit companies may have little chance of obtaining relief from FDA user fees under the agency's current legal framework. Nonprofit companies also report a general lack of awareness at the FDA of the role and value of nonprofit pharmaceutical companies. According to some roundtable

participants, although senior FDA officials have so far appeared supportive of their work, this has yet to translate to the practices of rank-and-file agency staff such as reviewers, who are bound by existing procedures. The nonprofit companies are not seeking to alter the FDA's safety and efficacy reviews, but would like to see additional assistance from the FDA or alternative pathways to take into account the value that nonprofit pharmaceutical companies may bring to the market.

SUPPLY CHAIN AND DISTRIBUTION SYSTEMS

Nonprofit pharmaceutical companies report that current supply chain and distribution channels for pharmaceutical products are optimized for service in the for-profit sector. This is likely attributable to the manner in which entities such as wholesalers operate. Points of entry to the standard pharmaceutical distribution channels are governed by wholesalers. The "tolls" these gatekeepers receive as payment are typically based on the list price of the medications they warehouse and distribute. According to the roundtable participants, if a nonprofit pharmaceutical company were to attempt to distribute its products via these channels, wholesalers would sustain opportunity cost compared to distributing higher cost for-profit drugs. For this reason, wholesalers may be disinclined to work with nonprofit companies without imposing prohibitive fees to recoup that loss. Moreover, some roundtable participants discussed that, because wholesalers may be distrustful of the ability of nonprofit entities to adequately supply their medicines, they may similarly demand high fees from nonprofit companies to offset perceived risk. Roundtable participants believe that these wholesaler-gated channels are in direct conflict with nonprofit companies' missions and present high barriers to the efficient distribution of their low-cost medicines.

Due to their low capitalization and slim margins, nonprofit pharmaceutical companies are ill-equipped to finance independent or internal distribution systems for their products. While direct distribution may be an effective option for some for-profit pharmaceutical companies, nonprofit companies' small scale could present a hurdle given that providers using group purchasing organizations (GPOs) realize cost savings due to scale and the streamlining of their drug procurement—sourcing a single drug from a new manufacturer could present a cost increase for provider networks. Nonprofit companies are unlikely to fare any better by engaging with pharmacy benefit mangers (PBMs). In pursuit of their share of supply chain profits, PBMs negotiate high prices. The prices that patients and insurers pay at the pharmacy are inflated, thus the savings introduced to the supply chain by nonprofit pharmaceutical companies would not be passed through to the end consumer, frustrating the goals of nonprofit companies to deliver low prices to patients.

REIMBURSEMENT IN FEDERAL HEALTH PROGRAMS

Current reimbursement and payment policies pose a challenge to nonprofit companies that seek to offer lower prices in multiple markets. The Medicaid outpatient drug rebate program (established under 42 U.S.C. § 1396r–8) presents one such obstacle, according to some roundtable participants. Under the Medicaid "best price" rules, drug manufacturers must provide statutory rebates to state Medicaid programs that purchase their drugs.[13] For example, the size of a brand-name drug's mandated rebate size is the larger of two formulas: 23.1 percent of the drug's average manufacturer price (AMP), or the difference between the drug's AMP and the cheapest price at which it is currently offered on the market.[14] The mandated rebate amount for generic drugs in Medicaid is equal to 13 percent of the drug's AMP.[15]

In order for nonprofit pharmaceutical companies to remain sustainable while pursuing their missions, some roundtable participates explained how they seek to vary the price of an individual drug for different market segments. This might entail, for instance, distributing a drug at a significantly reduced price to target populations (*e.g.*, low-income or uninsured patients), while offering

the product at a slightly higher price to other purchasers for the purpose of recouping operating costs and reinvesting in research and development. Price variation of this kind for a brand-name drug, however, would be foreclosed by Medicaid "best price" rules, which essentially require the lowest price available to be offered across Medicaid.

Some nonprofit companies have turned to the 340B Drug Pricing Program in order to circumvent this problem. Under Section 340B of the Public Health Service Act (42 U.S.C. § 256b), manufacturers participating in Medicaid must provide deeply discounted drugs to a list of statutorily defined safety-net hospitals and clinics; these discounts, moreover, do not trigger Medicaid best price. Yet this has proven only to be a partial solution. Entities eligible for 340B discounts serve only a portion of the low-income patients targeted by nonprofit companies, so for a significant population, accessible drugs remain out of reach. Furthermore, because the 340B program was intended to help safety-net providers stretch scarce federal resources and serve as many people as possible,[16] some roundtable participants expressed their belief that the program is an imperfect tool to deliver savings directly to patients.

Policy Options

Subject matter experts and roundtable participants identified a range of policy options that could help address the challenges faced by nonprofit pharmaceutical companies. These options are organized below in categories that correspond to the challenges discussed above.

TAX STATUS AND TAX INCENTIVES

To address the tax issues nonprofit pharmaceutical companies face, policymakers may consider creating a new tax-exempt designation for this class of nonprofit entity. Considering the breadth of business models employed by nonprofit pharmaceutical companies, this designation should be sufficiently accommodating and free of any restrictions that could challenge their ability to operate. On the other hand, this tax status must be selective enough to prohibit for-profit pharmaceutical companies and their subsidiaries or licensees from "gaming" the system. For instance, policymakers could condition eligibility for this new tax-exempt status on whether a nonprofit company is satisfying a specific, unmet public health need through either accessible pricing or increased supply. Also, to ensure the viability of the nonprofit pharmaceutical model, drug sales by nonprofit companies meeting this description could be classified as non-taxable revenue. Policymakers could establish a definition of affordability and require these entities to sell their products at an affordable price that is sufficient to fund operations and ongoing research and development.

Having established a new tax-exempt designation that accounts for the full scope of their funding and activities, the IRS would have a clear federal definition for what is considered a nonprofit pharmaceutical company. Recipients of this new tax-exempt status could then be provided access to existing and new tax-advantaged programs intended to support pharmaceutical research and development undertaken by these organizations. Moreover, a range of other federal incentives, exemptions, or funding opportunities could be made

available to organizations meeting this new federal definition. Some policy options to create or expand these opportunities are discussed below.

CAPITAL INVESTMENT AND FUNDING

To address the difficulties experienced by nonprofit companies in obtaining capital investment and funding, policymakers may explore adopting a combination of new federal incentives.[17] One idea would be to authorize programs to "push" forward drug research and development by nonprofit companies by means of upfront financial or in-kind support in areas where for-profit companies have not been willing to invest or have left the market. These programs could award grants, or no- or low-interest loans, to nonprofit pharmaceutical companies for the purpose of advancing research and development for drugs that meet certain criteria, such as whether the drug meets public health needs, addresses an access issue when drugs are unaffordable, or is deemed an "essential medicine." The U.S. Department of Health and Human Services (HHS) could likewise issue requests for proposals (RFPs) for particular products. A program of this kind could be patterned after existing federal programs that directly finance research and innovation, including the Biomedical Advanced Research and Development Authority (BARDA) within HHS. This would allow nonprofit companies to apply for and obtain funding to support the development of needed drugs in exchange for guarantees that the commercialized products will be priced affordably. One roundtable participant suggested that policymakers could consider funding these potential new programs in a way that recoups previous public investments in science that have led to drugs marketed and sold by for-profit companies (*e.g.*, royalty on the sales of drugs developed with public funding).

On top of "push" mechanisms, policymakers may also consider designing "pull" incentives, which would reward nonprofit companies for successfully bringing a product to market in areas where for-profit companies have not done so. A variety of approaches could be considered, such as opportunities for nonprofit companies to receive priority review vouchers, "wildcard" exclusivities, opportunities for expedited FDA review, advance market commitments, or monetary prizes. The federal government could also guarantee that suitable products developed and marketed by nonprofit companies are purchased by the Strategic National Stockpile—a storehouse of critical medical supplies for use in national emergencies.[18] Beyond encouraging the work of nonprofit companies in the pharmaceutical arena, these outcome-based incentives would also help bolster the nonprofit business case among prospective funders.

Finally, policymakers could examine options to incentivize partnership and collaboration among nonprofit companies and their for-profit counterparts. For instance, the policymakers may design incentives for for-profit companies (*e.g.*, tax breaks or other incentives) when they provide nonprofit companies access to proprietary resources, including analytical tools, compound libraries and other intellectual property, and laboratory space. Similarly, policymakers could engineer incentives to promote collaboration among nonprofit entities, charitable foundations, and other entities. These partnerships could, for example, take the form of "innovation hubs" in which member organizations are able to leverage collective resources and reduce costs through the sharing of manufacturing facilities, subject-matter experts, and regulatory compliance staff.

U.S. FOOD AND DRUG ADMINISTRATION (FDA) ISSUES

Policymakers could consider modifying FDA practices and rules that threaten to undermine the sustainability of nonprofit pharmaceutical companies. Roundtable participants discussed the option of waiving or reducing FDA user fees owed by nonprofit companies on their pharmaceutical products would help ensure that these organizations are not subject to disproportionate financial burdens compared to for-profit companies. Also, policymakers could consider formulating guidelines that

clearly define the unique role of nonprofit companies may play to affordably address unmet public health need for drugs. As mentioned above, drugs produced by nonprofit companies meeting this definition could then be granted opportunities for expedited review, advance market commitment, "wildcard" exclusivities, or prizes based on their willingness to solve a public health challenge, such as drug shortages, inaccessibility due to pricing, or another unique public health need. These benefits could be linked to a list of "essential medicines" identified by the FDA based on public health needs, analogous to work already performed by the World Health Organization (WHO),[19] such that nonprofit companies are granted FDA incentives for pursuing research and development of critical drugs.

SUPPLY CHAIN AND DISTRIBUTION SYSTEMS

The principal step in reforming the current for-profit pharmaceutical supply chain is transparency, according to subject-matter expert interviews and roundtable participants. Currently, PBMs and drug wholesalers have the privilege of obscurity giving them wide berth to make deals, set prices, disburse rebates, and sustain high margins.[20] Transparency at this point of contact and across the pharmaceutical supply chain (*e.g.*, manufacturing cost per unit, list price, cost before rebate, etc.) may correct the market failure embedded into today's system. With improved availability of information, stakeholders across the supply chain would be empowered to make better decisions and, subject to pressure from policymakers and patients, be incentivized to compete on price. This issue is already receiving attention as both houses of Congress consider federal legislation to address transparency gaps.[21]

While price transparency would provide policymakers with additional information that could shape future reforms, there are also policy options for the near term that could help to level the playing field for nonprofit pharmaceutical companies. Wholesalers and PBMs could be incentivized to purchase and distribute lower-cost medications. Or, alternatively, wholesalers could be required to contract with nonprofit pharmaceutical companies at cost, similar to "any willing provider" laws for inclusion in insurer networks.

Creating a nonprofit pharmaceutical wholesaler may also allow nonprofit pharmaceutical companies to operate in a model that reflects their missions instead of trying to wedge into the current distribution model. Learnings may be taken from the experiences of independent community pharmacies to inform how such a distribution model may operate. Independent community pharmacies are small businesses that operate apart from major retail pharmacies, supermarket pharmacies, and those embedded in mass merchandise retailers. Due to the smaller markets they serve (thus thinner margins and more unpredictable reimbursement income) these pharmacies endure considerable risk when procuring drugs. In order to better supply affordable medicines for their patients, independent community pharmacies have increasingly formed associations to create leverage in negotiations with wholesalers, and have even formed their own PBMs to provide more affordable pharmacy benefits.[22] But, as positive as their influence can be in lowering patient drug expenditures, independent community pharmacies are inadequately equipped to completely solve the onerous price and supply challenges in the prescription drug market on their own. Thus, policymakers might allocate funding to a nonprofit or federal office which might fill an analogous role in distribution and reimbursement among low-cost pharmacies and safety-net providers.

REIMBURSEMENT IN FEDERAL HEALTH PROGRAMS

Policymakers may also consider potential options to resolve the problems that confront nonprofit pharmaceutical companies in the area of reimbursement and payment. Exemptions from Medicaid "best price" rules could be narrowly tailored for products developed or marketed by nonprofits on the condition that certain affordability guarantees are met. This might be achieved,

for example, through the approval of Medicaid demonstration projects proposing alternative payment models for these drugs. Narrowly adjusting Medicaid "best price" rules in this manner would permit nonprofit pharmaceutical companies to offer low prices to target populations, such as uninsured patients or lower income individuals and their families regardless of their provider, without triggering Medicaid rebates that may have the unintended effect of forcing prices upward in certain instances. Reimbursement mechanisms could further be adjusted to promote nonprofit pharmaceutical companies that are dedicated to providing lower prices. For example, in order to establish a shared-savings model, federal health programs such as Medicaid and Medicare could provide enhanced reimbursement for certain drugs developed and marketed by nonprofits if they are priced significantly lower than competitors and then share the savings between the respective program and patients or providers. Or public payers could calibrate their reimbursement rates for groups of clinically comparable drugs based on the lowest price drug within that group—a "least costly alternative" policy—which would encourage the use of affordable drugs produced by nonprofit pharmaceutical companies.

Conclusion

Americans are in search of solutions to the high price of prescription drugs. Nonprofit pharmaceutical companies represent one potential alternative to the dominant for-profit drug industry, which has long prioritized the generation of profit over ensuring access and affordability. Despite their promise, however, nonprofit pharmaceutical companies face an uphill battle succeeding in the current policy environment. According to experts and nonprofit leaders, a number of barriers interfere with the ability of nonprofit companies to sustainably develop and market needed drugs in the U.S. Policymakers have a range of potential options they may consider to address these challenges, with the larger goal of ensuring greater sustainability for nonprofit pharmaceutical companies that are committed to increasing access to affordable drugs.

Endnotes

1 Sean Dickson and Jeromie Ballreich, West Health Policy Center, *How Much Can Pharma Lose?: A Comparison of Returns Between Pharmaceutical and Other Industries* (2019), *available at* https://www.westhealth.org/wp-content/uploads/2019/11/WHPC_White-Paper_How-Much-Can-Pharma-Lose_FINAL-November-2019.pdf (reviewing profit margins in the pharmaceutical industry); Juliette Cubanski and Tricia Neuman, Kaiser Family Foundation, *Assessing Drug Price Increases in Medicare Part D and the Implications of Inflation Limits* (2019), *available at* https://www.kff.org/medicare/issue-brief/assessing-drug-price-increases-in-medicare-part-d-and-the-implications-of-inflation-limits/.

2 For example, we predicted that federal tax credits or exemptions for research and development would be of comparatively little value to most nonprofit entities because of their low federal tax liability. *See, e.g.*, 26 U.S.C. §§ 41, 174, 45C. We also predicted that FDA user fees, which are levied from entities without regard to their missions or profitability, would pose a disproportionate burden for nonprofit companies. See Janet Woodcock and Suzanne Junod, FDA, *PDUFA Lays the Foundation: Launching Into the Era of User Fee Acts* (2011), *available at* https://www.fda.gov/media/110364/download (reviewing similar arguments against user fees on behalf of small manufacturers). Moreover, the increased scrutiny in recent years of patient assistance programs—through which for-profit manufacturers offer to cover co-pays and other expenses for low-income patients—led us to predict that the existing pharmaceutical supply chain, dominated by large companies, may disadvantage organizations with fewer resources in their ability to access the market. *See, e.g.*, Michael Hiltzik, "Why Big Pharma's patient-assistance programs are a sham," *Los Angeles Times* (Sept. 25, 2015), *available at* https://www.latimes.com/business/hiltzik/la-fi-mh-pharma-s-sham-patient-assistance-programs-20150925-column.html.

3 *See* 26 U.S.C. §§ 509(a), 170(b)(1)(A)(vi) (detailing "public support" requirements for public charities).

4 *See* 26 U.S.C. § 170(b)(1)(A)(iii) (defining "medical research organization").

5 Robert A. Wexler, Adler and Colvin, *Unrelated Business Income Tax: A Primer* (2012), *available at* https://www.adlercolvin.com/wp-content/themes/adlercolvin/pdf/Unrelated-Business-Income-Tax-A-Primer.pdf.

6 *Id.*

7 *E.g.*, 26 U.S.C. § 41 (tax credit for research and development); 26 U.S.C. § 174 (tax deduction for research expenditures).

8 Recent estimates of the total cost to bring one new drug to market have ranged widely, from $650 million to $2.6 billion per drug. Vinay Prasad and Sham Mailankody, Journal of the American Medical Association, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval* (Nov. 2017), *available at* https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653012; Joseph A.DiMasi, et al., Journal of Health Economics, *Innovation in the pharmaceutical industry: New estimates of R&D costs* (May 2016), *available at* https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub.

9 *See* U.S. Small Business Administration, "About SBIR," *available at* https://www.sbir.gov/about/about-sbir.

10 *See* Hayley Droppert and Sara Bennett, "Corporate social responsibility in global health: an exploratory study of multinational pharmaceutical firms," *Global Health*, (Apr. 9, 2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4403913/.

11 Congressional Research Service, *FDA Human Medical Product User Fee Programs: In Brief* (2017), *available at* https://fas.org/sgp/crs/misc/R44750.pdf.

12 *E.g.*, U.S. Food and Drug Administration, Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products Guidance for Industry (June 2018), *available at* https://www.fda.gov/media/113889/download.

13 *See generally* Medicaid and CHIP Payment and Access Commission (MACPAC), *Medicaid Payment for Outpatient Prescription Drugs* (2018), *available at* https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.

14 42 U.S.C. § 1396r–8(c).

15 *Id.*

16 Health Resources and Services Administration, "340B Drug Pricing Program," *available at* https://www.hrsa.gov/opa/index.html ("The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.").

17 While this paper focuses on potential solutions at the federal level, nonprofit pharmaceutical companies could also benefit from state funding and incentive programs that are analogous to those described here.

18 *See* U.S. Department of Health and Human Services, "Strategic National Stockpile," *available at* https://www.phe.gov/about/sns/Pages/default.aspx.

19 World Health Organization, "Essential medicines and health products," (Jun. 2019), *available at* https://www.who.int/medicines/publications/essentialmedicines/en/.

20 *See, e.g.*, Cardinal Health, "Cardinal Health Reports First Quarter Results for Fiscal Year 2020" (Nov. 2019), *available at* https://ir.cardinalhealth.com/news/press-release-details/2019/Cardinal-Health-Reports-First-Quarter-Results-for-Fiscal-Year-2020/default.aspx; AmerisourceBergen, "AmerisourceBergen Reports Fiscal 2019 Fourth Quarter and Year End Results" (Nov. 2019), *available at* https://investor.amerisourcebergen.com/news/news-details/2019/AmerisourceBergen-Reports-Fiscal-2019-Fourth-Quarter-and-Year-End-Results/; 46brooklyn, "New Drug Pricing Analysis Reveals Where PBMs and Pharmacies Make Their Money" (2019), *available at* https://www.46brooklyn.com/research/2019/4/21/new-pricing-data-reveals-where-pbms-and-pharmacies-make-their-money.

21 *E.g.*, Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act of 2019, H.R. 2115, 116th Cong. (2019); Payment Commission Data Act of 2019, H.R. 1781, 116th Cong. (2019); Prescription Drug Pricing Reduction Act of 2019, S. 2543, 116th Cong. (2019).

22 Bruce Kneeland, Drug Topics, "Buying groups: A powerful resource for indie pharmacies" (Apr. 10, 2016), *available at* https://www.drugtopics.com/community-practice/buying-groups-powerful-resource-indie-pharmacies.