

Generic Competition and Drug Prices

How Generic Competition Advances Public Health by Improving Access to Affordable Medication

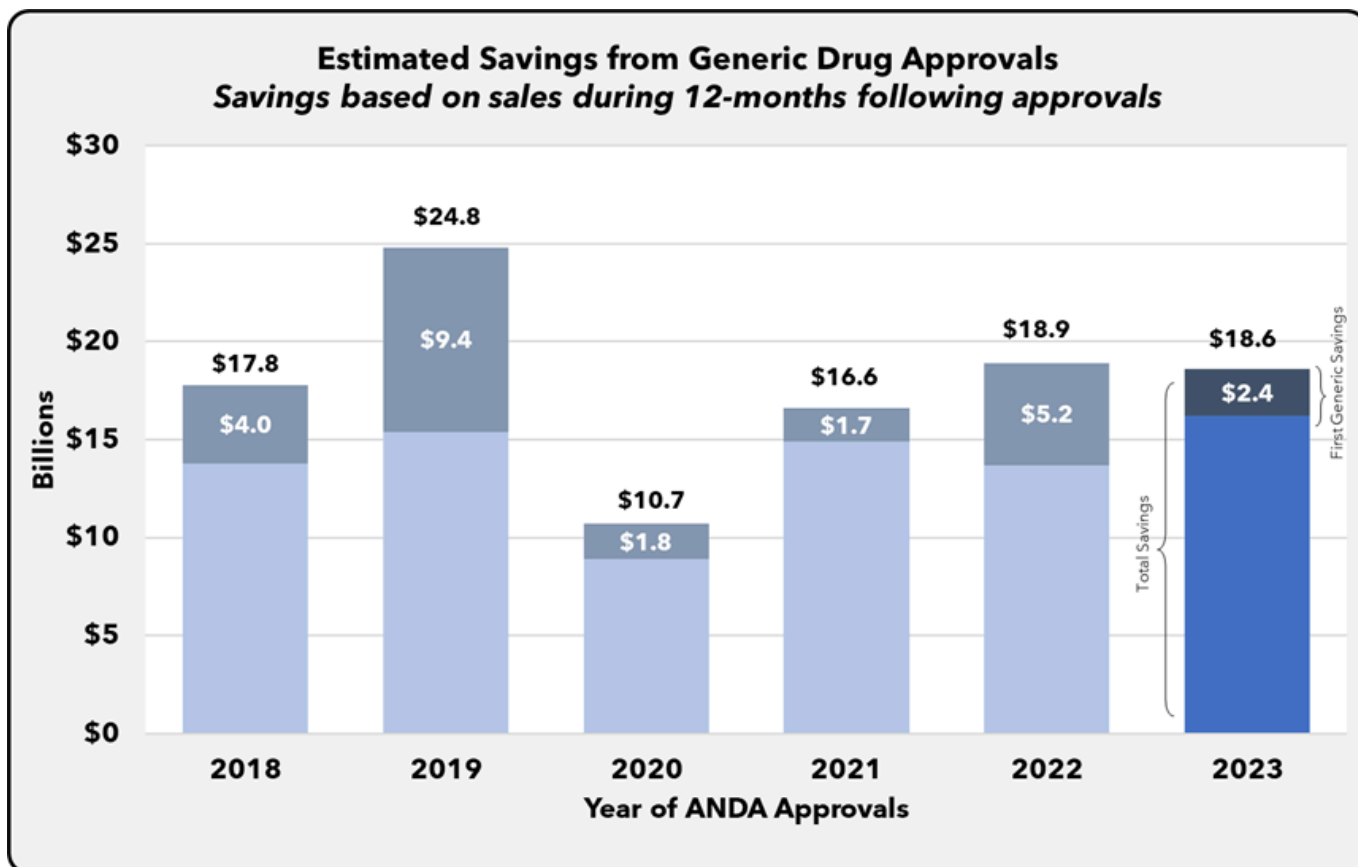
Access to affordable medicines remains a significant public health priority for FDA. The agency regularly conducts economic analyses to measure the impact additional approved generic equivalents can have on consumer generic drug prices. These studies have continually demonstrated that greater competition from generic drugs can help affordability and improve access to drugs for American patients and consumers.

Below is a listing of our most recent studies. FDA will publish new analyses here as they are completed.

- [Estimating Cost Savings from New Generic Drug Approvals in 2023](#)
([/media/189635/download?attachment](#)) (PDF, 479 KB)

This study estimates savings from the 773 generic drug applications fully approved by FDA in 2023. This work is a continuation of previous research using similar methods to estimate savings from generic drug approvals in earlier years, all of which shows the relationship between generic competition and drug prices, with market entry of just a few generic competitors yielding generic prices below the brand price (November 2025).

Feedback

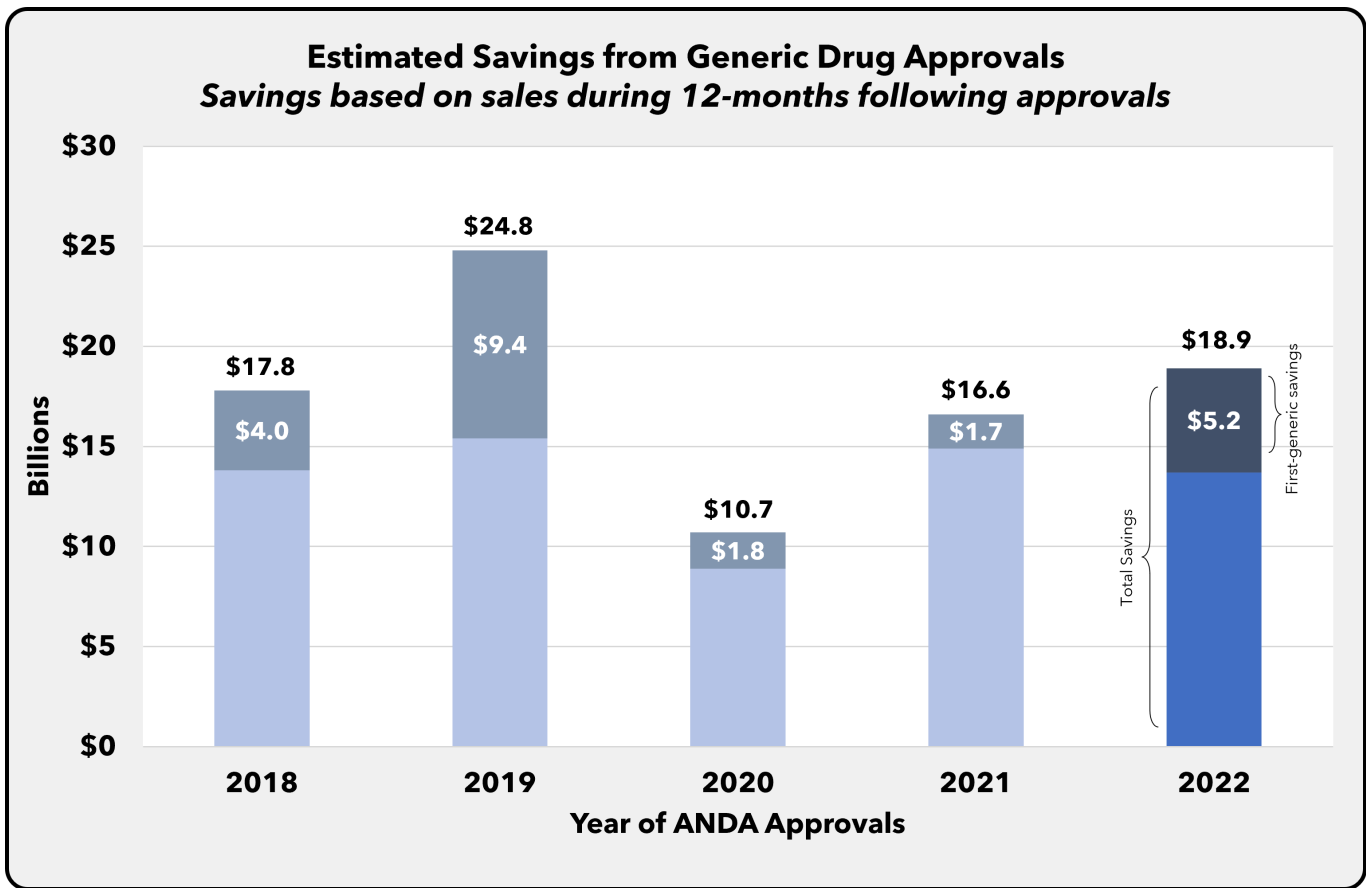


Estimated Savings from Generic Drug Approvals

- [Estimating Cost Savings from New Generic Drug Approvals in 2022](#)

([/media/182435/download?attachment](#)). (PDF, 492 KB)

This study estimates savings from the 742 generic drug applications fully approved by FDA in 2022. This work is a continuation of previous research using similar methods to estimate savings from generic drug approvals in earlier years, all of which shows the relationship between generic competition and drug prices, with market entry of just a few generic competitors yielding generic prices below the brand price (September 2024).



Estimated Savings from Generic Drug Approvals

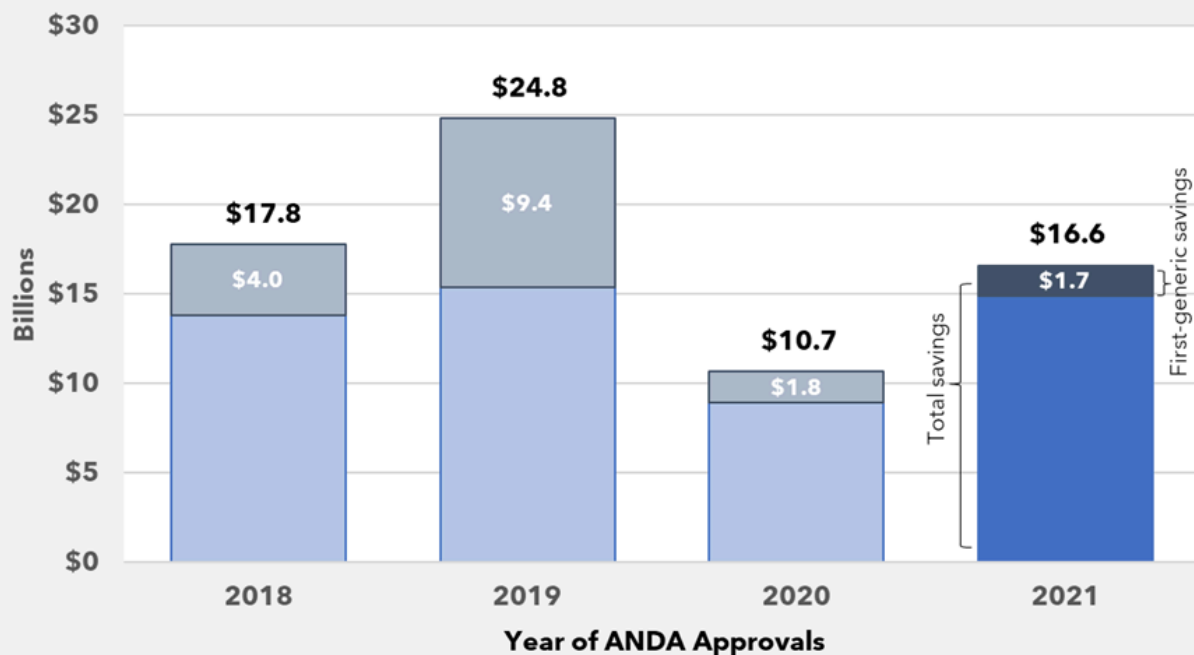
- Estimating Cost Savings from New Generic Drug Approvals in 2021

(</media/172608/download?attachment>) (PDF, 692 KB)

This study estimates savings from the 633 generic drug applications fully approved by FDA in 2021. This work is a continuation of previous research using similar methods to estimate savings from generic drug approvals in earlier years, all of which shows the relationship between generic competition and drug prices, with market entry of just a few generic competitors yielding generic prices below the brand price (September 2023).

Estimated Savings from Generic Drug Approvals

Savings based on sales during 12 months following approvals



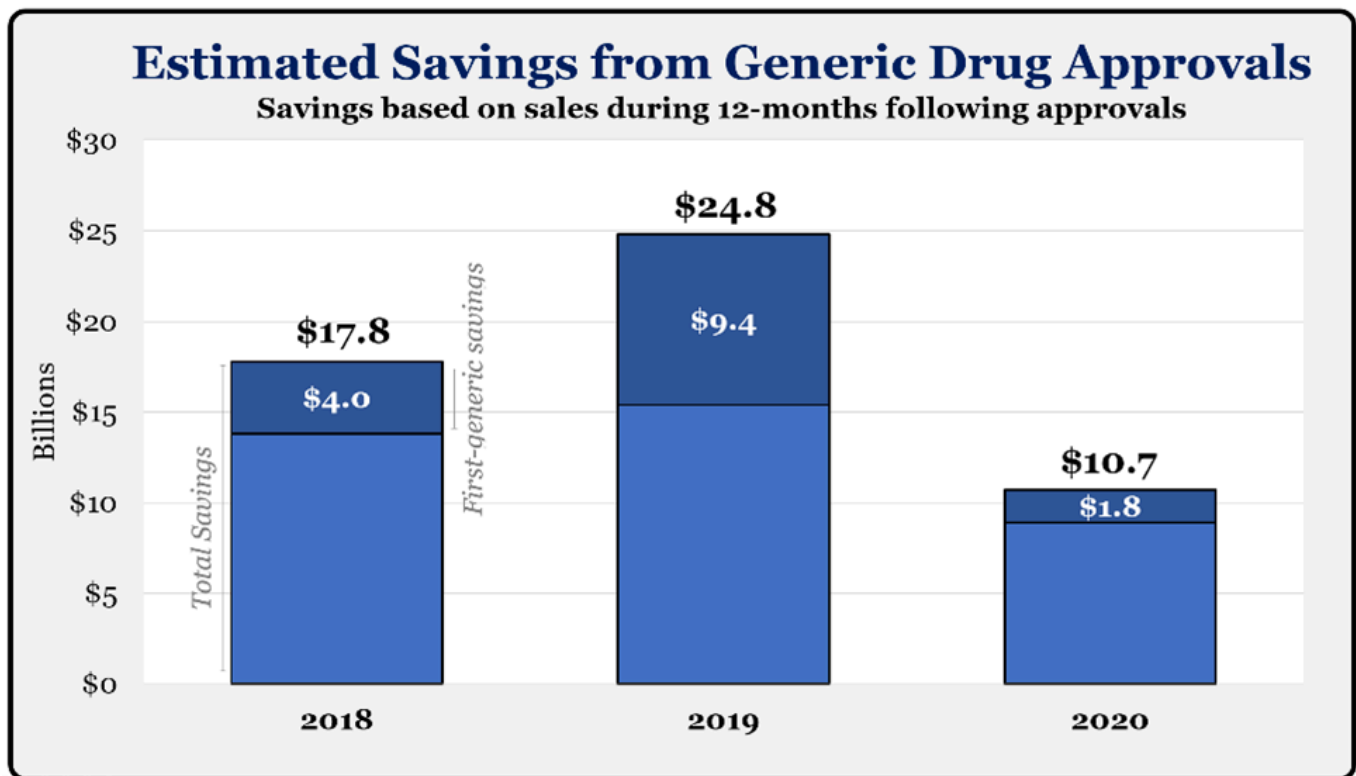
Estimated Savings from Generic Drug Approvals

We recognize that there has been increasing attention on whether the lower cost of generic drugs, especially as more generics enter the market over time, may place pressure on companies to adopt strategies that lower the cost of manufacturing, which in turn may lead to supply disruptions and shortages. This paper focuses on the savings from generic drug approvals in 2021 and this larger policy question is not the focus of this analysis.

- [Estimating Cost Savings from New Generic Drug Approvals In 2018, 2019, and 2020 \(/media/161540/download?attachment\)](#) (PDF, 580 KB)

This study estimates savings associated with the 2,400 new generic drugs approved in 2018, 2019, and 2020. Previous FDA research shows the relationship between generic competition and drug prices, with market entry of just a few generic competitors yielding generic prices below the brand price. This new work on the cost savings from generic approvals in 2018, 2019, and 2020 builds upon previous research, further illustrating the relationship between generic drugs, competition, lower drug prices, and consumer savings. In this study, we estimate total savings accrued during the 12 months following each generic drug approval. We also highlight savings estimates for first generic approvals. Year-to-year variations in savings are due primarily to the presence or lack of generic approvals for high-revenue products with large patient populations (July 2022).

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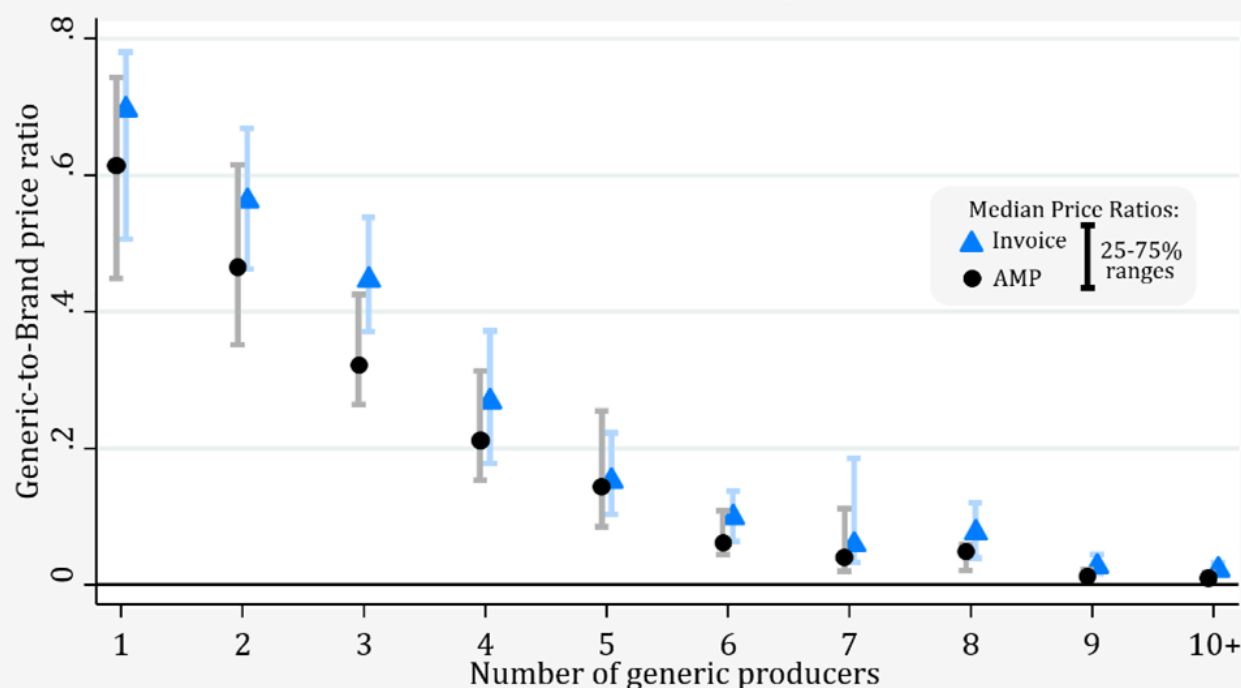


Estimated Savings from Generic Drug Approvals

- [Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices \(/media/133509/download?attachment\)](#) (PDF, 828 KB)
 This analysis, which uses two different sources for wholesale prices, demonstrates that greater competition among generic drug makers is associated with lower generic drug prices. We show that generic drug prices after initial generic entry decline with additional competition, using both the average manufacturer prices (AMP) reported to the Centers for Medicare and Medicaid Services (CMS) and invoice-based wholesale prices reflecting pharmacy acquisitions from IQVIA's National Sales Perspective database (NSP). Estimates using AMP show price declines associated with additional generic competition steeper than those based on invoices for pharmacy acquisitions, though most of the difference comes from wholesaler markups (December 2019).

Generic Competition and Drug Prices

Median generic prices relative to brand price before generic entry



Generic drug products with initial generic entry from 2015-2017.

Based on IQVIA NSP invoice-based sales and units sold to pharmacies (▲) and average manufacturer prices (AMP) reported to CMS (●).

- Estimating Cost Savings from Generic Drug Approvals in 2017

(<https://fda.report/media/113500/Estimating-Cost-Savings-From-Generic-Drug-Approvals-In-2017.pdf>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (PDF, 169 KB)

In 2017, FDA approved the highest number of generic drug applications in its history, with 843 fully approved applications and 184 tentatively approved applications. In this study, we provide an estimate of the cost savings (as of February 2018) to American prescription drug buyers associated with these 2017 generic product approvals. We also construct an estimate of the “first-year” of total savings from all generic applications approved in 2017 (June 2018).

Additional Resources

- Drug Competition Action Plan (</drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan>)

- Marketing of First Generic Drugs 2010-2017 Report (</media/154101/download>) (PDF, 4 MB)

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