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Impacts of a Nonprofit Membership-Based Pharmaceutical Company on Volume of Generic Drugs Sold and Drug Prices: A Case Study

Sonal Parasrampuria, Trinidad Beleche, Stephen Murphy, Oluwarantimi Adetunji

Key Findings

- Drug shortages, especially for generic drugs, are a persistent public health issue. The COVID-19 pandemic highlighted the need to enhance the resilience of the U.S. pharmaceutical supply chain to ensure medicines are affordable and accessible to those who need them. Non-traditional pharmaceutical business models have been increasingly touted as a potential solution to address drug shortages.
- We conducted a case study of Civica Rx, a U.S. nonprofit pharmaceutical company whose model is based on long-term hospital membership agreements with minimum volume commitments and buffer stock requirements. These features may be attractive to hospitals and health systems that are willing to trade off procurement agility for more reliability in drug supply.
- Between 2020 and 2022, the non-traditional pharmaceutical model sold 64 drugs, which were all generic sterile injectables. During that period, the non-traditional model sold 350.2 million units for total sales worth $255.9 million.
- We found that the quantities of drugs sold using the non-traditional model were similar to, or in some cases larger than, the quantities of drugs sold by the average traditional competitor. The product mix for the non-traditional model leaned toward production of drugs in shortage and essential medicines, which may reflect the needs of their membership.
- In some cases, the average price for the products was roughly equal between the non-traditional model and traditional model, and in some cases the non-traditional model's price was much lower. However, for certain generic drugs, the relative price in the non-traditional model was up to 2.15 times higher than the price in the traditional model; further research is needed to understand the factors that could explain these differences, though we note that the non-traditional model may promote reliability in the generic drug supply.

Introduction

Generic drug shortages threaten access to lifesaving therapeutics and pose a risk to the capacity of the U.S. health care system to mitigate and respond to public health emergencies and ongoing public health issues.[1] The COVID-19 pandemic highlighted the necessity of enhancing resiliency and reducing vulnerability risks in the supply chain, particularly with respect to drug shortages, and ensuring

[1] Bosworth, A., Sheingold, S., Finegold K., De Lew, N., & Sommers, B. D. (2022). *Price increases for prescription drugs, 2016–2022*. Issue Brief No. HP-2022-27. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. https://aspe.hhs.gov/reports/prescription-drug-price-increases

medicines are affordable and accessible.[2] Even before the COVID-19 pandemic, nearly two-thirds of hospitals (64 percent) reported having experienced more than 20 medical product shortages at any one time, including shortages of controlled substances, local anesthetics, antibiotics used to treat severe bacterial infections, and crash cart drugs required to stabilize and resuscitate critically ill adults.[3] The frequency and severity of these supply disruptions have been exacerbated over the last few years. The problem of drug shortages is particularly critical for medicines that are medically necessary to have available at all times and in an amount adequate to serve patient needs in the appropriate dosage forms.

Drug shortages have numerous causes, including manufacturing quality issues, increases in demand, supply chain disruptions from natural disasters or other unexpected events, or product discontinuations. Some have noted that old generic drugs are particularly vulnerable to shortage because of low margins, which represent a high-risk and low-reward financial outlook for manufacturers.[4,5] Faced with this outlook, manufacturers may be disincentivized from making investments such as upgrading existing or building new manufacturing facilities, adopting practices that promote proactive detection of vulnerabilities, and preventing manufacturing problems.[6,7] Furthermore, uncertainty about future demand by purchasers can drive market exits. Given these challenges and the increasing incidence of drug shortages, ensuring the resiliency of the generic drug supply chain is a public health priority.[8] Many solutions have been proposed to mitigate drug shortages.[9] These solutions include domestic manufacturing, buffer stocks (e.g., requiring that excess inventory be held and maintained to facilitate availability of certain products in case of unexpected supply disruptions), long-term contracts with guaranteed volume purchasing, and price guarantees. However, there is a literature gap on the prevalence of these practices in the United States.

We use a case study approach to examine one pharmaceutical company, Civica Rx (henceforth Civica or the non-traditional model), that uses a membership-based and long-term contracting model for the U.S. market. Civica was created as a nonprofit pharmaceutical company[10] in 2018 by seven health systems and three philanthropic organizations. The company's mission is "to reduce and prevent drug shortages and the price spikes that can accompany them…to make quality generic medicines accessible and

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[2] The White House. (2021). *Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth: 100-day reviews under Executive Order 14017*. https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

[3] Vizient Inc. (2019). *Drug shortages and labor costs: Measuring the hidden costs of drug shortages on U.S. hospitals*. https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129

[4] U.S. Food and Drug Administration. (2020). *Drug shortages: Root causes and potential solutions (revised)*. https://www.fda.gov/media/131130/download

[5] IQVIA. (2023). *Drug shortages in the U.S. 2023: A closer look at volume and price dynamics*. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023

[6] Frank, R. G., McGuire, T. G., & Nason, I. (2021). The evolution of supply and demand in markets for generic drugs. *The Milbank Quarterly*, *99*(3), 828-852. https://doi.org/10.1111/1468-0009.12517

[7] Sivashanker, K., Fanikos, J., & Kachalia, A. (2018). Addressing the lack of competition in generic drugs to improve healthcare quality and safety. *Journal of General Internal Medicine*, *33*, 2005–2007. https://doi.org/10.1007/s11606-018-4548-x

[8] United States Senate Committee on Homeland Security and Governmental Affairs. (2023). *Short supply: The health and national security risks of drug shortages*. https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf

[9] Wosińska, M. E., & Frank, R. G. (2023). *Federal policies to address persistent generic drug shortages*. The Hamilton Project. https://www.hamiltonproject.org/publication/policy-proposal/federal-policies-to-address-persistent-generic-drug-shortages/

[10] Classified as a 501(c)(4) social welfare organization, Civica is a nonstock company funded by its members and governed by a board.

affordable."[11] Civica's members are hospitals or health systems, and the company focuses on generic sterile injectables that are administered in a hospital setting. Features of the non-traditional model include guaranteed delivery, the same price per drug for all members regardless of volume, and a six-month buffer stock to supply drugs to its members. The members commit to purchase approximately 50 percent of their expected volume for specific drugs for a minimum duration that ranges from three to 10 years.[12] Civica's membership strategy and nonprofit status are different from the strategies and for-profit status of most other U.S. pharmaceutical companies; hence, we refer to Civica as the non-traditional model. While products typically flow in the traditional model from manufacturers to health systems or hospitals through wholesalers and group purchasing organizations (GPOs), Civica sells directly to its member health systems and hospitals without these intermediaries. Further, Civica entered the market by using contracting manufacturing organizations (CMOs) to manufacture its products. These CMOs had excess capacity and the Abbreviated New Drug Applications (ANDAs) required to market generic drugs in the United States. However, the use of CMOs is not a feature that is unique to the non-traditional model, as companies in the traditional model also use CMOs to produce their products. A recent study reported that the non-traditional model fulfilled its contractually guaranteed volume at 96 percent, while wholesaler orders were fulfilled at 86 percent.[13] However, that analysis did not compare the same sample of drugs, which limits the generalizability of the results.

In this study, we use U.S. national sales and volume data for the sample of drugs sold by Civica, and we compare its volume and price with the data for other pharmaceutical companies in the market. The results of our study have implications for understanding whether non-traditional business models are able to fill certain market gaps, particularly when it comes to shortages of critical medicines.

Methods

Data

We used IQVIA National Sales Perspective (NSP) data from January 2017 through December 2022. IQVIA NSP captures approximately 88 percent of U.S. drug sales across all payers and distribution channels.[14] IQVIA NSP includes information such as sales revenue, volume, National Drug Code (NDC), molecule, strength, form, and manufacturer name. We calculated price per unit by dividing total sales revenue by total volume of extended units.

The non-traditional model: We identified our sample by searching the IQVIA NSP dataset for "CIVICA RX" in the company name variable. Next, we defined Civica's list of products by combining a drug's molecule (i.e., the active ingredient), dosage form (e.g., injectable drug), and strength information.

The traditional model: We identified our comparison group as all other companies making drugs with the same molecule-form-strength combination (i.e., making the same "product") that Civica sold. The comparators were for-profit pharmaceutical companies without a membership-based model—i.e., companies using the "traditional model." The sample of drugs included all drugs marketed by Civica and

[11] Civica Rx. (n.d.). *Why Civica?* https://civicarx.org/#talking_points
[12] Dredge, C., & Scholtes, S. (2021). The health care utility model: A novel approach to doing business. *NEJM Catalyst (non-issue content)*, *2*(4). https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0189
[13] Dredge, C., & Scholtes, S. (2023). Vaccinating health care supply chains against market failure: The case of Civica Rx. *NEJM Catalyst Innovations in Care Delivery*, *4*(10), CAT-23. https://doi.org/10.1056/CAT.23.0167
[14] IQVIA. (n.d.). *Available IQVIA data: U.S. national data*. https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data

a matched list of all equivalent drug products from the traditional competitors.[15] We retained distinctions on strength (5GM, 10GM, etc.) because these can impact the cost and utilization of a drug.

To identify drug shortages, we used the U.S. Food and Drug Administration (FDA) Drug Shortages Database, downloaded on February 15, 2023.[16] This database includes information such as the shortage posting date, reason for the shortage, and status of the shortage (current, resolved, or discontinued). FDA's Drug Shortages Database defines a shortage at the molecule level but also provides information on the NDCs associated with the shortage.

To identify essential medicines, we used the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs (hereinafter referred to as the "EO 13944 List"), as developed by FDA.[17] The list defines "essential medicines" as those medical products that have the greatest potential impact on public health and are most needed by patients in medical facilities for acute and urgent medical conditions. The essential medicines list provides medicines by drug name and dosage form.

We merged the IQVIA NSP data and FDA Drug Shortages Database by NDC. Then we matched this dataset to the essential medicines list at the molecule-form level, in consultation with a clinical pharmacist. The final database's unit of analysis was at the year-month-combined molecule-form-strength level. To create a shortage indicator, we assigned shortage start and end dates to the entire combination of molecule-form-strength if one or more NDCs were in shortage for that combination. The earliest shortage date among all NDCs for a combination was listed as the shortage start date, and the latest shortage date among all NDCs for a combination was listed as the shortage end date.

Analytical Approach

The goal of our analyses was to identify whether there are differences in market performance between the traditional and non-traditional models. Differences in market performance were measured by the sales revenue, volume of extended units sold, and price per unit for the same cohort of drugs. Specifically, we examined changes between 2017 and 2022 to capture the time before and after the non-traditional model first began marketing drugs in 2020. Our study only looked at those drugs that the non-traditional model produced at any point during the period of analysis, and the results may not be generalizable to all hospital-based drugs.

We then performed two subgroup analyses—one focused on drugs in shortage, the other focused on essential medicines—to understand whether there are differences between the traditional and non-traditional models in supplying these types of drugs to the market. For these drugs, we compared the percentage of total sales, the percentage of total volume, and the price per unit between the traditional and non-traditional models.

[15] Matching non-traditional and traditional company drugs: Only four of these unique combinations did not have an initial exact match, three due to differences in form and one due to difference in strength. For the three with differences in form, matches were identified by matching the NDC-specifying text. For the one with difference in strength, matches were identified after correcting strength information from 20MG/10ML to 2MG/ML. After manual corrections for the four unique combinations, there was a 100 percent match rate between non-traditional drugs and traditional alternatives.

[16] U.S. Food and Drug Administration. (n.d.). *FDA drug shortages: Current and resolved drug shortages and discontinuations reported to FDA*. Retrieved February 15, 2023, from https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

[17] U.S. Food and Drug Administration. (2020). . https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs

Although we identified a cohort of drugs that is selected over the entire period of analysis, the mix of products changed over time, which may be an omitted variable in our primary analysis. For example, as the non-traditional model introduced more drugs to market across the sample period, the number and types of products changed, and some products had larger (and differentially growing) markets than others in terms of volume, sales, or number of traditional manufacturers. Moreover, since each drug treats different medical conditions and faces different market conditions, the equilibrium price (all else equal) may be naturally greater for some products than others. Hence, to examine the robustness of our aggregate estimates, we conducted a sensitivity analysis in which we calculated, for each drug in the sample, the volume share and relative price of the non-traditional model vis-à-vis the traditional model. By examining the distribution of prices and volumes for exactly equivalent drug products between the two models, we can test the robustness of our primary results to any potential impacts of the changing drug mix through time. (For additional details, see the Appendix.)

Limitations

As noted above, the non-traditional model has two distinguishing characteristics—its nonprofit, social welfare status and its membership-based model with long-term minimum volume purchase agreements. While there are a few other nonprofit pharmaceutical companies in the United States, none had directly launched their own drugs onto the market during the period examined in this study. We are unaware of any other pharmaceutical companies adopting a membership model; thus, we cannot disentangle how these two factors—being a nonprofit drug company and having a membership model—contribute to any differences we observe between the non-traditional model and its more traditional competitors. As a result, our analyses may not be generalizable to other nonprofit companies that enter the market at a later date and other companies utilizing membership models.

Another limitation is that our period of analysis includes about two years of post-marketing data for the non-traditional model. This limits our understanding of long-term impacts. Nonetheless, understanding the short-term impacts of the non-traditional model is a critical first step to understanding overall impacts of non-traditional models.

There are also a few limitations specific to the FDA Drug Shortages Database. First, because the database is based on information self-reported by manufacturers, it is missing information on some variables. For example, almost 70 percent of drugs in our sample do not have an identified or known cause of shortage. This may be because the information is not known, because release of the information would exacerbate a shortage, or because the information is not allowed to be released because it has been designated as commercially confidential information. FDA uses the self-reported information submitted as the starting point to assess the nature of a shortage and the underlying reason for it; however, the publicly available database may not reflect all the information that FDA uses. For example, it is possible for a manufacturer to select “Other” as the cause of a shortage, and then FDA may learn during its assessment that the underlying cause is manufacturing delays.

Results

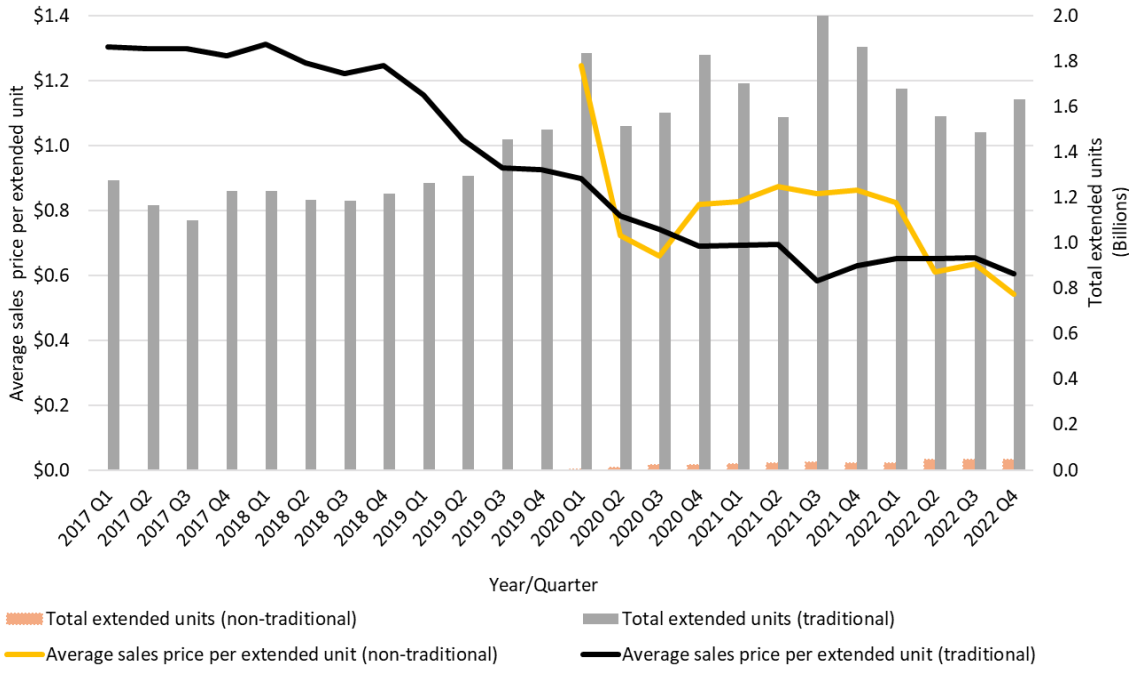
Between 2020 and 2022, there were 64 unique drug products (defined at the molecule-form-strength level) marketed by the non-traditional model, which were also marketed by 88 traditional competitors. See Appendix Exhibit 1 for a list of these drugs. In the same period, the non-traditional model sold 350.2 million units for total sales worth $255.9 million. This represented 1.7 percent of total sales and volume for these drugs when including the drugs marketed by the traditional model, which sold 20.2 billion

units for total sales of $14.0 billion. Because the aggregate for the traditional model includes many companies, we standardized the average units sold per company—on average, each traditional company produced 230.1 million units worth $158.9 million in sales, which is less than the non-traditional model.

Over the three-year period of interest, there was an increase in production by the non-traditional model. In the first quarter (Q1) of 2020, the non-traditional model sold 1.8 million units for $2.2 million, both of which represented 0.1 percent of the total market size (i.e., the sample of drugs produced by the non-traditional model and its traditional competitors). The drugs sold by the non-traditional model increased to 47.7 million units in the fourth quarter (Q4) of 2022 for total sales of $25.9 million, or 2.6 percent of the market. After standardizing the Q4 2022 production to a per-company basis, we found that, on average, each traditional company produced 23.7 million units.

Figure 1 shows the total units sold and average sales price for all drugs in our sample, comparing the non-traditional and traditional models. In Q1 2020, the average sales price for the non-traditional model was $1.25 per unit while the price for the traditional model was $0.90 per unit. From Q4 2020 to Q1 2022, the average sales price of the non-traditional model was higher than that of the traditional model, with the largest difference (46 percent, $0.85/$0.58) occurring in the third quarter (Q3) of 2021. By the second quarter (Q2) of 2022, the average sales price was approximately $0.60 per unit for both the traditional and non-traditional competitors, and the average sales price remained relatively unchanged through the end of 2022.

Figure 1. Total Units and Average Sales Price, Non-traditional Model versus Traditional Model, United States, 2017–2022



Source: ASPE analysis of IQVIA National Sales Perspective data.

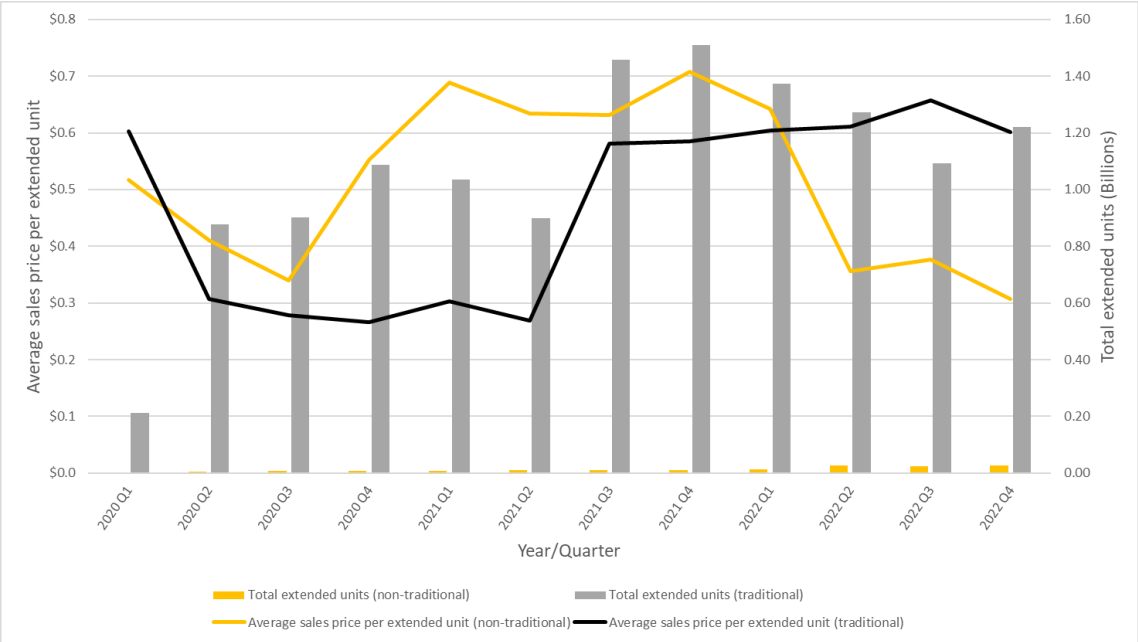
Drug Shortages

Of the 64 unique drug products in the sample, 28 drugs (44 percent) were in shortage at some point during the period of analysis (see Appendix Exhibit 1 for more details). Similar to the findings in the previous section, total sales revenue for the non-traditional model represented a small percentage of the total market, peaking at 2.2 percent in Q4 2022. In Q1 2020, there were nine drugs manufactured by the non-traditional model that FDA listed as in shortage. For these nine drugs, the non-traditional model sold 652,350 units worth $337,018 in sales, both of which represented 0.3 percent of the total market, the lowest percentage over the period of analysis.

Over time, the number of drugs in shortage sold by the non-traditional model increased, as did the share of drugs in shortage sold by the non-traditional model; production increased to 27.4 million units in Q4 2022 compared with 1.2 billion units for the traditional model. However, the non-traditional model's share of sales—$8.4 million relative to $736.7 million for the traditional model—was only 1.1 percent of the total market in Q4 2022. After standardizing volumes per company, we observed that the volume for the non-traditional model was nearly equal to the per-company volume—the non-traditional model produced 27.4 million units compared to 27.7 million units per traditional competitor.

As shown in Figure 2, in Q1 2020, the average sales price per unit of drugs in shortage sold by the non-traditional model was $0.10 lower than the average price of the competitors ($0.60 versus $0.50 per unit). Over the next eight quarters, the average price of drugs sold in the traditional model was lower than that of drugs sold in the non-traditional model. The price of drugs sold in the non-traditional model began to drop in Q1 2022; in Q4 2022, the average price was $0.31, or about half the price of drugs sold by traditional model competitors ($0.60). Notably, while the volume remained relatively unchanged for the non-traditional and traditional competitors, the non-traditional model's price drop resulted in a lower share of total sales.

Figure 2. Total Units and Average Sales Price for Drugs in Shortage, Non-traditional Model versus Traditional Model, United States, 2017–2022



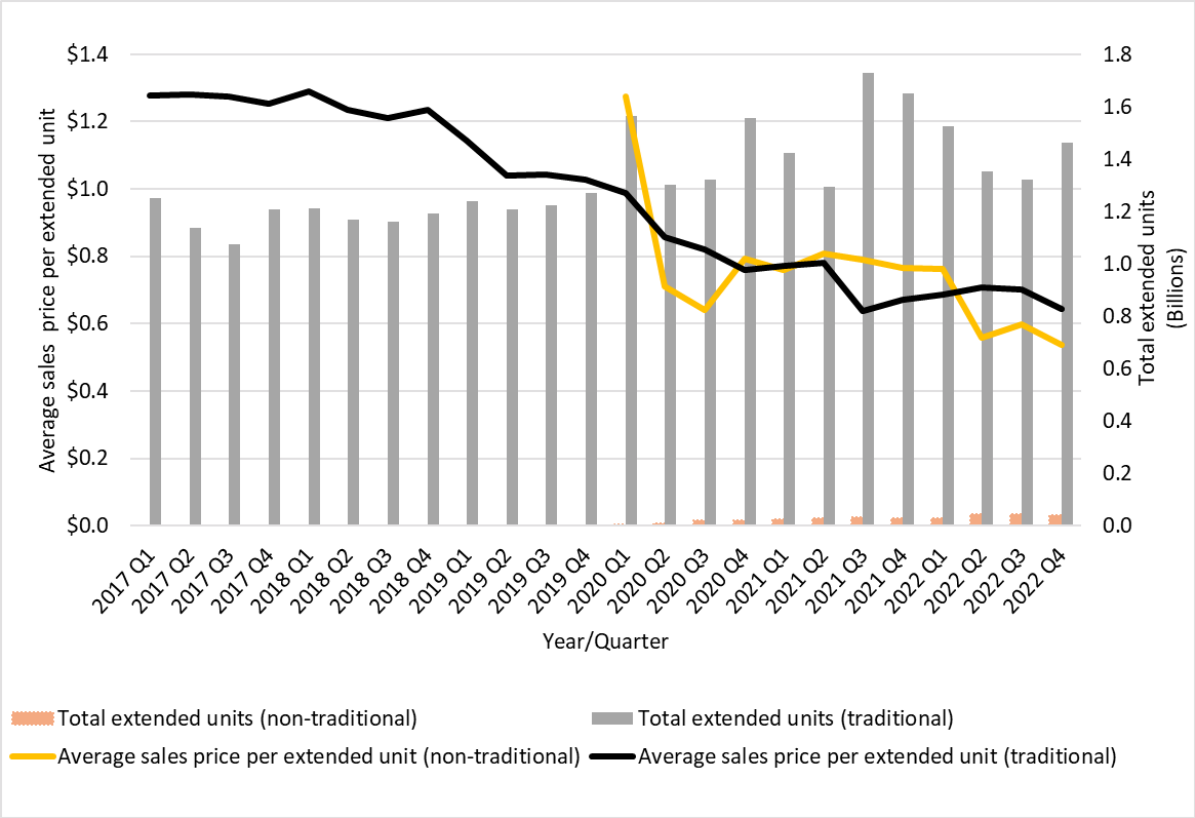
Source: ASPE analysis of IQVIA National Sales Perspective data.

Essential Medicines

The majority of the drugs in the sample—53 out of 64 drugs (83 percent)—were identified as essential medicines (see Appendix Exhibit 1 for more details). In Q1 2020, the non-traditional model sold 1.6 million units of essential medicines for sales of $2.1 million, which represented 0.1 percent of the market. By Q4 2022, the non-traditional model was supplying 41.6 million units (3 percent of the market) while the traditional model competitors produced 1.4 billion units. With respect to sales, the non-traditional model had sales of $22.3 million in Q4 2022, which made up 2 percent of the market ($962.7 million). After standardizing volumes of essential medicines per company, we observed that the non-traditional model supplied 1.9 times as much as a traditional model competitor in Q4 2022 (41.6 million units compared to 21.5 million units per traditional model competitor).

As shown in Figure 3, in Q1 2020, the average sales price for essential medicines sold under the non-traditional model was $1.27 per unit, which decreased to $0.54 per unit in Q4 2022. When output peaked for the non-traditional model in Q2 2022, prices were $0.56 per unit. In contrast, the average sales price for drugs sold under the traditional model was $0.99 in Q1 2020 and $0.64 by Q4 2022. This translates to the price for the non-traditional model being 29 percent higher than the price for the traditional model competitors in Q1 2020, and 17 percent lower in Q4 2022.

Figure 3. Total Units and Average Sales Price for Essential Medicines, Non-traditional Model versus Traditional Model, United States, 2017–2022



Source: ASPE analysis of IQVIA National Sales Perspective data.

Sensitivity Analysis

Our analysis shows that the sales, volume, and price of the drugs sold by the non-traditional model vary across time. These trends could reflect changes across time in market share or in the mix of products sold. We conducted two analyses to examine these issues further (see the Appendix for additional information on the methods). First, we examined the share of market in terms of volume across time and key percentiles (Appendix Exhibit 2). We found wide variation in that market share. For example, the shares of market volume by the non-traditional model at the 10th and 90th percentiles were 2 percent and 100 percent, respectively, which suggests that the non-traditional model may have more market power in certain product markets.

Second, to examine the robustness of our results with respect to changes in the product mix, for each drug in our sample we calculated the relative price of the non-traditional model, defined as the price for a given drug sold by the non-traditional model relative to the price of the same drug sold by the traditional model (Appendix Exhibit 2). We found that the relative pricing of the non-traditional model varied across time and key percentiles. For example, the relative prices at the 10th and 90th percentiles were 0.38 and 2.15, respectively, which indicates that, compared to prices charged by traditional competitors, the prices for drugs sold by the non-traditional model ranged from being close to two-thirds cheaper to being more than twice as expensive.

Discussion

This study found that, as of 2022, the one example of a non-traditional model was a relatively small player in the pharmaceutical drug market with regards to their total market share. However, the results suggest that a company using the non-traditional model may be able to produce drugs in volumes that are equal to—and, in some cases, larger than—the volumes produced by the average traditional model competitor. This was most salient in the case of essential medicines, where the non-traditional model's volume was significantly larger than the traditional model's volume. The variation in market share across different drugs sold by the non-traditional model suggests that the non-traditional company spreads its risk across a large portfolio of drugs. This means that as the market changes (due to factors such as drug shortages and new generic entrants, for example) the non-traditional model has the ability to adapt its portfolio to ensure its longer-term viability, possibly considering factors such as demand of its membership or the underlying profitability of certain drugs. In this way, non-traditional-model companies have the potential to distinguish themselves, create a niche market, and leverage economies of scale and other efficiencies that may be associated with product specialization.

The observed results show heterogeneity in prices across the cohort of drugs sold by the traditional and non-traditional models. In general, the average price of drugs sold under the non-traditional model was higher than the average price of the same drugs sold by the traditional model, although there were some notable exceptions in which the non-traditional model's price was much lower. It is possible that the non-traditional model's strategy of long-term purchasing agreements with hospitals gives it more flexibility to set prices to ensure longer-term supply, rather than focusing on the lowest price that may not guarantee future supply. As the non-traditional model increases its membership base, there may be higher predictability in its future stream of revenue and demand, allowing for more price stabilization.

An important caveat for the study findings is that there is only one non-traditional pharmaceutical company, so results may not be generalizable outside of this case study. This analysis suggests that non-traditional pharmaceutical companies could have impacts on volume, price, and resiliency across a broader set of products if they were to become more mature in the market. However, the variability in prices over time shows that it takes several years for new entrants to find their optimal pricing, product mix, and production levels. This case study of the non-traditional model included only one company that was able to ramp up production in a relatively short timeframe. Several factors may have contributed to this. First, the non-nontraditional model launched only generic products, which have a shorter timeframe and are less expensive to bring to market than new originator drugs. Second, the non-traditional model leveraged the large volume and long-term commitments from its membership to extend long-term purchasing agreements with CMOs. The long-term purchasing agreements with these CMOs, those capable of producing and marketing generic drugs, might have incentivized reentry and utilized excess capacity to ramp up production.[18]

An important context for the findings is that the non-traditional model ramped up operations during the COVID-19 pandemic, which was a period of unprecedented challenges for drug manufacturing. There was a significant increase in drug shortages triggered by unexpected sharp increases in demand, often exceeding manufacturers' production capacities.[19] In addition, the international nature of drug supply chains exacerbated shortages due to disruptions in the production and shipping of pharmaceutical

[18] Dredge & Scholtes, 2021.

[19] Socal, M. P., Sharfstein, J. M., & Greene, J. A. (2021). The pandemic and the supply chain: Gaps in pharmaceutical production and distribution. *American Journal of Public Health*, *111*(4), 635–639. https://doi.org/10.2105/AJPH.2020.306138

ingredients caused by lockdowns, understaffing, and travel and export bans.[20] From a regulatory perspective, there were delays in FDA inspections due to travel restrictions that limited FDA's capacity to inspect drug-manufacturing plants overseas, in turn further reducing its ability to authorize new entrants for manufacturing medications. These challenges were not specific to the non-traditional business model, but the confounding effects make it difficult to generalize the non-traditional volume capacity with future non-traditional entrants. However, despite these challenges, the non-traditional model sold essential medicines and drugs in shortage in volumes that were equal to or greater than the volumes sold by traditional model competitors. This points to the distinguishing features of the non-traditional model: long-term contracts with its members, diversified purchasing, and maintaining six-month buffer stock of its products, which may help to ensure that there is a reliable supply for the non-traditional model's products. These features may be attractive to hospitals and health systems that are willing to trade off the lowest cost at any given time for more reliability in drug supply.

Future research should examine if the variability in prices between the two models could be capturing the cost to engage in practices that enhance supply chain resiliency. This cost may not be reflected in the pricing of competitors, who need to incorporate profit for shareholders in pricing and might forgo resiliency investments for products with low margins.

Conclusion

This study compared the sales and volume of a non-traditional pharmaceutical model, which utilizes long-term purchase volume guarantees from its members, with the sales and volume of a traditional model. This non-traditional model sold drugs in volumes similar to the volumes sold by traditional model competitors. The non-traditional model's product mix emphasized drugs in shortage and essential medicines, which may reflect the needs of its membership. Further, the prices of the non-traditional model were not always lower than the prices of its traditional competitors. Non-traditional models may provide an opportunity to identify and address market gaps, but further research is needed to better understand long-term effects and implications.

[20] Mulcahy, A. W., & Kareddy, V. (2021). *Prescription drug supply chains: An overview of stakeholders and relationships.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. https://aspe.hhs.gov/reports/prescription-drug-supply-chains

Appendix

Appendix Exhibit 1. Drugs Used in Analysis by Form, Strength, Shortage Status, and Essential Medicines Status

Combined Molecule	Form	Strength	Drug in Shortage	Essential Medicines
Albuterol	Kc Inhalant Aerosol Systmc	90MCG	2021–2022	Yes
Aminocaproic acid	Fdb Vial Regular I.V. Only	250MG/ML	-	-
Ampicillin	Fed Dry Vial Reg I.M./I.V./S.C.	1GM, 2GM	2022	Yes
Ampicillin sulbactam	Fed Dry Vial Reg I.M./I.V./S.C.	1.5GM, 3GM	-	Yes
Bacitracin	Fea Dry Vial Reg I.M. Only	50MU	-	-
Bivalirudin	Feb Dry Vial Reg I.V. Only	250MG	-	-
Bumetanide	Fdd Vial Regular I.M./I.V./S.C.	0.25MG/ML	2018–2022	-
Calcium	Fdb Vial Regular I.V. Only	100MG/ML	2021–2022	-
Ceftriaxone	Fed Dry Vial Reg I.M./I.V./S.C.	1GM, 2GM	-	Yes
Clindamycin	Fgb Piggy Back Reg I.V. Only	600MG/50ML, 900MG/50ML	-	Yes
Daptomycin	Feb Dry Vial Reg I.V. Only	350MG, 500MG	2021–2022	Yes
Dexamethasone	Fdd Vial Regular I.M./I.V./S.C.	10MG/ML, 4MG/ML	-	Yes
Dexmedetomidine	Ffb Bottle Regular I.V. Only	200MCG/50ML, 400MCG/100ML	2019–2022	Yes
Diazepam	Fcd Disp Syr Reg I.M./I.V./S.C.	5MG/ML	-	Yes
Ephedrine	Fdd Vial Regular I.M./I.V./S.C.	50MG/ML	-	-
Etomidate	Fdb Vial Regular I.V. Only	2MG/ML	2022	Yes
Fentanyl	Fdd Vial Regular I.M./I.V./S.C.	0.1MG/2ML, 0.25MG/5ML, 2.5MG/50ML	-	Yes
Glycopyrrolate	Fdd Vial Regular I.M./I.V./S.C.	0.2MG/ML	-	Yes
Heparin	Fdd Vial Regular I.M./I.V./S.C.	1MU/ML, 5MU/ML	-	Yes
Hydralazine	Fdd Vial Regular I.M./I.V./S.C.	20MG/ML	2020–2021	Yes
Ketamine	Fdd Vial Regular I.M./I.V./S.C.	100MG/ML, 50MG/ML	2018–2022	Yes
Labetalol	Fdb Vial Regular I.V. Only	5MG/ML	-	Yes
Lidocaine	Fdd Vial Regular I.M./I.V./S.C.	1%, 2%	2018–2022	Yes
Lorazepam	Fdd Vial Regular I.M./I.V./S.C.	2MG/ML	2018–2022	Yes
Meropenem	Feb Dry Vial Reg I.V. Only	1GM, 500MG	-	Yes
Metoprolol	Fdb Vial Regular I.V. Only	5MG/5ML	-	Yes
Micafungin	Feb Dry Vial Reg I.V. Only	100MG	-	Yes
Midazolam	Fdd Vial Regular I.M./I.V./S.C.	2MG/2ML, 5MG/5ML	2020–2022	Yes
Morphine	Fdd Vial Regular I.M./I.V./S.C.	4MG/ML	2018–2022	Yes

Naloxone	Fdd Vial Regular I.M./I.V./S.C.	0.4MG/ML	-	Yes
Neostigmine	Fdb Vial Regular I.V. Only	0.5MG/ML, 1MG/ML	-	-
Nicardipine	Fdb Vial Regular I.V. Only	25MG/10ML	-	-
Norepinephrine	Fdf Vial Regular Infusion	1MG/ML	2022	Yes
Ondansetron	Fdb Vial Regular I.V. Only	4MG/2ML	2018–2022	Yes
Pantoprazole	Feb Dry Vial Reg I.V. Only	40MG	2019–2022	Yes
Phenylephrine	Fdb Vial Regular I.V. Only	10MG/ML	-	Yes
Piperacillin tazobactam	Fef Dry Vial Reg Infusion	3.375GM, 4.5GM	-	Yes
Prochlorperazine	Fdd Vial Regular I.M./I.V./S.C.	10MG/2ML	-	-
Propofol	Fdb Vial Regular I.V. Only	10MG/ML	2020–2022	Yes
Rocuronium	Fdb Vial Regular I.V. Only	10MG/ML	2018	Yes
Sodium	Fdb Vial Regular I.V. Only	1MEQ/ML	-	Yes
Succinylcholine	Fdd Vial Regular I.M./I.V./S.C.	20MG/ML	-	Yes
Tacrolimus	Aaa Caps Regular Ordinary	0.5MG, 1MG	2019–2022	Yes
Vancomycin	Feb Dry Vial Reg I.V. Only	10GM, 1GM, 5GM	-	Yes
Water for injection	Fdd Vial Regular I.M./I.V./S.C.	N/A	2021–2022	-

Sensitivity Analysis

Methods

We performed a sensitivity analysis that examined the variability of the relative price and production volume for each drug product marketed by the non-traditional and traditional models. To avoid the potential confounding effects of a differential (and changing) mix of drugs actively produced by the non-traditional model compared to the traditional model, we calculated the share of each product produced by the non-traditional model versus companies in the traditional model at the drug level and then plotted quantiles of this distribution through time, including the median (i.e., 50th percentile), the 25th and 75th percentiles, and the 10th and 90th percentiles.

We did this for two reasons. First, the non-traditional model's products were new to the market and introduced in a staggered fashion across the sample period. The methodology examined the changing distribution of relative price and production volumes as new products were being introduced onto the market. The goal was to provide insight into whether the non-traditional model's market performance was moving towards an equilibrium with regards to relative pricing and sales revenue per drug. The methodology also allowed us to examine the plausible range of market performance that non-traditional companies might produce once they move towards a stable market presence. Second, the sensitivity analysis allowed for disentangling the impacts of individual drugs, because a few outliers could affect the aggregate-level findings.

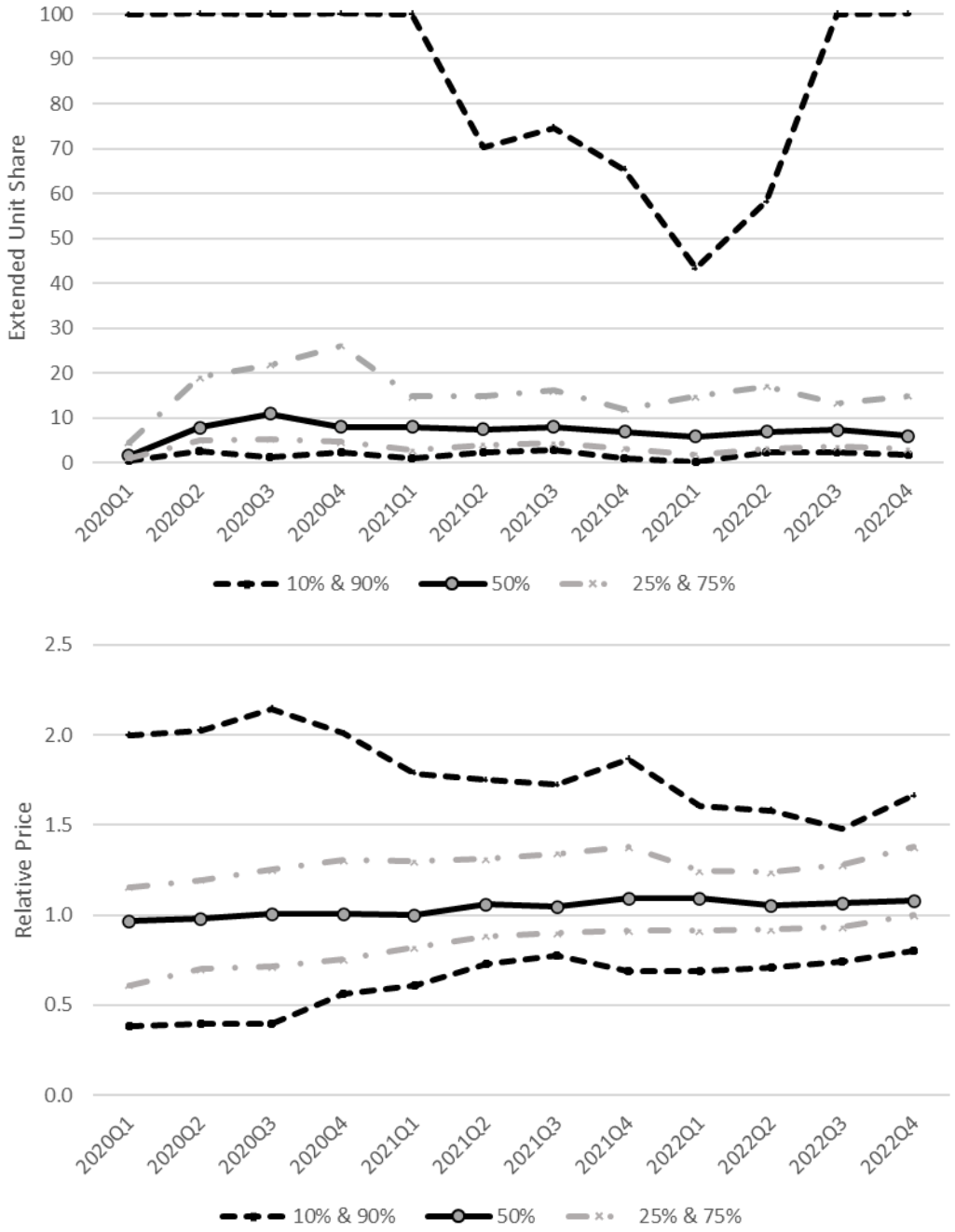
Results: Understanding Potential Future Impacts

The top graph in Appendix Exhibit 2 shows the distribution of the share of total *units* produced by the non-traditional model. Consistent with the primary findings, when the non-traditional model first launched, its median production share was approximately 2 percent. Production then increased quickly but had significant variation over time, with the median production share ranging from 6 percent to 11

percent. By taking the median of the individual drug market shares instead of the overall average, which the primary results did, this approach is more robust to potential changes in the mix of drug production over time. An additional advantage of this approach is the ability to evaluate the heterogeneity in the non-traditional model's performance across the drug product markets through time as it became more established. The range of performance is represented by the trends in the 25th to 75th percentile range (marked with a dash/dot line) and trends in the 10th to 90th percentile range (marked with a dashed line). Across the 25th to 75th percentile range, the non-traditional model's share of total units sold was between 3 percent and 16 percent of their drug portfolio. Across the 10th to 90th percentile range, there was significant variation, as the non-traditional model represented as much as 100 percent of the market in some periods at the 90th percentile. This graph provides some evidence that while the non-traditional model is generally not yet a dominant player in the overall market, in some more narrow submarkets it has the ability to play a significant role in helping to fill production capacity for certain products. The graph also provides evidence that over time non-traditional companies have the ability to significantly increase their production volume.

The bottom graph in Appendix Exhibit 2 shows an equivalent analysis applied to the distribution of the relative price of the non-traditional model compared with its traditional competitors. We observed a smooth and stable trend of modestly rising relative prices for the non-traditional model compared to traditional competitors. When the first products were launched by the non-traditional model, their median price was 4 percent lower than the median price charged by traditional competitors. Over time, the median relative price rose such that by the end of the sample, the price of the non-traditional model's drugs was 8 percent higher than the traditional alternative. Examining the range across the 25th and 75th percentiles shows that relative pricing between the non-traditional and traditional companies narrowed over time. In 2020, the non-traditional model's prices ranged from 39 percent lower than to 16 percent higher than the traditional competitors' prices. By the end of 2022, this range had narrowed: at the 25th percentile, the non-traditional model's prices were equivalent to the traditional alternative's; at the 75th percentile, its prices were 38 percent higher. These results show that as non-traditional companies become more established, their prices become less variable and closer to the traditional competitors' prices. Moreover, we find a similar result when looking at the price distribution across the 10th to 90th percentile range; in 2020, prices for the non-traditional model ranged from 62 percent lower than to 100 percent higher than the prices charged by traditional companies, but by 2022 this range had decreased to 20 percent lower than to 67 percent higher than the prices charged by traditional companies. This range reduction of nearly 50 percent over a two-year period reiterates that pricing is likely to be similar between the non-traditional and traditional competitors once the non-traditional model becomes more established.

Appendix Exhibit 2. Distribution of Relative Volume and Prices Comparing the Non-Traditional and Traditional Models



Source: ASPE analysis of IQVIA National Sales Perspective data.

Notes: The numbers in the legend represent the percentile of the share of units produced by the non-traditional model or the percentile of the relative price of the non-traditional model measured against its traditional competitors.

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Office of the Assistant Secretary for Planning and Evaluation

200 Independence Avenue SW, Mailstop 434E
Washington, D.C. 20201

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ABOUT THE AUTHORS
Sonal Parasrampuria was a Social Science Analyst and FDA portfolio lead in the Office of Science and Data Policy in ASPE when this work was conducted.
Trinidad Beleche is a Senior Economist in the Office of Science and Data Policy in ASPE.
Stephen Murphy is an Economist in the Office of Science and Data Policy in ASPE.
Oluwarantimi Adetunji is an Economist in the Office of Science and Data Policy in ASPE.

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