An Examination of the Return on Investment of Generic Injectable Prescription Drugs

Nicholas Holtkamp and Stephen Murphy

This issue brief analyzes the revenues, costs and return on investment of recently launched generic injectable drugs.

KEY POINTS

- The generic injectable drug market has recently experienced numerous shortages, which impose substantial public health costs. One potential cause of these shortages is the low profitability of generic injectables.
- This brief examines the profitability of recently launched generic injectables. In aggregate, the market achieves between zero and 42 percent return on investment (ROI) by the third year after launch, under varying cost estimates.
- This aggregate profitability is driven by a small number of highly profitable outliers. 70 percent of drugs in this market do not achieve profitability by their third year after launching.
- Generic injectables are less profitable than generic orals, which have not experienced shortages to the same extent as injectables. The generic injectable market is also composed of fewer manufacturers per molecule than the generic oral market.
- Our results are consistent with the economic theory that low expected profits of generic injectables may lead to a thinner market less resilient to shortages.
- Our analysis is limited by a lack of data on costs, which necessitates employing estimates that involve substantial uncertainty.

INTRODUCTION

In recent years, the domestic United States market for generic injectable drugs has been characterized by persistent shortages (American Society of Health-System Pharmacists 2024). These shortages have interrupted access to critical drugs, negatively impacting patient care. The lack of adequate treatment options has forced some patients to switch to clinically inferior alternatives, resulting in complications and, in some cases, death (Fox et al. 2014, Goldsack et al. 2014, Mazer-Amirshahi et al. 2014). Moreover, financial impacts of drug shortages are estimated to be in the hundreds of millions of dollars annually for health systems across the United States (American Society of Health-System Pharmacists 2023, Fox et al. 2014).

There are a number of potential causes of these shortages. On the supply side, these include a low average number of active manufacturers, production issues, and low profit margins (Wosinska and Frank 2023, Woodcock and Wosinska 2013, Fox et al. 2014,).[a] In particular, it is hypothesized that low profitability may disincentivize entry into the generic injectable market, leading to a thin market that is susceptible to negative supply shocks. Recent policy proposals have suggested solutions to addressing these issues, including plans to provide financial support to strengthen manufacturing capabilities for generic injectables (Wosinska and Frank 2023, Office of the Secretary, Department of Health and Human Services 2024, Drug Shortage Prevention and Mitigation Act 2024). These proposals highlight the importance of understanding the profitability of generic injectables.

This brief provides new evidence on the profitability of generic injectables. We examine the return on investment (ROI) for a sample of generic injectables launched in the United States between July 2018 and July 2021. Our results suggest that rates of profitability vary substantially between new products across the generic injectable market. While a small number of new generic injectables achieve high profitability within three years, most do not. When viewed as an aggregate portfolio, these highly profitable products make the entire market seem profitable, even though most products have yet to achieve profitability. We also follow Frank et al. (2021) in comparing the generic injectable market to the generic oral market. Our results suggest that, on average, generic injectables are less profitable than generic orals, which do not suffer shortages to the same extent as generic injectables. Moreover, we find that the generic injectable market is thinner with fewer manufacturing companies per molecule than generic orals.

Due to data limitations, we are not able to definitively quantify the long-run profitability of generic injectables. But for the sample of drugs and timeframe that we are able to analyze, our results are consistent with the hypothesis that low expected profits of generic injectables may be connected with a relatively thin market, which in turn may raise the risk of supply chain vulnerabilities.

METHODS

Data

Calculations of ROI require information on both sales and costs to compare the two. Therefore, for our analysis of ROI we utilize revenue data and estimate cost flows relative to the entry of a given manufacturer producing a given drug. For revenue, we utilize IQVIA National Sales Perspective (NSP) pharmaceutical market data on sales and volumes for the universe of generic injectable prescription drug products manufactured from July 2018 – June 2024. IQVIA NSP data include pharmaceutical sales data collected from wholesalers, distributors and pharmaceutical manufacturers. It comprises 90% of the pharmaceutical market, which is projected to national totals. We employ these data to identify all unique firm-drug market entries for generic injectables and orals, along with their monthly flow of revenues.

For costs, we do not have access to data on the numerous types of expenses incurred in the development, production and distribution of generic drugs. Consequently, we lean on literature that estimates average fixed costs of development, as well as variable costs measured as a percentage of revenue. Prior work from the U.S. Department of Health and Human Service's Assistant Secretary for Planning and Evaluation (ASPE) in partnership with Eastern Research Group Inc. has estimated risk-adjusted capitalized costs of generic manufacturers coming to market for various types of drugs. From these estimates, we develop our own three estimates of the fixed costs for generic injectables: a low ($5,921,504), medium ($9,164,082) and high ($12,218,777) fixed cost estimate (Eastern Research Group, Inc. 2021). Further, we utilize estimates from Positano et al. (2019) of the average cost of goods sold (COGS) as a percentage of revenue separated by type of drug. For generic injectable and oral drugs, we use estimates of 42% and 36%, respectively.

[a] There are also important demand side considerations, such as hospital purchasing practices (Wosinska and Frank 2023).

Lastly, we utilize two additional data sources. Our work incorporates a discount rate of 8.82%, an estimate that originates from earlier ASPE work that surveyed the peer reviewed literature on estimates of cost of capital rates of generic pharmaceutical companies (Eastern Research Group, Inc. 2021). We also normalize all dollar figures to January 2024 dollars using the Consumer Price Index to adjust dollar amounts so that they are comparable across time periods. [b]

Empirical Approach

To provide estimates of return on investment, we decompose ROI into its underlying constituent parts, including the flow of revenues and costs that accrue to a given generic pharmaceutical manufacturer entering a given injectable drug market (henceforth, "products"). We then use these revenue and cost flows to make average net-present value calculations across all products in our sample by time measured relative to the date of market entry for each product. Our analysis focuses on the 36 months post entry so as to balance the amount of time we track the evolution of ROI with the number of products in our sample.

We then estimate the average ROI for the sector as well as the expected amount of time post launch for the average entrant to financially break-even. This time to break-even enables us to evaluate how soon, on average, a product achieves positive profitability after launch under our cost assumptions. Furthermore, we analyze the generic injectable market in more detail by estimating the ROI for each product in our sample 36 months after launch and then plotting the resulting distribution. This provides a more nuanced snapshot of ROI than that obtained when examining the sector as a whole over time.

In addition to analyzing ROI, we also examine the depth of the market. Since we do not have data on the substitutability of products, we instead examine the number of manufacturers operating within each market, which we define at the combined molecule level. While this is an imperfect measure of market depth, it still serves as a useful proxy to understand how resilient a market may be to supply disruptions.

Lastly, we estimate the ROI for generic orals in the same manner as for generic injectables. The generic oral market is not characterized by shortages to the same extent as the generic injectable market. Therefore, comparisons between the two markets for each of our analyses allows us to provide suggestive evidence linking profitability to shortage risk.

Limitations

This analysis is subject to several limitations. First, we do not directly observe data on manufacturer costs, and instead estimate these costs using prior research that models potential costs of entry for the generics industry. We use a variety of cost scenarios to address this lack of direct data on firm-drug level cost structure, but our estimates still retain substantial uncertainty as these cost estimates are speculative. For instance, we are unable to differentiate between more and less cost-effective firms, drug markets with higher or lower average development or manufacturing costs, and correlations between drug sales and costs. The cost of producing generic injectables is likely higher than other types of generics, such as generic orals, due to factors such as specialized facilities, stricter sterility requirements, and often more complex formulation processes. Second, while we provide suggestive evidence on the relationship between profitability and shortage risk by comparing the generic injectable and oral markets, we are unable to definitively establish a relationship between the two. Lastly, we are able to provide estimates for only a sample of drugs that entered the market between July 2018 and July 2021 and were on the market for at least 36 months after entry.

---

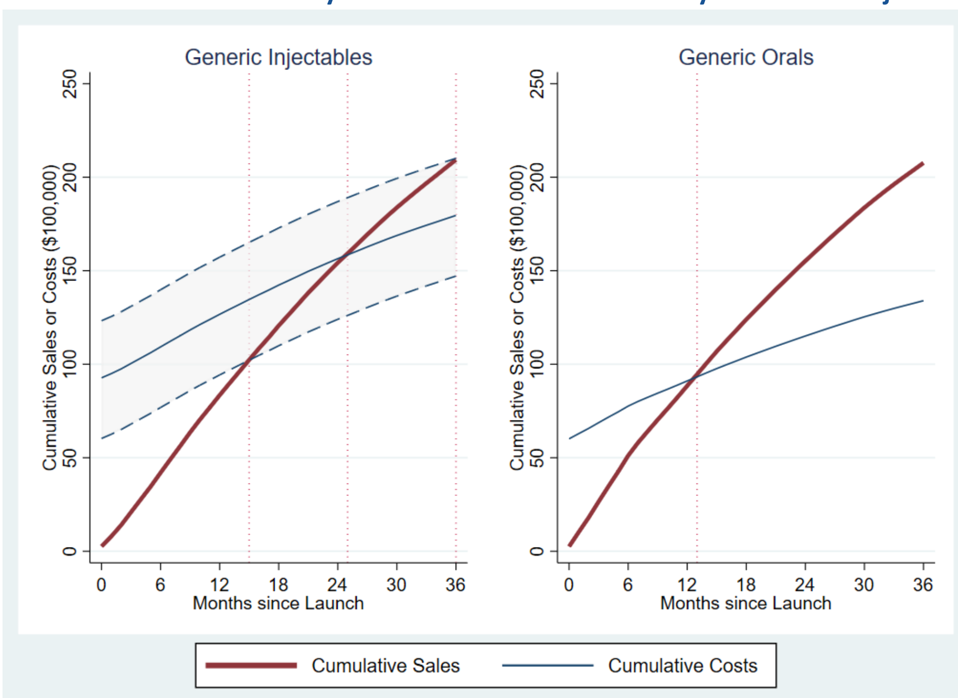
[b] We obtain our CPI data from the Federal Reserve Bank of St. Louis: https://fred.stlouisfed.org/series/USACPIALLMINMEI

RESULTS

Average Sales and Costs Since Market Entry

We first display average sales and estimated costs separately for all generic injectables and orals in our sample. This enables us to identify how soon, on average, generic injectables and orals achieve positive profitability. Figure 1 shows the average cumulative sales and average cumulative costs each month after market entry. The panel on the left covers the generic injectable cohort; the panel on the right covers the generic oral cohort. In the left panel, there is a cumulative sales curve and three cumulative cost curves, each based on a different fixed cost scenario. The area between these three lines is shaded to represent the uncertainty that exists in estimating cost curves for generic injectables without direct access to firm-drug level cost data.[c] In the right panel, there is a cumulative sales curve and only one cumulative cost curve due to the availability of a more direct estimate of the costs of generic orals than those for generic injectables.

Figure 1. Cumulative Sales and Costs by Time Relative to Market Entry for Generic Injectables and Orals



Note: This figure displays average cumulative sales and costs for generic injectable (left plot) and oral (right plot) products. Average cumulative sales for generic injectables are separated into three separate scenarios: high fixed costs (upper dashed line), medium fixed costs (middle line), low fixed costs (lower dashed line). Vertical dashed lines represent the time period in which average cumulative sales equal average cumulative costs. For generic injectables, these time periods are 15 months (low fixed costs scenario), 25 months (medium fixed costs scenario), and 36 months (high fixed costs scenario). For generic orals, the break-even time period is 13 months. The data originate from IQVIA's National Sales Perspective data and include all generic injectable and oral products launched after June 2018 with at least 36 months of post entry data.

The points of intersection between the sales curve and each of the cost curves provide estimates of financial break-even points, where average cumulative revenues first exceed average cumulative costs. In the panel on the left, we plot this break-even analysis for generic injectables, and find break-even points of

---

[c] Prior work from ASPE in partnership with ERG has modeled the fixed costs of entry for generic manufacturers for a variety of cases. See Eastern Research Group, Inc. (2021): https://aspe.hhs.gov/sites/default/files/documents/20e14b66420440b9e726c61d281cc5a5/cost-of-generic-drugs-erg.pdf

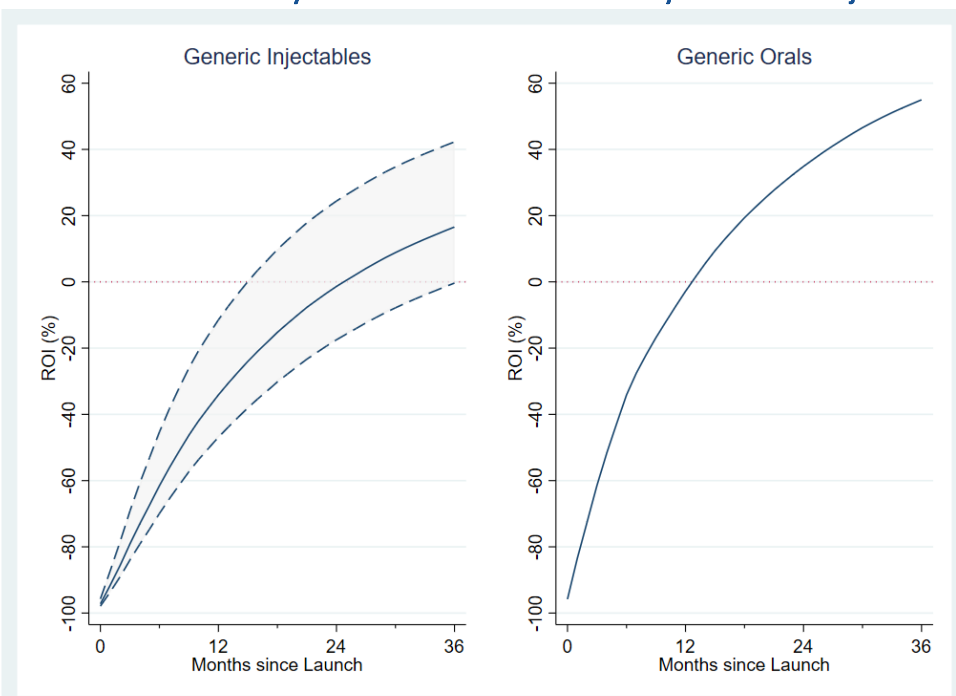
approximately 15, 25 and 36 months post entry for the low, medium and high fixed cost estimate scenarios, respectively. As expected, we find that as the assumed fixed costs of development and approval increase, the expected time to recoup enough (appropriately discounted) net-cash flow streams to break-even increases in turn.

For comparison, the panel on the right plots generic orals in the same manner. We find a break-even point of 13 months post entry. This is earlier than each of the break-even points estimated for the generic injectable market. This suggests that, on average, generic orals are more profitable than generic injectables in that they reach positive profitability earlier than even the earliest estimate for generic injectables.

Average Return on Investment Since Market Entry

We next examine average ROI across firm-drug entrants. Figure 2 illustrates net present value adjusted ROI as a function of time elapsed since market entry. We calculate this by subtracting the average cumulative flow of total costs from the average cumulative flow of sales revenues, and then dividing this difference by the average cumulative total costs. We additionally plot a horizontal line representing an ROI of zero, whose intersection with the ROI curves represents the earliest point after market entry where the first-drug entrant would break-even under each of the hypothesized cost structures.

Figure 2. Return on Investment by Time Relative to Market Entry for Generic Injectables and Orals



Note: This figure displays average return on investment for generic injectable (left plot) and oral (right plot) products. Return on investment for generic injectables is separated into three separate scenarios: high fixed costs (upper dashed line), medium fixed costs (middle line), low fixed costs (lower dashed line). For generic injectables, 36 months post launch, average return on investment is 42% (low fixed costs scenario), 17% (medium fixed costs scenario), and 0% (high fixed costs scenario). For generic orals, 36 months post launch, average return on investment is 55%. The data originate from IQVIA's National Sales Perspective data and include all generic injectables and oral products launched after June 2018 with at least 36 months of post entry data.

To the left of these intersection points, the ROI curves are negative because each firm-drug entrant starts with negative profitability due to the fixed costs associated with entry into the pharmaceutical market.

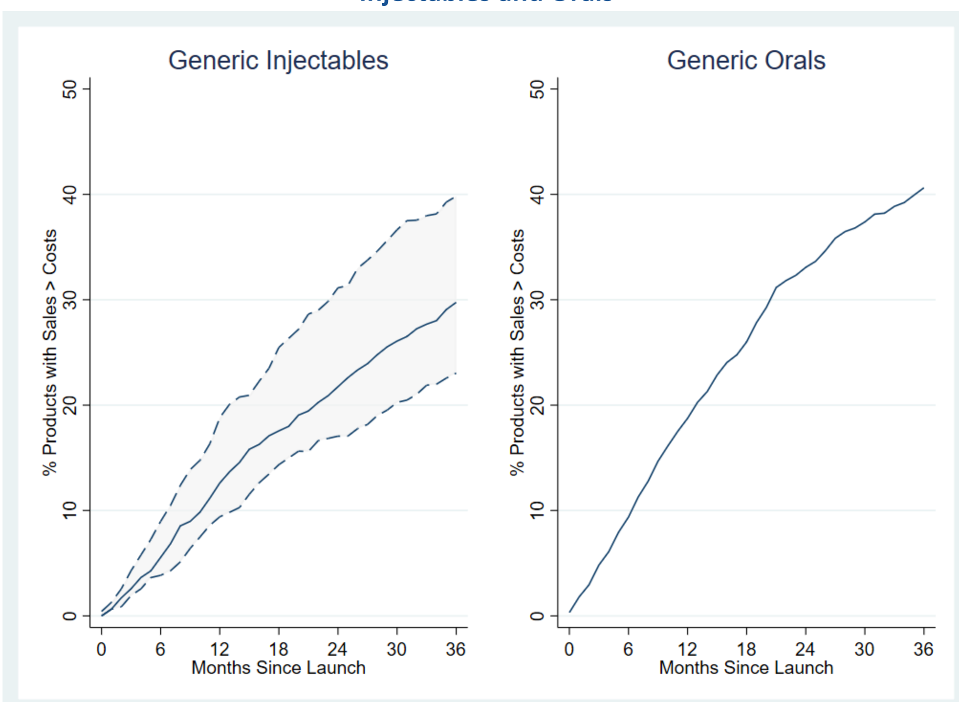
This negative profitability then begins to abate as revenue flows exceed (variable) cost flows, and eventually in almost all cost scenarios ROI becomes positive within our 36 month post launch sample period.

In the case of generic injectables, by the end of the 36 month sample period we find estimates of aggregate ROI of 42% under the low fixed cost scenario, 17% under the medium fixed cost scenario, and 0% under the high fixed cost scenario. This broad range of ROI estimates demonstrates the significant role that cost structure plays in determining profitability. We similarly estimate the ROI for generic orals, finding it to be 55% 36 months after entry, on average. This is substantially higher than even our most optimistic estimate of generic injectable ROI, demonstrating that on average generic injectables are less profitable than generic orals.

Net Profitability of Individual Firm-Drug Entrants by Time Since Launch

Our analysis so far has examined average profitability of the injectable market as a whole, which may obfuscate heterogeneity within products. Therefore, we next examine profitability at the level of individual products.

Figure 3. Percent Share of Products that are Net Profitable by Time Relative to Market Entry for Generic Injectables and Orals



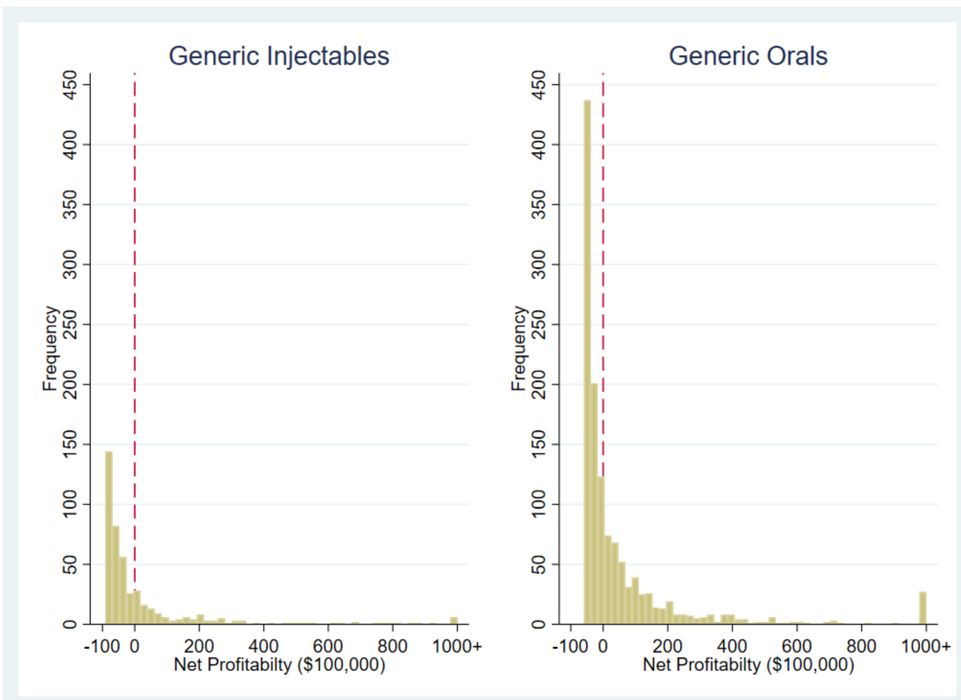
Note: This figure displays the percent of products with cumulative sales higher than cumulative costs for generic injectables (left plot) and generic orals (right plot). This percentage for generic injectables is separated into three separate scenarios: high fixed costs (upper dashed line), medium fixed costs (middle line), low fixed costs (lower dashed line). For generic injectables, 36 months post launch, the percent of products with cumulative sales higher than cumulative costs is 40% (low fixed costs scenario), 30% (medium fixed costs scenario), and 24% (high fixed costs scenario). For generic orals, 36 months post launch, this percentage is 41%. The data originate from IQVIA's National Sales Perspective data and include all generic and oral products launched after June 2018 with at least 36 months of post entry data.

Figure 3 shows the percent share of products that are net profitable over the 36 months following their entry, measured relative to the market entry of a given generic manufacturer in a given injectable drug market. We find that only 40% of generic injectable firm-drug entries are net profitable 36 months post launch under the low fixed cost scenario—and even lower—only 30% and 24% of products are net profitable under the medium and high fixed cost scenarios, respectively, 36 months post launch. In all three cases, it appears that even 36 months post firm-drug entry, the majority of generic injectable drugs are financially underwater based on net-present value calculations.

By comparison, generic orals achieve a higher rate of cumulative net profitability at each point in time relative to launch dates. By 36 months after launch, we find that approximately 41% of generic oral products are net profitable, which is higher than even the most optimistic estimate for generic injectables. This again indicates that generic injectables are less profitable than generic orals.

These results underscore the importance of understanding not just the average, but the distribution of revenues accruing across the cohort of generic injectables. It suggests there is a small subset of firm-drug entries responsible for a disproportionately large share of revenues among injectable generics. This in turn pulls up the average revenue calculations (shown in Figure 1) and the average ROI calculations (shown in Figure 2), making the generic injectable market look more profitable on average than the actual marginal firm-drug entrant would actually expect to be.

Figure 4. Distribution of Net Profitability 36 Months Post Launch for Generic Injectable and Oral Firm-Drug Entries



Note: This figure displays the distribution of net profitability for generic injectables (left plot) and generic orals (right plot) 36 months post launch. The distribution for generic injectables uses the middle fixed cost scenario to calculate net profitability. The data originate from IQVIA's National Sales Perspective data and include all generic and oral products launched after June 2018 with at least 36 months of post entry data.

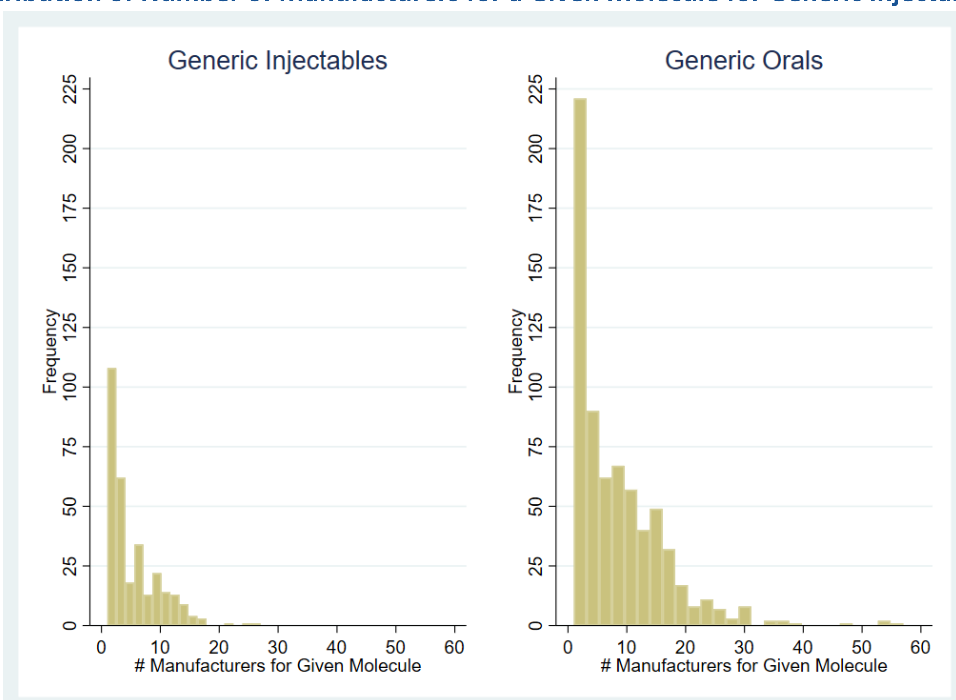
Therefore, to further analyze heterogeneity within products, Figure 4 presents the distribution of profitability of firm-drug entrants in more detail. The panel on the left shows this distribution of net profitability (measured in $100,000 increments) 36 months post entry for the cohort of generic injectable drugs using the middle fixed cost scenario. It shows that net profitability is right-skewed, where a small number of firm-drug entries enjoy a dramatically above average level of net profits. Indeed, 6 of the 447 products enjoyed net profitability surpassing $100,000,000. This profitability was high enough to result in the average ROI for the market as a whole reaching 17% (as shown in Figure 2), even though most firm-drug entrants (70%) had not yet achieved profitability 36 months post entry.

For comparison, the panel on the right shows the distribution of net profitability 36 months post entry for generic orals. A larger percentage of firm-drug entries in the branded generic cohort achieve net profitability by 36 months post launch (41%). Moreover, 25 of the 1243 products enjoyed net profitability surpassing $100,000,000.

Number of Manufacturers per Molecule

Lastly, we evaluate the number of products in the two markets in more detail. One potential contributor to the injectable market being at higher risk of shortages may be the fact that the market lacks an adequate number of active manufacturers, which may result in a shallower market more susceptible to shocks. Figure 5 displays the distribution of the number of manufacturers per molecule for all generic injectables and orals in July 2024. We do not limit the sample to only more recently launched products given that we are not examining profitability as we have done in previous analyses. The figure's x-axis shows the number of manufacturers for each of the molecules in their respective markets, and the y-axis shows the number of molecules binned by the number of manufacturers producing them.

Figure 5. Distribution of Number of Manufacturers for a Given Molecule for Generic Injectables and Orals



Note: This figure displays the distribution of the number of manufacturers for a given molecule for generic injectables and orals. The sample is limited to all generic injectables and orals in July 2024. The data originate from IQVIA's National Sales Perspective data.

We find that not only is the generic injectable market characterized by a smaller number of products than the generic oral market, but overall it exhibits a thinner market in terms of number of manufacturers per molecule. On average, the generic injectable market has 5 manufacturers per molecule, whereas the generic oral market has 9 manufacturers per molecule. The generic injectable market also has a shorter right tail in its distribution, with the maximum number of manufacturers for a given molecule being 27, whereas the maximum is 57 for the generic oral market.[d]

---

[d] As a robustness test, we also examine number of manufacturers per *productsum*, an IQVIA variable that defines a product at a finer level than at the molecule level. Our results are similar to those when we examine the number of manufacturers within molecules.

DISCUSSION

This brief estimates the ROI of generic injectables that launched between July 2018 and July 2021. We find that in aggregate the generic injectable market achieves profitability 36 months post launch. However, an examination of heterogeneity at the level of individual firm-drug entrants shows that this aggregate profitability is driven by a small number of highly profitable outliers. Most products remain unprofitable even 36 months after launch. We also find that the generic injectable market is on average less profitable than the generic oral market with substantially fewer manufacturers per molecule.

Recent policy proposals to address drug shortages due to supply chain disruptions cite as motivation the low profitability of generic injectables. While this brief cannot definitively identify the full landscape of generic injectable profitability or characterize market resiliency, it does provide novel evidence that aligns with the hypothesis that the relatively low profitability of the generic injectable market, in conjunction with its inherently complicated and costly manufacturing processes, may be a contributing factor to its propensity for shortages. This interpretation is bolstered by our results showing that generic orals, which do not exhibit the same propensity for shortages, are on average more profitable with thicker markets. This coincides with other work showing the oral market to exhibit higher rates of entry and lower rates of exit (Frank et al. 2021).

Due to data limitations, we are unable to definitively identify ROI for generic injectables and generic orals; nor are we able to definitively link specific levels of profitability with shortage risks. There are numerous considerations in understanding how specific levels of profitability and supply chain characteristics affect shortages, many of which this brief cannot account for. Future work may further explore this link by better accounting for cost structure, exploring in more detail the link between profitability and shortages, and examining a broader sample of products. For instance, older generics are frequently highlighted as being especially prone to shortage risk due to low profitability. Since our work focuses on newer generics, future work may expand to examine this older cohort.

APPENDIX: Alternative Cost Function and Returns to Scale

Throughout the above report, we utilize a hypothetical cost structure based on three different levels of fixed costs, but a single per unit cost based on 42% of the per unit price. However, we have yet to incorporate the possibility of economic returns to scale (RTS). Thus, in this Appendix we further develop the hypothetical cost function based on three different parameterizations of RTS.

We posit a marginal cost function that has a constant elasticity with regards to the amount of a given drug molecule actively produced by a given firm in a given time period. We force the aggregate drug-molecule weighted average cost flows to be exactly 42% of the total revenues in accord with the COGS estimate of 42% cited earlier, but we allow individual company-by-time level marginal cost observations to depend on the volume produced with respect to this constant elasticity cost function. We additionally consider three different levels of RTS by changing the elasticity of the constant elasticity function, including -0.05 (low RTS, a 10-times multiple of production would yield approximately 10 percent lower marginal cost per unit), -0.10 (medium RTS, a 10-times multiple of production would yield approximately 20 percent lower marginal cost per unit), and -0.15 (high RTS, a 10-times multiple of production would yield approximately 30 percent lower marginal cost).

We impute our variable cost streams using an exponential function based on a single parameter (β) that can be varied to produce different intensities of RTS. Specifically, we model the per unit cost of a given manufacturer's production of a given drug as below in Equation (1) using values of $\beta = 0.05$, $\beta = 0.10$, and $\beta = 0.15$ for low, medium, and high RTS, respectively:

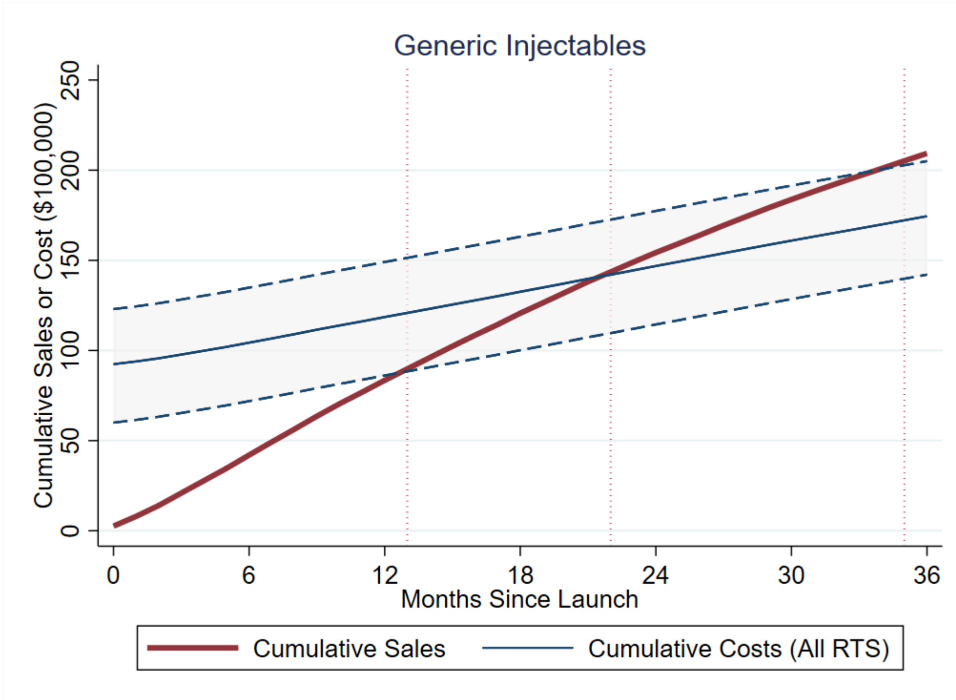
$$PerUnitCost_{(f,m,d)} = \alpha_{(m)} * VolumeShare_{(f,m,d)}^{(-\beta)} \qquad \text{(Eq. 1)}$$

In Equation 1, the subscript "*f*" denotes the given firm, "*m*" denotes the given molecule, and "*d*" denotes the given date. $VolumeShare_{(f,m,d)}$ therefore is defined as the volume that firm *f* produces of molecule *m* in date *d* divided by the aggregate volume of that given drug summed across all firms and time periods in our sample. Additionally, $\alpha_{(m)}$ is a molecule-level scaling parameter adjusted to match the weighted average total variable cost to remain equal to 42% of total revenues for the given drug. In the remainder of the Appendix, we reproduce our analytics for generic injectables utilizing these enhanced cost functions.

Average Sales and Costs Since Market Entry

Figure A1 displays the flow of revenues for 36 months post entry with the heavy solid line, which are identical to the original Figure 1. There are now nine cost curves plotted—based on the three different levels of fixed costs, each with the three different levels of RTS. Note that in the figure there appears to be only three curves. This is because the net results of incorporating the three different RTS for each of the three fixed costs is that the aggregate cost flows almost identically average out independent of the level of RTS used. Consequently, the only noticeable difference is the differential fixed costs. It may be surprising that the three levels of RTS appear to not substantially differ. However, since these are average aggregate results that still respect the average variable cost being 42% of revenues, where one firm operating at higher scale is more profitable given its lower costs, another firm must therefore have higher than average costs with lower profitability. Hence, in aggregate the impact of RTS appears to wash out.

Figure A1. Cumulative Sales and Costs by Time Relative to Market Entry for Generic Injectables, Incorporating Economies of Scale

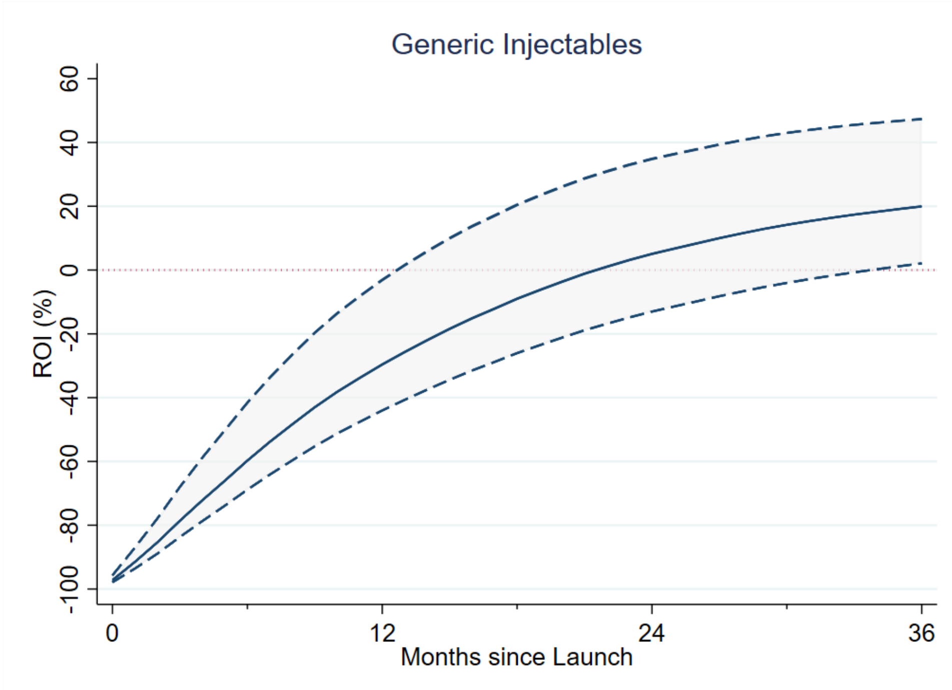


Note: This figure reproduces Figure 1 with the addition of incorporating RTS (high, medium and low) for each of the three fixed cost curves (high, medium and low). There is one curve for cumulative sales, and nine curves for cumulative costs (for each combination of RTS and fixed costs). These nine cumulative cost curves resemble only three cumulative costs curves in the figure because for each fixed cost (high, medium and low), the three cumulative cost curves that represent different RTS (high, medium and low) overlap one another.

Average Return on Investment Since Market Entry

We extend our original analysis of ROI by using the same underlying three fixed cost scenarios as in the main body of the brief, but with the addition of the three RTS parameterizations in Figure A2. Previously, we found 36 month post launch ROI estimates generic injectables of -1%, 16%, and 41% for the low, medium and high fixed cost scenarios. Now with the RTS models we find nearly identical ROI estimates. Within each of the three given fixed cost structures, the ROI estimates for each of the three hypothetical RTS are essentially identical to one another, resulting in them being plotted on top of one another.

Figure A2. Return on Investment by Time Relative to Market Entry for Generic Injectables, Incorporating Returns to Scale

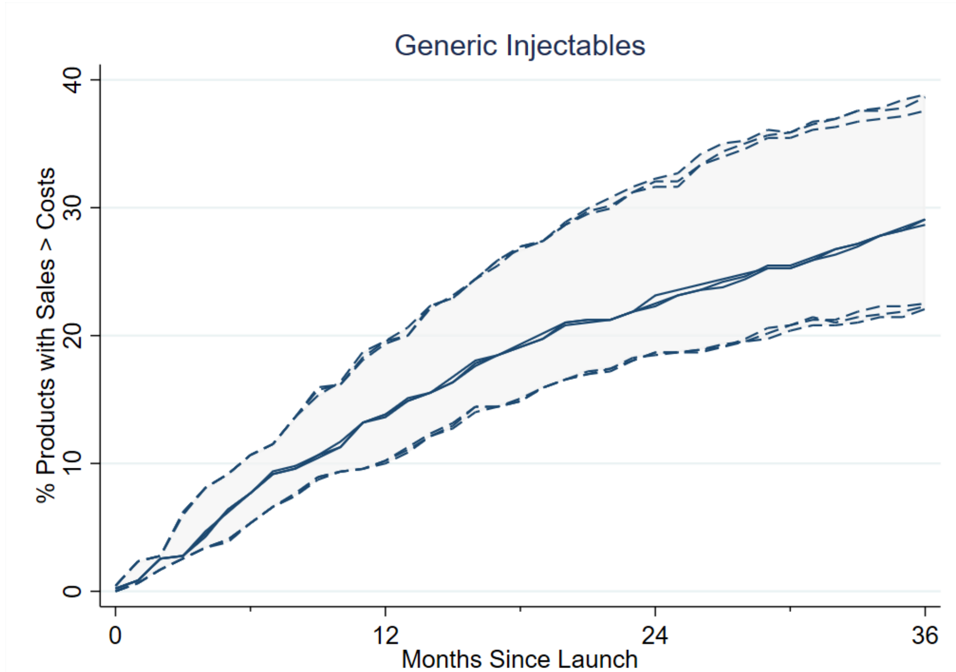


Note: This figure reproduces Figure 2 with the addition of incorporating RTS (high, medium and low) for each of the fixed cost scenarios (high, medium and low). The solid lines represent the medium fixed cost scenario, and the dashed lines represent the high and low fixed cost scenarios). These nine cumulative cost curves resemble only three cumulative cost curves in the figure because for each fixed cost (high, medium and low), the three cumulative cost curves that represent different RTS (high, medium and low) overlap one another.

Net Profitability of Individual Firm-Drug Entrants by Time Since Launch

We lastly revisit our analysis of the percent of product entries that are cumulatively net profitable by month after launch by modifying the original version to incorporate the three RTS parameterizations in Figure A3. This is the first figure incorporating RTS where the differences between the degrees of returns-to-scale can be seen on the figure as being distinct from one another. This is due to this figure examining individual firm-drug level data, and not relying on the aggregate market as in the previous two figures. Hence, a firm with larger production can achieve lower costs, enabling it to reach net profitability faster than another firm that has higher costs for the same drug molecule due to lower production volumes. However, even in this environment in which there are noticeable differences due to RTS, these differences are still minor and do not meaningfully change the results.

Figure A3. Percent Share of Products that are Net Profitable by Time Relative to Market Entry for Generic Injectables, Incorporating Returns to Scale



Note: This figure reproduces Figure 3 with the addition of incorporating RTS (high, medium and low) for each of the fixed cost scenarios (high, medium and low). The upper trio of dashed lines represent three different RTS for the high fixed cost scenario, the middle trio of solid lines represent three different RTS for the medium fixed cost scenario, and the lower trio of dashed lines represent three different RTS for the low fixed cost scenario.

References

1. American Society of Health-System Pharmacists (2024). National Drug Shortages January 2001-June 2024. https://www.ashp.org/-/media/assets/drug-shortages/docs/2024/2024-Drug-Shortages-Survey.pdf
2. American Society of Health-System Pharmacists (2023). Severity and Impact of Current Drug Shortages June/July 2023. https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf
3. Drug Shortage Prevention and Mitigation Act (2024). Compiled May 1, 2024: https://www.finance.senate.gov/imo/media/doc/050124_sfc_drug_shortages_discussion_draft_legislative_text.pdf
4. Eastern Research Group, Inc. (2021). Cost of Generic Drug Development and Approval. https://aspe.hhs.gov/sites/default/files/documents/20e14b66420440b9e726c61d281cc5a5/cost-of-generic-drugs-erg.pdf
5. Fox ER, Sweet BV, & Jensen V. (2014). Drug shortages: a complex health care crisis. *Mayo Clinic Proceedings.* 89(3), 361-373.
5. Frank RG, McGuire TG, & Nason I. (2021). The evolution of supply and demand in markets for generic drugs. *Milbank Q.* 99(3), 825-52.
6. Goldsack JC, Reilly C, Bush C, et al. (2014). Impact of shortages of injectable oncology drugs on patient care. *Am J Health Syst Pharm*. 71(7), 571-8.
7. Mazer-Amirshahi M, Pourmand A, Singer S, Pines JM, & van den Anker J. (2014). Critical drug shortages: implications for emergency medicine. *Academic Emergency Medicine*. 21(6), 704-711.
8. Office of the Secretary, Department of Health and Human Services (2024). Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States. https://aspe.hhs.gov/reports/preventing-shortages-supply-chain-vulnerabilities
9. Positano L, Chen L, Cheng YY, & Aggrawal P. (2019). Getting a Grip on COGS in Generic Drugs. https://www.bcg.com/publications/2019/getting-a-grip-on-cogs-in-generic-drugs
10. Woodcock J, & Wosinska M. (2013). Economic and technological drivers of generic sterile injectable drug shortages. *Clinical Pharmacology & Therapeutics*. 93(2), 170-176.
11. Wosinska M, & Frank RG. (2023). Federal policies to address persistent generic drug shortages. *The Hamilton Project*.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation

200 Independence Avenue SW, Mailstop 447D
Washington, D.C. 20201

For more ASPE briefs and other publications, visit:
aspe.hhs.gov/reports

ABOUT THE AUTHORS

Nicholas Holtkamp is an Economist in the Office of Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation.
Stephen Murphy is an Economist in the Office of Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation.

SUGGESTED CITATION

Holtkamp, Nicholas; Murphy, Stephen. An Examination of the Return on Investment of Generic Injectable Prescription Drugs. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. December 2024.

COPYRIGHT INFORMATION

DISCLOSURE

For general questions or general information about ASPE:
aspe.hhs.gov/about