FDA | U.S. FOOD & DRUG ADMINISTRATION

Report

Estimating Cost Savings from New Generic Drug Approvals in 2021

Authors:
Ryan Conrad, PhD
Kristin Davis, JD

U.S. Food & Drug Administration
Center For Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993
FDA.gov

Estimating Cost Savings from New Generic Drug Approvals in 2021
September 2023

Access to affordable medicines continues to be a significant public health priority for FDA. Each year FDA approves hundreds of new generic drugs. These approvals stimulate competition, making medicines more affordable and improving access to care for American patients and consumers.

This study estimates savings associated with the 633 generic drug applications fully approved by FDA in 2021. This work is a continuation of previous research that used similar methodology to estimate savings from generic drug approvals in earlier years. Results show market entry of just a few competitors can yield generic prices well below the brand price.[1]

In this report, we estimate the total savings accrued during the 12 months following each generic drug approval made in 2021.[2] We also highlight savings estimates for first generic approvals (products that are the first generic versions approved for the brand product), which can often yield substantial cost savings.
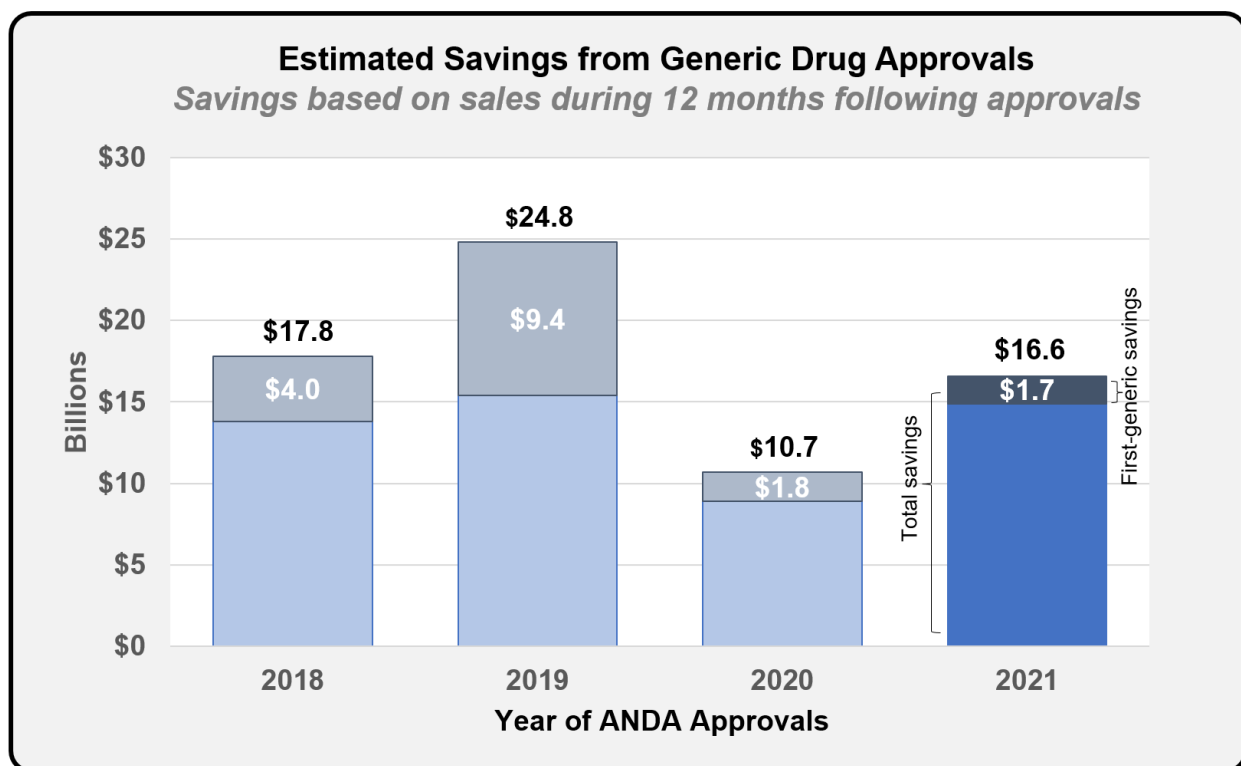
Estimates show that generic drugs approved in 2021 yielded $16.6 billion in total savings during the 12 months following their approvals, of which $1.7 billion is attributed to first generic approvals. The estimates from the 2021 approval cohort are in line with savings estimates from previous approval years. Current results along with results from 2018-2020 ANDA approval cohorts are shown below.

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 it is not the focus of this analysis.

---

[1] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices
[2] This requires observed sales data through December 2022 to capture savings from approvals made in December 2021, hence the release of this report in 2023.

Figure 1. Savings from generic drugs approved in 2021, compared to earlier years.

Estimated Savings from Generic Drug Approvals
Savings based on sales during 12 months following approvals

Billions — Year of ANDA Approvals

Year	First-generic savings	Total savings
2018	$4.0	$17.8
2019	$9.4	$24.8
2020	$1.8	$10.7
2021	$1.7	$16.6

Variations in yearly savings are primarily due to the mix of products for which generics were approved each year. For example, high-priced, large-market products tend to yield more savings when new generics enter the market compared to products with smaller markets. Total savings from new generic approvals in years when more of these high-revenue products are approved can be significantly larger than in years when relatively few high-revenue products have generic approvals.

This report also highlights the importance of price reductions and savings associated with first generic approvals. The timing of these first generic approvals is often dictated by patent expiry dates of the brand product. First generics approved in 2021 contributed a relatively smaller share of the total savings than in recent previous years due to the specific products for which first generics were approved, which tended to be products with smaller markets.

Within a year of the first generic approval, we often see prices fall by more than 75 percent compared to the brand price. For products that serve smaller patient populations total savings may be modest. However, for the patients that rely on these drugs even minor price reductions are often meaningful and can improve their access to important medicines.

1. Data and Methods

We identify all new generic drug applications that were fully approved by FDA in 2021.[3] In some cases, these approvals were the first ever generics for the drug product. These first generic approvals can yield relatively large price declines when they enter markets with only a brand drug and no existing generic producers. In other cases, new generic approvals enter markets with existing robust competition from previously approved generic drugs. These approvals may be associated with modest price reductions.

For each newly approved generic drug, we identify the NDA number of the brand drug that is the reference listed drug (RLD), along with ANDA numbers of all other previously approved generics sharing this RLD.[4] These sets of bioequivalent brand (NDA) and generic (ANDA) drug applications define what we refer to as a "drug product" throughout this work, representing all approved applications of each drug product.[5]

Price and market share can vary widely among competing producers of the same drug product. For example, a brand drug may be priced 10 times that of its generic equivalent, yet the generic may hold 90 percent of the market share. Given these variations within the same product, we use the producer-specific prices and market shares to compute a single average price for each drug product.

This price measure is computed using the combined total dollar sales of all brand and generic equivalents of each drug product and dividing by the total unit sales of the product. It represents a weighted average that accounts for within-product differences in price and market share between all competing brand and generic producers of the same drug product. This average price is computed each month, starting with the ANDA approval month through the following 12 calendar months after the approval.

Prescription drug unit sales and pricing data are from the IQVIA National Sales Perspective (NSP) database.[6] We use the national drug code (NDC) numbers associated with each NDA and ANDA to identify the correct products in the NSP database. All dollars are inflation-adjusted to a January 2023 base using the Consumer Price Index (CPI) from the Bureau of Labor Statistics, allowing for consistent

---

[3] Abbreviated new drug applications (ANDAs) are identified using FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book).

[4] Brand drugs are approved via new drug applications (NDAs); generic drugs are approved via abbreviated new drug applications (ANDAs). A reference listed drug (RLD) is an approved drug product to which an ANDA applicant must show, among other things, that its proposed generic drug is bioequivalent. A sponsor seeking approval of a generic product must refer to an RLD in its ANDA. The RLD is ordinarily also the reference standard (RS), which is the drug product selected by FDA that ANDA applicants must use in conducting any in vivo bioequivalence testing required to support approval of ANDAs, but if the RLD is no longer marketed, FDA may select a previously approved ANDA product that referred to and is therapeutically equivalent to the RLD as the RS. If the RLD for a newly approved generic included in this study was not marketed, the baseline price was computed using information for the RS.

[5] For this work we consider different strengths to all be the same drug product. For example, everolimus tablets of 2.5 mg, 5 mg, 7.5 mg, and 10 mg are considered the same drug product despite being of different strengths.

[6] See this IQVIA NSP fact sheet (pdf) for a complete description of the data. NSP data represent invoice-based wholesale prices reflecting pharmacy acquisitions, and may not perfectly reflect out-of-pocket costs faced by patients given the presence of insurance-based copays, coinsurance, rebates, and other price adjustments.

comparisons across time. The logical process used to identify our sample is summarized in Figure 2.

Figure 2. Data identification process
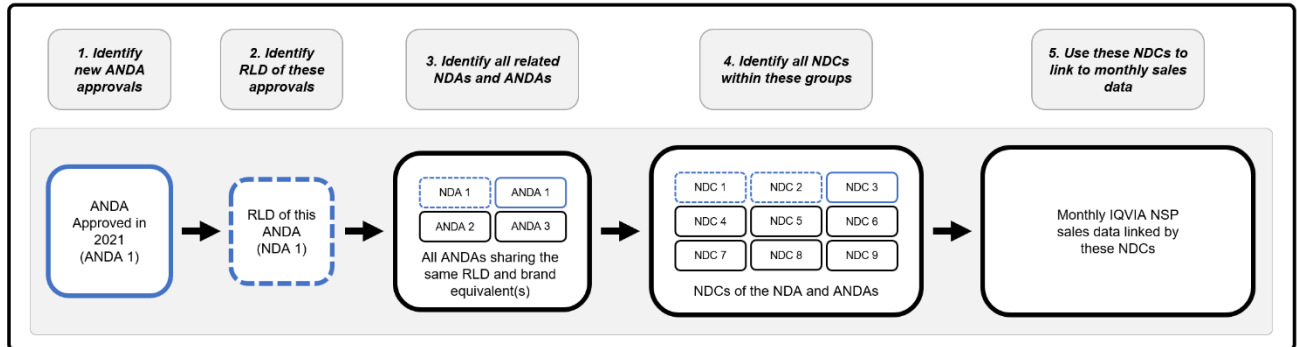
Savings estimates depend on both the price decline observed after new generic drug approvals and the unit sales of the product in each month. A baseline price is computed for the 6 months prior to the ANDA approval. For products that had a first generic entry, the baseline price includes only brand sales prior to generic entry as no generics were yet on the market. If generics were already approved, the baseline price includes sales of all generic equivalents along with the brand equivalent. This baseline price is computed similarly to the monthly weighted average product price described earlier except we combine sales for the 6 months prior to the generic drug approval. Using 6 months rather than a single month helps to mitigate any month-to-month price variations. The baseline price used for each approval does not change over time.

Using the monthly product price and the baseline price we can estimate savings associated with price reductions from new generic drug approvals. Monthly savings for each drug product are calculated by first taking the difference of the baseline price and the observed price, and then multiplying this price difference by the units sold in the given month.

Savings for product i in month t are estimated as:

$$Savings_{i,t} = Units_{i,t} * (Price_{i,base} - Price_{i,t})$$

Total savings for a given product i are computed by summing each monthly savings estimate for the product over the full 12 months of follow-up:

$$Savings_i = \sum_{t=1}^{12} Savings_{i,t}$$

Finally, we can calculate total savings for the 2021 approval cohort by summing these product-level savings from all products (N_Y) in the given year:

$$Savings_Y = \sum_{i=1}^{N_Y} Savings_i$$

The Technical Appendix explains in more detail how these price measures and savings estimates are computed, including a discussion on how drug products that have multiple ANDAs approved throughout the year are handled.

2. Results

In 2021, FDA fully approved 633 ANDAs representing 408 unique drug products. Sales data are available for 384 of these 408 RLD product families, representing 604 of these ANDAs.[7,8] Following each ANDA approval for 12 months, we estimate yearly savings of $16.7 billion.[9] Table 1 summarizes these results and compares them to previously published estimates from earlier ANDA approval cohorts.

Table 1. Summary of yearly generic drug approvals and savings, 2018-2021.

	2018	**2019**	**2020**	**2021**
ANDAs fully approved	810	836	754	633
ANDAs with available sales data	755	788	708	604
Unique Drug Products with sales data	413	430	404	384
Total 12-month savings for ANDA approvals (billions)	**$17.8**	**$24.8**	**$10.7**	**$16.7**

Although 2021 saw fewer approved ANDAs than recent years, the total savings derived from these new generic products are in line with the average savings from the previous 3 years.[10]

Savings from first generic approvals are also in line with results from previous years. In 2021 there were 48 drug products with their first-ever ANDA approval, and of these 48 products, 21 are for generic versions of brand drugs that were new molecular entities (NMEs),[11] representing the first ever generic versions containing those active pharmaceutical ingredients (APIs). The remaining 27 non-NME first generics represent generic entry for brand products that contain APIs that were in previously approved

---

[7] Sales data are limited to prescription drugs; over-the-counter products are excluded. NSP data also may exclude certain products with limited distribution and low revenue.

[8] Because we identify sales from all ANDAs and NDAs in each product family, generics approved in the study period need not actually enter the market to be included in the sample data as sales from these other sponsors in the product family are included.

[9] All dollars in this report are inflation adjusted to a January 2023 base period.

[10] The relatively lower approval numbers in 2021 were expected given that efforts to take action on older applications in previous calendar years had led to record approval numbers in those years; those efforts had largely been completed prior to 2021. The COVID-19 public health emergency also impacted ANDA submissions during this time period, which in turn affected the number of approvals.

[11] New molecular entities (NMEs) are products for which the active pharmaceutical ingredient (API) has never previously been used in an approved drug.

drugs but that differ from those drugs in some way, such as a reformulation or novel dosage form of an existing drug product.

These 48 first generic approvals in 2021 yielded about $1.7 billion in savings over 12 months, most of which was due to the 21 NME first generics approved that year. These 21 NME generics accounted for nearly $1.4 billion of the $1.7 billion in savings from all first generics.

Table 2. Summary of yearly savings attributed to first generic approvals.

	2018	**2019**	**2020**	**2021**
Drug products with first generic approvals	*42*	*60*	*46*	*48*
12-month savings from first generic approvals (billions)	$4.00	$9.40	$1.80	$1.69
NME drug products with first generic approvals	*22*	*32*	*15*	*21*
12-month savings for NME first generic approvals (billions)	$2.70	$7.10	$1.10	$1.37

Similar to results from prior years, the total savings from 2021 approvals were concentrated among high-revenue drug products. About half of the $1.7 billion in savings was attributed to the ten drug products with highest per product savings.

The product with the greatest amount of savings, emtricitabine and tenofovir disoproxil fumarate tablets (brand: Truvada), accounted for a quarter of all savings associated with the 2021 generic approvals – about $4.1 billion in savings. Although there were five previously approved ANDAs for this product, there were five additional generic approvals in 2021. This resulted in the price per tablet falling from about $50 in late 2020 down to $3 by the end of 2022.

Table 3. Top ten products by estimated 12-month savings, 2021 ANDA approvals.

Drug product	Savings (Millions)	First generic	NME	Share of total savings
Emtricitabine; Tenofovir Disoproxil Fumarate: Tablet	$4,168			25.1%
Dimethyl Fumarate: Capsule, DR	$938		✓	5.7%
Everolimus: Tablet	$572		✓	3.4%
Droxidopa: Capsule	$491	✓	✓	3.0%
Nebivolol Hydrochloride: Tablet	$379		✓	2.3%
Fingolimod Hydrochloride: Capsule	$359		✓	2.2%
Amphetamine Salts: Capsule, XR*	$297			1.8%
Vasopressin: Solution IV	$294	✓		1.8%
Metformin Hydrochloride: Tablet XR	$274			1.6%
Lenalidomide: Capsule	$191	✓	✓	1.2%

* Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate

Generic approvals for dimethyl fumarate delayed-release capsules (brand: Tecfidera) accounted for over 5 percent of the total savings in the 2021 cohort, equal to about $938 million. The price for this drug fell from about $90 per capsule in early 2021 down to less than $30 per capsule by the end of 2022.

Although these top-10 products yielded about $8 billion of the $16.7 billion in total savings from all 2021 generic approvals, another important consideration is savings at the patient level.

For example, 58 drug products in the 2021 approval cohort had price drops of more than 50 percent compared to their prices prior to the 2021 generic drug approvals. An additional 161 products had price reductions between 25 and 50 percent after the 2021 generic drug approvals.

Many of the drugs with large price declines treat smaller patient populations. Although the total savings from these approvals represent a small share of the total savings from 2021 approvals, these price reductions can be meaningful to the individual patients using these drugs. For example, a 10 mL course of treatment of tavaborole topical solution (brand: Kerydin) was priced at about $1,300 before generic approvals, then fell to under $60 with generics. This led to total savings of around $60 million, while individual patients likely saw substantial savings, with the wholesale price of a 10 mL bottle falling by more than $1,000.

Some drugs with more modest price reductions still resulted in substantial total savings thanks to the relatively large patient population they serve. For example, generics approved for icosapent ethyl (brand: Vascepa) resulted in a price reduction of about 20 percent, from $2.80 per capsule prior to the 2021 generic approvals, falling to about $2.20 per capsule within 12 months of the 2021 approvals. Nearly 580 million capsules of this drug are dispensed annually, and the 2021 generic approvals for this drug are associated with $150 million in total savings.

Table 4. Drug products with the 10 largest price declines in percentage terms. Comparing the price before generic drug approval to the price 12 months after generic drug approval.

Product	First generic	Price: Before Approval	Price: 12 months after approval	Percent Change of Price	Savings (millions)
Tavaborole: Topical		$129.94	$5.82	96%	$60
Efavirenz; Emtricitabine; Tenofovir Disoproxil Fumarate: Tablet		$35.68	$2.14	94%	$131
Emtricitabine; Tenofovir Disoproxil Fumarate: Tablet		$49.90	$3.07	94%	$4,168
Sildenafil Citrate: Oral suspension		$20.46	$2.13	90%	$134
Droxidopa: Capsule	✓	$57.71	$9.23	84%	$491
Fingolimod Hydrochloride: Capsule		$284.27	$56.78	80%	$359
Pregabalin: Tablet XR	✓	$14.41	$3.06	79%	$8
Fluphenazine Hydrochloride: Tablet		$4.64	$1.02	78%	$94
Vasopressin: IV solution	✓	$195.74	$44.91	77%	$294
Niacin: Tablet XR		$0.90	$0.22	76%	$21

Note: Price is measured per unit. I.e., per tablet, capsule for
oral solids, or per mL for other forms.

Several of the products with the large price declines also yielded the largest nominal savings. For example, the product with the greatest nominal savings due to generic approval, emtricitabine and tenofovir disoproxil fumarate tablets, saw its price drop by 94 percent with approximately $4.2 billion in savings; droxidopa capsules had a price decline of 84 percent, yielding $491 million in savings; and fingolimod capsules saw a price drop of 80 percent, with $359 million in savings.

Several other products with substantial price decreases have smaller markets and yielded smaller total savings. However, these products also yielded meaningful savings for the patients relying on these medicines. For example, as noted above, tavaborole topical solution (brand: Kerydin) saw its price fall by 96 percent; the price of a 10 mL vial fell from about $1,300 to under $60. The price of a 30-day equivalent prescription of efavirenz, emtricitabine, and tenofovir tablets fell from about $1,000 to around $65. Generic approvals for these products yielded total savings of $60 million and $131 million, respectively. Although neither represent a "top saver" in nominal terms, both demonstrate the value of competition in promoting affordable access to the individual patients using these drugs.

Figure 3. Distribution of price changes, comparing the drop in price (percentage) before and 12 months after 2021 generic drug approvals.
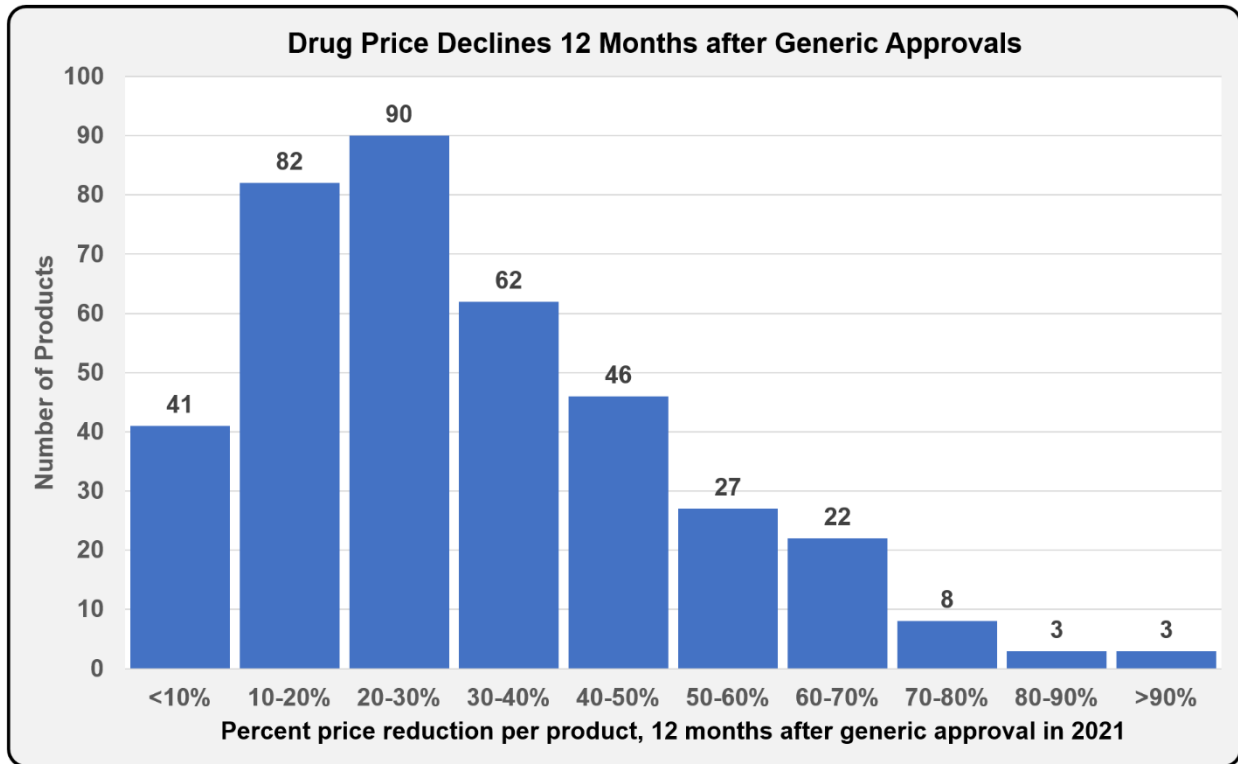

Figure 3 shows the distribution of price declines for all 384 drug products with a generic approval in 2021 for which sales data are available. Many products experienced modest price declines between 10 and 40 percent comparing the price prior to generic approval to the price observed 12 months after generic approval: 234 of the 384 products (61 percent) fall into this group. An additional 95 products (25 percent) had price declines between 40 and 70 percent. There were 14 products (4 percent) whose price dropped by more than 70 percent after generic approval.

This supports the idea that, although not every new generic drug approval directly results in massive annual savings, the more modest savings represented by some members of a given approval cohort add up. As a result, in the 12 months following each of the 2021 generic drug approvals, the associated price reductions yielded a total of $16.6 billion in savings to patients in the United States.

Technical Appendix

A1. Data Sources

The analysis in this report used several publicly available and proprietary data sources:

- FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database (commonly known as the Orange Book): Identifies ANDAs approved in 2021, along with their reference listed drug (usually an NDA) and other bioequivalent generic approvals (ANDAs). Includes approval dates.[12]
- FDA's National Drug Code (NDC) Directory: Links ANDA and NDA numbers to their NDC product identifiers.[13]
- IQVIA National Sales Perspectives: Sales volume ($) and quantity sold (units) at the drug product level, monthly.[14] Links to NDAs and ANDAs via NDCs.
- Bureau of Labor Statistics, Consumer Price Index: Used to inflation-adjust all dollar values, set to a January 2023 base period.[15]

A2. Methods

The analytic dataset in this report was prepared using the following methodology:

- ANDAs approved in 2021 are identified in the Orange Book.
- The reference listed drug (RLD) is identified for each of these ANDAs. The RLD is usually an NDA (brand drug) but can be an ANDA.[16]
    - All other ANDAs sharing these RLDs are identified.
- NDC numbers for each of these NDAs and ANDAs are identified using NDC Directory.
- These NDC numbers are linked to the IQVIA NSP database, and then aggregated to the drug product level, to identify monthly sales for each drug product. All dollars are inflation adjusted to a January 2023 base.

From this analytic dataset we then calculated monthly prices and a baseline price for each product.

- A monthly price for each product, equal to the total dollar sales divided by the total unit sales, is calculated.

---

[12] https://www.accessdata.fda.gov/scripts/cder/ob, data extracts downloaded April 2023.
[13] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm, data extracts downloaded April 2023.
[14] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information, data extracts downloaded April 2023.
[15] https://www.bls.gov/cpi/, data extracts downloaded April 2023.
[16] See footnote 4.

The baseline price for each product market was calculated by taking the aggregate sales volume up to 6 months prior to the ANDA approval and dividing that value by the aggregate units sold in the same period:

- If the ANDA approval is the first generic equivalent ever approved for that market, the baseline period is six months and will include sales of only the brand product.
- If the ANDA approval was for a product for which there were existing generic approvals, the baseline period includes both brand and generic sales. In addition, the baseline period only includes the months prior to the approval in which the number of competitors was stable (i.e., no new generics entered), up to 6 months.
- Monthly cost-savings, per market, are calculated monthly, starting with the approval month, and continuing for 12 months.

Special calculations were used for the baseline price when there are multiple ANDAs approved for the same RLD in different months throughout the year:

- Multiple ANDAs sharing the same RLD are often approved at different times throughout a year.
- Savings for each ANDA are followed for 12 months. Savings accrued during the overlapping 12-month periods of two ANDAs are not double counted.
    - For example, savings from ANDAs sharing the same RLD approved in January 2021 and June 2021 are calculated using sales data from January 2021 through July 2022.
- The baseline price in place for the 12 months January 2021 through January 2022 is equal to the baseline price prior to the January 2021 approval.

Total overall savings are calculated by taking the sum of all monthly savings across all markets, aggregated by approval year cohorts.

The calculations used to measure prices and savings are formally shown below. We define indices to track approval year cohorts, drug products, months elapsed since ANDA approval, the number of unique producers of each product, and the appropriate number of months used in calculation of the baseline prices.

$Y = [2021]$. Index of approval year cohorts.

$i_Y = [1, 2, \dots, N]$. Index of drug products approved in year Y.

$t = [1, \dots, 12]$. Index of the 12 months following an ANDA approval.

$p_{i,Y} = [1, 2, \dots, P]$. Index of producers making drug product i in year Y.

$a = [1, ..., A_{i,Y}]$. Index of the months with an ANDA approved for product i in year Y. If ANDA approvals occur in only a single month, then $a = [1]$. If ANDAs for a product are approved every month of the year, then $a = [1, ..., 12]$.

$b^a_{i,Y} = [-m, ..., -1]$. Index of the months used to calculate the base-period price, for each of the A ANDAs approved for product i in year Y; $m \leq 6$. If no other ANDAs were approved during the 6 months prior to this approval, then $m = 6$. But if, for example, another ANDA was approved 3 months earlier then $m = 3$. This is necessary so that the base price is calculated during periods when there were no other ANDAs approved which could change the monthly prices.

Using this notation, we can then explicitly write the pricing and savings calculations as follows:

(1) The baseline price for ANDA approval A, for product i in year Y is calculated as:

$$Baseline\ Price = \widehat{Price}_{i,a,Y} = \frac{\sum_{b^a_{i,Y}=-m}^{-1}(DollarSales_{i_Y,b,Brand} + DollarSales_{i,b,Generic})}{\sum_{b^a_{i,Y}=-m}^{-1}(UnitSales_{i,b,Brand} + UnitSales_{i,b,Generic})}$$

This baseline price is composed of sales observed no more than 6 months prior to the approval, i.e., $m \leq 6$. In the case of first generic approval, the baseline price calculation uses only sales from the brand product, so the dollar and unit sales of the generic products are both taken as zero.

(2) The average price of for product i, in month t, in year Y is calculated as the sum of all sales from all P brand and generic producers of the product:

$$Price_{i,t,Y} = \frac{DollarSales_{i,t,Y}}{Units_{i,t,Y}} = \frac{\sum_{p_{i,Y}=1}^{P}(DollarSales_{i,t,p,Brand} + DollarSales_{i,t,p,Generic})}{\sum_{p_{i,Y}=1}^{P}(UnitSales_{i,t,p,Brand} + UnitSales_{i,t,p,Generic})}$$

This does not need to be indexed by the ANDA approval a as this calculation is simply price observed in each month of the product.

(3) Savings for product i, in month t, in year Y after ANDA approval a is calculated as:

$$Savings_{i,a,t,Y} = Units_{i,t} * (\widehat{Price}_{i,a,Y} - Price_{i,t,Y})$$

(4) Savings from the 12 months following ANDA approval a, for product i, approved in year Y is calculated as:

$$Savings_{i,a,Y} = \sum_{t=1}^{12} Savings_{i,a,t,Y}$$

(5) Total savings from all ANDAs approved in year Y is calculated as the sum of all product-level savings:

$$Savings_Y = \sum_{i=1}^{N_Y} \sum_{a=1}^{A_{i,Y}} Savings_{i,a,Y}$$