REPORT

Estimating Cost Savings From Generic Drug Approvals In 2017

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Executive Summary

- In 2017, FDA approved the most generic drug applications ever, with 843 fully approved applications and 184 tentatively approved applications
- FDA estimates total cost-savings associated with 2017 ANDA approvals to be $11.8 billion through February 2018, with $8.8 billion in savings occurring through December 2017
- FDA estimates total cost-savings over one full year after each generic approval in 2017 to be $16.0 billion.

Background & Motivation

FDA set records in 2017 with respect to generic drug approvals. FDA approved 843 abbreviated new drug applications (ANDAs) and tentatively approved an additional 184 ANDAs.[1] While estimates of total patient savings attributed broadly to the generics program exist, we are unaware of publicly available estimates of cost savings attributed to generic approvals in 2017.

In this study, we provide a new estimate of the to-date (February 2018) cost-savings to American prescription drug buyers associated with 2017 ANDA approvals. We also construct an estimate of the "first-year" of total savings from all ANDAs approved in 2017.

Data sources

This analysis uses several public, non-public, and private data sources:

- Approved Drug Products with Therapeutic Equivalence Evaluations (FDA's "Orange Book") – Identifies 2017 ANDA approvals with approval dates[2]
- IQVIA National Sales Perspectives (sales through February 2018) – Sales volume ($) and quantity sold (what IQVIA calls "eaches", such as pills), monthly[3]
- FDA Electronic Drug Registration and Listing System (eDRLS) – Marketing status and NDC identifiers[4]
- FDA Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) – Additional reference listed drug information used for matching[5]
- Bureau of Labor Statistics, Consumer Price Index – Inflation adjustment (of sales) to January 2018 base[6]

Methodology

We construct a dataset using the following steps:

- 2017 ANDA approvals are identified in the Orange Book.
- NDC numbers of these 2017 approvals are identified using eDRLS.

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[1] If a generic drug product otherwise meets the requirements for approval but cannot be approved due to patent or exclusivity issues, FDA issues a tentative approval letter to the applicant.

[2] See https://www.accessdata.fda.gov/scripts/cder/ob, data extracts downloaded March 27, 2018.

[3] See https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information, data extracts downloaded April 16, 2018.

[4] See https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm, data extracts downloaded April 17, 2018.

[5] Data extracted on April 2nd, 2018

[6] See https://www.bls.gov/cpi/, data extracts downloaded April 16, 2018.

- Additional NDC numbers are identified by directly matching ingredient/route/dosage forms to corresponding ingredient/route/dosage forms in IQVIA NSP.
- We define a "market" to be the same ingredient/route/dosage form, over all producers, and use data on the monthly sales of all products in a market.
- We compile a final dataset consisting of monthly sales (sales volume and quantity sold) of all products with the same ingredient/route/dosage form as the 2017 ANDA approvals, including both the branded drug (reference listed drug) as well as any other previously approved ANDAs.

We generate three estimates of cost-savings. The first is an estimate of the savings attributed to all fully approved 2017 ANDA approvals through February 2018. We calculate:

- A baseline price for each market (product) by taking the aggregate sales volume across all products with the same ingredient and dosage form, up to six months prior to the 2017 ANDA approval and dividing that value by the aggregate quantity sold.
    - If the first 2017 approval is the first generic approval for that market, the baseline period will include only branded sales.
    - If the 2017 approval is in a market in which there already exists generic competition, the baseline price reflects both branded and generic sales – in addition, the baseline period includes only the months prior to the 2017 approval in which the number of competitors is unchanged, up to six months.
- An average "current" market price by dividing the aggregate sales volume of the market by the aggregate quantity sold of the market, per month
- Monthly cost-savings, per market, for each month from January 2017 through February 2018, using the following formula, where we assume that the month of approval counts as "post approval"

$$= Q_m * (P_B - P_m)$$

Q_m: Aggregate quantity sold post-ANDA approval in month m
P_B: Baseline average price
P_m: Average post-ANDA approval price in month m

- Total overall cost savings by taking the sum of all monthly savings across all markets, starting with the ANDA's approval month in 2017 through February 2018.

This procedure yields total savings of $11.8 billion.

To develop our second estimate, we follow the previously outlined procedure but did not include any savings that occurred in January and February of 2018. This method generates an estimate of total savings in 2017 of $8.8 billion.

Finally, we calculate cost savings for the first year following each approval in 2017 of a generic drug[7] to be $16.0 billion. We construct this estimate using the sum of observed savings over one year for each approval combined with the sum of extrapolated savings over one year for each approval without a full year of observed savings.

The methodology behind the per-approval savings calculation and the extrapolation of unobserved savings is described below.

A. Savings estimates

We calculate monthly savings attributed to a market with only one ANDA approval in 2017 as the units sold in that month times the difference in pre-period price and the observed market price in that month. We focus

[7] Information on the timing of 2017 ANDA approvals by calendar month is available at https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/

on savings during the 12 months starting with the approval of each ANDA.

However, there are often multiple ANDA approvals throughout the year for the same reference listed product. These subsequent approvals are also expected to reduce the market price. Until the second ANDA is approved, the savings from the first ANDA are calculable as described above. The savings from the second ANDA's approval are also calculable in this manner, using as a baseline the market price observed before that approval (average market price based on the months prior to the approval absent changes in the number of competitors, up to six months). For the months when two ANDAs are approved, the savings attributable to the first is calculated as total savings relative to the baseline prior to the first approval, less the savings from the second.

Thus, we calculate the savings from approval of ANDA 1, in the months after approval of ANDA 2, using the number of units sold during these months,

Units sold *(Market price before approval of ANDA 1 – market price after approval of ANDA 2) less

Units sold *(Market price before approval of ANDA 2 – market price after approval of ANDA 2),
which simplifies to

Units sold * (Market price before approval of ANDA 1 – market price before approval of ANDA 2).

We use this concept to estimate savings for all ANDA approvals.

B. Extrapolation

We do not (yet) have 12 months of observed data for approvals that occur relatively late in 2017. We estimate the remaining months of savings for these approvals using an extrapolation that assumes that the ratio of observed savings in a given month after ANDA approval, relative to earlier savings, is applicable to products without such observations. Thus the missing data are assumed to follow the same pattern after ANDA approval as for other ANDAs without such missing data. The extrapolation involves the following steps.

- We assign all 2017 ANDA approvals to one of three "competition groups" defined by the number of approved ANDAs in each market, including ANDAs approved before 2017;
- We calculate average savings for each month since approval for all ANDAs in each competition group, using all observations;
- We then calculate the ratio of these average savings to average savings over all sets of previous months, among products in that competition group;
- For approvals with unobserved sales data, we compute the missing savings by multiplying this ratio by total observed savings for the product with missing data;
- The total estimated 12-months of savings attributed to all approvals is the sum of observed savings and the sum of extrapolated savings across all approvals.

We present a detailed explanation of this methodology in the appendix.

Results

We find that from January 2017 to March 2018, total savings to American drug buyers from FDA's 2017 ANDA approvals are approximately $11.8 billion. This is the sum of all observed cost savings from the first month of approval through February 2018, for all 2017 ANDA approvals. We find the total savings through calendar year 2017 to be $8.8 billion.

We also find that the estimated total savings over the first 12-months after approval for these markets, using both observed and extrapolated data, is $16.0 billion.

We note several caveats to this analysis. (1) These sales data represent the pharmacy acquisition cost of the medicine, and do not reflect any rebates, discounts, or off-invoice adjustments. (2) We measure cost-savings for each market after the date of approval, not marketing – a product's actual marketing start date may be after the approval date. (3) We only examine markets with ANDAs fully approved in 2017 and not tentatively approved applications – these tentatively approved applications face delays before full approval due to patent or exclusivity issues.

Conclusion

FDA approved a record number of generic drug applications in 2017. We estimate that the generic drug approval pathway in 2017 contributed to American drug buyers saving $11.8 billion in drug costs to-date, $8.8 billion in drug costs in 2017 alone, and expect that these buyers would save, over the course of one full year, approximately $16 billion. Since its inception in 1984, the generic drug approval pathway has played a critical role in increasing access to safe, high-quality, and affordable medicines for the American public.

Appendix

We first assign each 2017 ANDA approval to a "competition group" based on the preceding number of ANDA approvals for the same reference listed drug. We identify groups by ω, with ω = [1, 2, 3] where ω = 1 if a 2017 approval has 3 or fewer ANDA approvals for its RLD. We then define ω = 2 for an ANDA approval if the number of all prior approvals for its RLD are greater than or equal to 4 and less than or equal to 8. We define ω = 3 for all others ANDAs, that is those with 9 or more previously approved ANDAs for the same RLD. Note that this ordering accounts for ANDA approvals prior to 2017, e.g. the first ANDA approval in 2017 for a given product could be the 10th all-time approval for that product.

We then calculate the average savings in month *m* since approval for all approvals in each competition group ω, with *m* = [1, 12] serving as an index for the months elapsed since approval. That is *m*=1 is the month of approval, *m*=2 is the next month, …, *m*=12 is the 12th month since approval. $S_{i,m}^{\omega}$ is the observed market savings (among all products in the market) from ANDA *i* observed in month *m*, for competition group ω. N_m^{ω} is the number of approvals in competition group ω with observed data in month *m*. The average savings resulting from these generic approvals in month *m* after the approval month is equal to:

$$\overline{S_m^{\omega}} = \frac{\sum_{i_{\omega}=1}^{N_m^{\omega}} S_{i,m}^{\omega}}{N_m^{\omega}} \quad (1)$$

Let *C* be the calendar month of the approval in 2017: Jan=1, Feb=2, …, Dec=12. Note that there is no need to extrapolate savings from approvals with *C* = [1, 3] as they have 12 observed months of sales data; hence we only extrapolate savings for approvals with *C* = [4, 12] . Note that 15-*C* is equal to the number of months with observed sales data, which end in February 2018.

We extrapolate using a multiplier. We compute the denominator for approvals in month *C*, using (1), to be:

$$D_C^{\omega} = \sum_{m=1}^{15-C} \overline{S_m^{\omega}} \quad (2)$$

where *m* = [16-*C*, 12] are months with missing data for an approval in calendar month *C*≥4. Next, we compute the extrapolation multipliers to be:

$$Mult_{C,m}^{\omega} = \frac{\overline{S_m^{\omega}}}{D_C^{\omega}} \quad (3)$$

For example, approvals in April (*C*=4) have a single month of unobserved savings, and that month is the 12th month after its approval, so *m*=[12], or March, 2018, for April, 2017 approvals. Approvals in December, 2017, (*C*=12) have 9 months of unobserved savings, starting in the 4th month after approval, so we calculate nine multipliers for all December approvals belonging to a given competition group, with m = [4, 12].

Hence the resulting value for $Mult_{C,m}^{\omega}$ depends on the competition group (ω), the calendar month of the approval (C), and the number of months (m) beginning with the approval in question.

We use the multiplier only in months m≥16-C, which are months with no observed sales data due to truncation.

Next we sum the observed savings for each product. Those with C≤3 (i.e., approvals occurring in January, February, or March, 2017) will have 12 observed months and will not need to be extrapolated. For C≥4 (i.e. approvals occurring in or after April, 2017), we compute their observed savings for the available months:

$$S_i^{\omega} = \sum_{m=1}^{15-C} S_{i,m}^{\omega} \quad (4)$$

and compute the extrapolated savings in unobserved months *m* = [16-*C*, 12] to be

$$\widehat{S_{i,m}^{\omega}} = Mult_{C,m}^{\omega} * S_i^{\omega} \quad (5)$$

Finally, we sum the observed savings (S) for each product (i) as well as the extrapolated savings ($\hat{S}$) for each product (i), over all months since approval (m), with approval in calendar month C, and over all three competition groups (ω).

$$Total\ Savings = Observed\ Savings + Extrapolated\ Savings$$

$$= \sum_{\omega=1}^{3} \sum_{i_\omega=1}^{N^\omega} \sum_{m=1}^{15-C} S_{i,m}^{\omega} + \sum_{\omega=1}^{3} \sum_{i_\omega=1}^{N^\omega} \sum_{m=16-C}^{12} \widehat{S_{i,m}^{\omega}} \quad (6a)$$

$$= \sum_{\omega=1}^{3} \sum_{i_\omega=1}^{N^\omega} \left[\sum_{m=1}^{15-C} S_{i,m}^{\omega} + \sum_{m=16-C}^{12} \widehat{S_{i,m}^{\omega}} \right] \quad (6b)$$

We find that the total cost savings for the first year following each approval in 2017 of a generic drug to be $16.0 billion.
