

Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers

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Executive Summary

340B Health commissioned Dobson | DaVanzo to assess the financial impact of discounts provided under the 340B Drug Pricing Program on drug manufacturers and evaluate the plausibility of claims that the 340B Program is a cause of pharmaceutical price increases, cost shifting, and reductions in private sector research and medical discovery.

We calculated the total size of 340B discounts and found that the 340B Program cannot plausibly be a major driver of U.S. drug spending or a major cause of cost shifting by drug manufacturers to make up for 340B discounts.

The 340B Drug Pricing Program and the U.S. Drug Market



Key findings in support of this conclusion include:

- The **total 340B discount in 2015 was \$6.1 billion, which was 1.3 percent of the \$457 billion in net U.S. drug spending.** Of the total discount amount, \$1.9 billion was due to a penalty for manufacturers raising prices higher than inflation or because manufacturers voluntarily offered a lower price. Excluding this amount, the **baseline portion of the 340B discount** required under the 340B statute was **\$4.2 billion, or 0.9 percent of the total drug spending.**

Executive Summary

- The **total 340B discount was 4.0 percent of the \$150.8 billion in total specialty drug spending** in 2015 and the **baseline discount was 2.8 percent**. The literature commonly cites the specialty drug market as a driver of overall drug spending. These data indicate that the 340B Program is a small share of the specialty market and is therefore unlikely to be driving overall drug spending.
- The \$6.1 billion in total 340B discounts accounted for only **3.6 percent of the \$170.2 billion in total discounts and rebates provided by manufacturers in 2015, and the baseline 340B discount was only 2.5 percent**. In comparison, manufacturer-negotiated rebates to health plans and PBMs were \$57.7 billion, which accounted for 33.9 percent of all rebates and discounts and 54.2 percent of all brand-name rebates.
- Manufacturers spent more than four times the amount of money on advertising than they provided in total 340B discounts, and more than six times the amount of the baseline 340B discount.
- The expiration of patents for brand name drugs led to a \$14.2 billion spending loss for brand-name drugs in 2015, more than twice the size of the total 340B discount and more than four times the baseline discount.

Introduction and Purpose

The drug industry has alleged that the 340B Program is a cause of pharmaceutical price increases, cost shifting, and reductions in private sector research and medical discovery. However, the literature shows that the size of the 340B Program is small compared to the rest of the drug market, suggesting that it is unlikely that manufacturers' obligations under the 340B Program to offer discounted prices would significantly impact how they set their prices. The purpose of this paper is to examine the plausibility of this claim and to analyze the potential financial impact of the 340B Program on drug manufacturers in the context of the broader pharmaceutical industry.

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible health care organizations¹ or covered entities at reduced prices. To participate in the 340B Program, eligible organizations or covered entities must register and be enrolled with the 340B Program, as well as comply with all 340B Program requirements.

The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents U.S. biopharmaceutical companies, has suggested that manufacturers' 340B obligations play a role in increasing drug prices. In a recent publication, PhRMA highlighted the 340B program as an example of “price controls and government-mandated discounts.” PhRMA

The literature shows that the size of the 340B Program is small compared to the rest of the drug market, suggesting that it is unlikely that manufacturers' obligations under the 340B Program to offer discounted prices would impact how they set their prices.

¹ Eligible entities include federally qualified health centers, urban Indian organizations, family planning clinics, sexually transmitted disease grantees, Native Hawaiian Health Centers, state-operated Ryan White AIDS Drug Assistance Programs, other Ryan White grantees, hemophilia treatment centers, and black lung clinics. Eligible hospitals include certain DSH hospitals, critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), freestanding cancer hospitals, and children's hospitals. Additionally, providers that meet all of the requirements for the federally qualified health centers program, but do not receive federal grants—referred to as federally qualified health center look-alikes—are eligible to participate in the 340B Program.

Introduction and Purpose

wrote, “By holding prices for prescriptions artificially low, this approach can lead to cost shifting within the market and/or reductions in private sector research and medical discovery.”² Subsequent paragraphs point to the 340B Program solely and specifically. A related article states that “the scope of the 340B Program is currently so vast for drugs that are commonly infused or injected into patients by physicians that their prices are probably driven up for all consumers.”³

Given the implications of these claims, Dobson | DaVanzo was asked to assess the potential financial impact of the 340B Program on drug manufacturers, and to evaluate the plausibility of the claim that the Program is a major cause of pharmaceutical price increases, cost shifting, and reductions in private sector research and medical discovery. To evaluate the plausibility of this claim, this report will seek to answer the following questions:

1. What is total drug spending in the United States and how has it changed over time? What factors are noted in the literature as influencing this change, and do they cite to the 340B Program?
2. What is the financial impact to drug manufacturers of providing discounted drug prices to covered entities under the 340B Program? How does the size of the 340B discount compare to rest of the drug market, particularly the specialty drug market?
3. How does the monetary size of the 340B discount compare to pharmaceutical industry spending in other areas, particularly other market rebates and discounts?

Each of these questions will be addressed in subsequent sections of this report.

² PhRMA. *Addressing Market Distortions*. March 2016.

³ Conti RM and Rosenthal MB. *Pharmaceutical Policy Reform – Balancing Affordability with Incentives for Innovation*. *New England Journal of Medicine* 2016; 374:703-706.

U.S. Drug Spending

To assess the financial impact of the 340B Drug Pricing Program on the pharmaceutical industry, and to evaluate the plausibility of the claim that the 340B Program is a major cause of pharmaceutical price increases, cost shifting, and reductions in private sector research and medical discovery, it is important to first understand the magnitude of drug spending in the United States and what is driving the spending. This section of the report provides contextual data on drug expenditures overall. It also provides a review of the literature regarding factors that influence changes in drug spending over time to determine if the 340B Program is cited as a major factor in causing drug price increases.

Estimating drug expenditures in the U.S. is a complex process. Between drug manufacturers and drug recipients lie a number of stakeholders through which flow both the drugs and the drug dollars. These stakeholders include, but are not limited to, wholesalers, pharmacies, health plans, and pharmacy benefit managers. Discounts and rebates occur at many transaction points throughout the drug distribution process. As such, many estimates of U.S. drug spending exist, accounting for various pieces of the supply chain. We draw our estimates of the various aspects of drug spending from many sources, as no one source provides a complete picture of the industry.

While no one set of estimates is definitive, this paper uses estimates of retail and non-retail prescription drug spending compiled by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE). Retail spending comprises drug spending at outlets that directly serve patients, while non-retail includes spending by medical providers for drugs they provide directly to patients. Any discussion of 340B spending, which includes hospitals providing drugs directly to patients, must therefore include both retail and non-retail expenditures. The estimates from ASPE are based upon the National Health Expenditure Accounts, produced by the Office of the Actuary at the Centers for Medicare and Medicaid Services (OACT). These estimates are net of rebates for retail purchases; that is, they have been adjusted to account for manufacturers' rebates that reduce net payments for drugs.⁴

⁴ Office of the Actuary, Centers for Medicare and Medicaid Services. *National Health Expenditure Accounts: Methodology Paper*, 2015.

U.S. Drug Spending

U.S. Drug Expenditures

Table 1 provides estimates of pharmaceutical expenditures in the United States from 2011 to 2015. In addition to providing estimates of total net drug expenditures, Table 1 also includes specialty drug spending, which is a subset of overall drug expenditures. Estimates of specialty drug spending come from the IMS Institute for Healthcare Informatics (IMS)⁵ and are defined as “products that are often injectable, high-cost, biologics or other medicines that require cold-chain distribution. Specialty medicines are mostly initiated by specialists, and include treatments for cancer and other chronic conditions.”⁶ We include specialty drug spending because many 340B drugs, including oncologic therapies, fall into this category, and specialty drugs are a large component of 340B spending.

Table 1. Estimates of U.S. Pharmaceutical Expenditures, 2011-2015, in Billions of U.S. Dollars

	2011	2012	2013	2014	2015
U.S. Net Prescription Drug Expenditures (Retail and Non-Retail) ^a	\$366.0	\$367.0	\$377.0	\$424.0	\$457.0
Gross Spending on Specialty Drugs (Retail and Non-Retail) ^b	\$82.0	\$88.0	\$97.3	\$124.1	\$150.8

Sources: ^aOffice of the Assistant Secretary for Planning and Evaluation

^bIMS Institute for Healthcare Informatics. Net spending on specialty drugs was not available for all years 2011-2015.

Causes of Changes in Drug Spending

Table 1 demonstrates that net drug expenditures have risen every year from 2011 to 2015. A number of published reports discuss factors that have influenced these yearly increases. ASPE indicates that within retail drug spending, both estimated expenditures and the number of prescriptions rose substantially between 2010 and 2014, with drug prices growing at a higher rate than growth in quantities of prescriptions. The change in drug prices increased retail drug spending by approximately 15 percent during this time.⁷ Because economy-wide inflation rose approximately 7 percent from 2010 to 2014, about half of the rise in drug prices was in excess of overall inflation. In fact, ASPE estimates that 30 percent of the rise in prescription drug spending is due to increased use of higher priced products or price increases for drugs beyond general inflation, with the remaining 70 percent caused by population growth, increased prescriptions per person and overall economy-wide inflation.⁸ These estimates apply to the entire industry, and ASPE does not relate changes in estimated drug expenditures or prescription volume to any one segment of the industry alone, such as the 340B Program.

⁵ Now Quintiles IMS Institute

⁶ IMS Institute for Healthcare Informatics. *Medicines Use and Spending in the U.S. A Review of 2015 and Outlook to 2020*. April 2016.

⁷ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. *ASPE Issue Brief: Observations on Trends in Prescription Drug Spending*. March 8, 2016.

⁸ Ibid.

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Similarly, OACT has noted increases in prescription growth spending in recent years. Although the percent growth in spending reported by OACT was slightly less in 2015 than in 2014 (9 percent versus 12.4 percent), spending on prescription drugs outpaced spending for all other services.⁹ OACT has attributed the growth in spending to four main factors, all of which are seconded by IMS.^{10,11}

- 1) Increased spending on new medicines
- 2) Price growth for brand name drugs
- 3) Increased spending on generics
- 4) Fewer expensive blockbuster drugs going off-patent

OACT predicts that prescription drug expenditure growth will decelerate in the future due to a reduction in the use of specialty drugs used to treat conditions such as Hepatitis C, as well as a higher number of brand-name drugs losing patent protection.¹² This implies that it is specialty drugs in general that are impacting overall drug spending. OACT makes no mention of 340B driving increases in specialty drug spending. That is, prescription drug spending growth in recent years has been driven by the overall use of new and typically expensive specialty drugs generally and is not specific to those used as part of the 340B Program. Table 1 shows that spending on specialty medications has grown rapidly since 2011. This is due to both increased use of these medications as well as increased prices per unit of medication.¹³

This literature implies that while many market factors affect the overall trend toward increased drug spending, both in terms of drug volume and price increases, the 340B Program is not mentioned by the experts as a key driver of increased drug expenditures in either context.

Causes of Changes in Drug Prices

Because rising drug prices are a major driver of increased drug expenditures in the U.S., it is important to look to the literature for the magnitude and causes of this price growth. According to FiercePharma, a recent report by Credit Suisse indicates that drug prices

⁹ Office of the Actuary, Centers for Medicare and Medicaid Services. *National Health Expenditures 2015 Highlights*. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

¹⁰ Ibid

¹¹ IMS Institute for Healthcare Informatics. *Medicines Use and Spending in the U.S. A Review of 2015 and Outlook to 2020*. April 2016.

¹² Office of the Actuary, Centers for Medicare and Medicaid Services. *National Health Expenditure Projections 2016-2025*. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf>.

¹³ Lotvin AM, Shrank WH, Singh SC, Falit BP, Brennan TA. "Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on these Costly Drugs." *Health Affairs* October 2016; 33(10): 1736-1744.

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increased 10.8 percent in 2015, and 9.8 percent in 2016.¹⁴ A recently published article in the *Journal of the American Medical Association* estimated that prices for the most commonly used brand-name drugs increased 164 percent between 2008 and 2014. This was much higher than the 12 percent rise in the consumer price index.¹⁵ The authors of this article theorize that drug manufacturers are able to maintain drug prices in the U.S. that are higher than in the rest of the industrialized world because they have protection from competition and negotiating power. Similarly, in discussing pharmaceutical prices, Uwe Reinhardt has written that large pharmaceutical companies merge primarily to reduce price competition, and “there is ample empirical research in health economics showing that consolidation on the supply side of the health care sector has served to drive up prices.”¹⁶ Anecdotal evidence supports this theory; David Lazarus of the *Los Angeles Times* reported in an article about generic drug prices that “each of the experts I spoke with cited industry consolidation as a key reason for rising prices. Rather than the half-dozen or so competitors that many economists believe are necessary to lead to lower prices, only two or three manufacturers now make some generic meds.”¹⁷

Drug manufacturers have historically justified price increases as being necessary to cover the costs of research and development. However, Reinhardt points out that many manufacturers spend more on sales [marketing] and general and administrative expenses than they do on research and development.¹⁸ Similarly, a more recent post on the *Health Affairs Blog* indicates that the amount of money earned from higher drug prices in the U.S., as compared to the rest of the world, is higher than that spent on research and development.¹⁹

Furthermore, pharmaceutical manufacturers are consistently among the most profitable companies. According to *Forbes*, healthcare technology was the most profitable industry in 2015 and within this category, the most profitable entities were major pharmaceutical companies.²⁰ Ultimately, “although prices are often justified by the high cost of drug development, there is no association between research and development costs and prices;

¹⁴ Sagonowsky E. “Report: Price hikes are still driving pharma’s earnings growth. Who’s most at risk?” FiercePharma April 19, 2017. <http://www.fiercepharma.com/pharma/despise-scrutiny-price-hikes-still-driving-pharma-s-eps-growth-report>.

¹⁵ Kesselheim AS, Avorn J, Sarpatwari A. “The High Cost of Prescription Drugs in the United States. Origins and Prospects for Reform.” *Journal of the American Medical Association* 2016; 316(8): 858-871.

¹⁶ Reinhardt, U.E. “‘Value Creation’ and ‘Value Shifting’ in Health Care.” *Health Affairs Blog* June 1, 2016.

¹⁷ Lazarus, D. “What’s behind the huge price jump for some generic drugs?” *Los Angeles Times* October 20, 2014.

¹⁸ Reinhardt, U.E. “‘Value Creation’ and ‘Value Shifting’ in Health Care.” *Health Affairs Blog* June 1, 2016.

¹⁹ Yu N., Helms Z., Bach P. “R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices.” *Health Affairs Blog* March 7, 2017.

²⁰ Chen, L. “The Most Profitable Industries In 2015.” September 23, 2015. <https://www.forbes.com/sites/liyanchen/2015/09/23/the-most-profitable-industries-in-2015/#25e794e76b73>.

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rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.”²¹

It is noteworthy that the literature on the pharmaceutical industry in general does not mention the 340B Program as influencing either increases in drug spending or drug prices. In the next section, we look at 340B spending and the size of the 340B discount specifically to determine whether it is plausible that this segment of the industry is, in fact, a major driver of change.

²¹ Kesselheim AS, Avorn J, Sarpatwari A. “The High Cost of Prescription Drugs in the United States. Origins and Prospects for Reform.” *Journal of the American Medical Association* 2016; 316(8): 858-871.

The Size of the 340B Discount

To evaluate the magnitude of the impact that the 340B Program has on drug manufacturers, we first quantify the size of the 340B Program and its discounts in relation to U.S. drug spending. We then compare the size of the 340B discount to measures of the broader drug market.

Under the 340B Program, drug manufacturers wishing to participate in the Medicaid and Medicare Part B programs must enter into a pharmaceutical pricing agreement with the Secretary of the Department of Health and Human Services and agree to the statutory requirement that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices.²² These ceiling prices are based on quarterly pricing data and are generally equal to the average manufacturer price (AMP) minus a rebate percentage, or unit rebate amount (URA). The minimum rebate percentage is the same as the statutory rebate for a given drug under the Medicaid Drug Rebate Program. This percentage is 23.1 percent for most brand-name prescription drugs, 17.1 percent for pediatric and hemophilia drugs, and 13 percent for generic and over-the-counter drugs.

Several factors can increase the amount of the Medicaid rebate, which therefore also increases the amount of the 340B discount. To discourage drug manufacturers from raising drug prices quickly, the rebate percentage increases when a manufacturer raises the price of a brand-name drug faster than the rate of inflation. As of January 2017, this is also true for generic drugs.²³ Also, manufacturers must provide brand-name drugs to Medicaid at the best price available elsewhere on the market, and therefore must offer greater rebates if the best price for a brand-name drug is lower than the AMP minus the URA.²⁴

Discounts resulting from these potentially avoidable inflationary penalties and best price requirements should not be considered when analyzing the overall impact of the 340B

²² Ibid

²³ 42 CFR Part 10

²⁴ 340B University. Glossary of 340B Terms. <https://docs.340bpvp.com/documents/public/resourcecenter/glossary.pdf>

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Program to the pharmaceutical industry, as these are potentially avoidable discounts resulting from manufacturers' actions. We will therefore estimate what portion of the 340B discount is mandated by statute as a baseline discount and what portion is due to potentially avoidable inflationary penalties or the best price requirement.

In addition to mandatory discounts, the Prime Vendor Program (PVP) negotiates drug prices with manufacturers, allowing covered entities at times to pay manufacturers less than the 340B ceiling prices.²⁵ We will additionally remove from the estimate of the aggregate 340B discount any discounts that manufacturers voluntarily provided through PVP negotiations.

We first estimate the average 340B discount across all drugs. Because 340B ceiling prices are proprietary, it is difficult to estimate the average 340B discount percentage. Given the range of drugs and potential discounts, various entities have provided different estimates. GAO has noted that “the amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid.”²⁶ MedPAC has estimated that “on average, hospitals in the 340B Program receive a minimum discount of 22.5 percent of the average sales price for drugs paid under the outpatient prospective payment system,” not taking into account the additional discounts required by the best price discount or inflationary penalty. MedPAC also estimates an overall average 34 percent discount.²⁷ HRSA, which administers the 340B Program, has approximated that “In CY 2015, 340B covered entities spent approximately \$12 billion on the total purchases of 340B drugs under the 340B Program... Assuming covered entities pay 25 to 50 percent less than non-340B prices, HHS calculated the estimated total savings in CY 2015 to be approximately \$6 billion.”²⁸ HRSA does not provide a methodology for calculating this estimated total savings. For purposes of this study, we assume MedPAC's estimate of a 34 percent average discount, which, as explained below, results in an estimate of the 340B discount that is in line with HRSA's estimate.

The Size of the Total 340B Discount

HRSA estimated that 340B spending totaled \$12 billion in 2015. This spending accounted for a small portion of the \$457 billion net drug spending in the U.S. in 2015 - just 2.6 percent of the total (Table 3). Assuming a 34 percent average discount²⁹ and applying it to

²⁵ Office of the Inspector General. *Part B Payments for 340B-Purchased Drugs*. November 2015.

²⁶ Government Accountability Office (GAO). *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*. June 2015 (GAO-15-442).

²⁷ Medicare Payment and Advisory Committee. *Report to the Congress: Medicare Payment Policy*. March 2016.

²⁸ Final Rule, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

²⁹ Medicare Payment and Advisory Committee. *Report to the Congress: Medicare Payment Policy*. March 2016.

The Size of the 340B Discount

the actual 340B Program drug spending of \$12 billion, the total 340B Program discount was \$6.2 billion in 2015:

$$\frac{\$12 \text{ billion}}{(1 - 0.34)} - \$12 \text{ billion} = \$6.2 \text{ billion}$$

In addition, we estimate that sub-ceiling discounts, as negotiated by the Prime Vendor Program, were \$95 million in 2015.³⁰ These discounts are voluntary on the part of the manufacturer, and thus should not be considered as part of the mandated 340B discount. Thus, the total 340B discount was \$6.1 billion in 2015 (\$6.2 billion – \$0.1 billion). This figure is consistent with the estimate from HRSA of \$6 billion,³¹ and represents just 1.3 percent of total (retail and non-retail) U.S. net drug spending in 2015 (see Table 3). Furthermore, we estimate that covered entities would have spent \$18.1 billion in 2015 without the 340B Program (\$12 billion + \$6.1 billion = \$18.1 billion).

The Size of the 340B Baseline Discount

Upon determining the total 340B discount to be \$6.1 billion, we next determine the portion to remove due to potentially avoidable actions by the manufacturer in order to isolate the amount of the 340B discount due to baseline obligations under the 340B statute. Data reported by the Department of Health and Human Services Office of the Inspector General (OIG) show that many drugs have 340B discounts that go beyond the mandated 23.1 percent for brand-name drugs due to manufacturer actions. In 2012, the OIG found that inflation-based rebates represented 54 percent of total rebates provided under the Medicaid Drug Rebate Program for 200 brand name drugs.³² This means that many discounts for 340B drugs contain inflationary penalties, and that portions of the \$6.1 billion 340B discount are potentially avoidable by drug manufacturers, as inflationary penalties serve as a disincentive to raising drug prices faster than the rate of inflation. Other discounts may result from the drug being offered for a better price elsewhere on the market. Put differently, the 340B Program only requires that manufacturers offer a discount on brand-name drugs of 23.1 percent; any additional discounts they must offer are a result of potentially avoidable actions.

Table 2 demonstrates the discount that manufacturers would have provided had they not incurred inflationary penalties or offered lower prices elsewhere. It shows that, if 340B savings were \$6.1 billion and 340B covered entities would have spent \$18.1 billion without access to 340B discounted prices, the baseline 340B discount would be 23.1 percent of 18.1

³⁰ Based upon HRSA Budget Justification 2017 and HRSA Budget Justification 2018

³¹ 82 Fed. Reg. at 1227.

³² Department of Health and Human Services Office of Inspector General. *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin*. April 2015.

The Size of the 340B Discount

billion, or \$4.2 billion. The remaining \$1.9 billion is due to the manufacturers' actions. Thus, the "net" rebate cost to manufacturers due to the 340B Program would be \$4.2 billion, not \$6.1 billion.

We note that this analysis assumes that all 340B purchases are of brand-name drugs, and we therefore apply the 23.1 percent baseline discount for brand-name drugs against the entire 18.1 billion in gross 340B sales. However, this is a conservative estimate as some portion of 340B sales are for generic drugs. The discount for generic drugs in 2015 would have been 13 percent off the sale of the drug, not 23.1 percent, and there was no inflationary penalty in 2015 for generic drugs.

Table 2. Breakdown of 340B Discount in 2015 by Baseline Discount and Discount Resulting from Inflationary Penalty and Best Price Requirement

340B Spending Category	Dollar Amount (in Billions)
Actual 340B Spending	\$12.0
340B Discount Components	
340B Baseline Discount	\$4.2
Discount Resulting from Inflationary Penalty / Best Price Requirement	\$1.9
Total 340B Discount	\$6.1
Spending on 340B Drugs Without 340B Discount	\$18.1

Source: Dobson | DaVanzo analysis of MedPAC and HRSA 340B spending estimates.

The Size of the 340B Discount Compared to the U.S. Drug Market

Quantifying the size of the 340B Program allows us to next examine the amount of the 340B discount in relation to other parts of the drug market. As demonstrated in Table 3, the total 340B discount represents 1.3 percent of total U.S. net drug spending in 2015 and the baseline 340B discount was 0.9 percent. It would be difficult to argue that a segment that represents roughly 1 percent of the industry spending could be a major factor in stimulating manufacturers to increase drug prices.

Table 3. 340B Program Spending and Discounts, 2015

	Dollar Amount	Percent of U.S. Net Drug Spending (\$457 Billion)
Actual 340B Drug Spending	\$12.0	2.6%
Total 340B Discount	\$6.1	1.3%
340B Baseline Discount	\$4.2	0.9%

Source: Dobson | DaVanzo analysis of MedPAC and HRSA 340B spending estimates.

The Size of the 340B Discount

As noted previously, multiple sources have cited specialty drugs as being a primary cause of the increase in drug spending in recent years. According to IMS, “spending on specialty medicines doubled in the past five years, contributing 70% of overall medicine spending growth between 2010 and 2015.”³³ Furthermore, “the largest proportion of the new medicines launched in the last five years have been specialty drugs, and specialty share of spending has risen while traditional net medicine spending has declined...over the past decade.”³⁴

Because the literature commonly cites to growth in the specialty drug market as a reason for overall increases in drug spending, it is also important to examine the size of 340B within the context of specialty drugs alone. This is particularly important because covered entities may only purchase outpatient drugs at 340B prices, and specialty drugs make up a significant share of outpatient drug spending. In “non-retail settings, specialty medicines represent 58 percent of invoice spending.”³⁵ Therefore, specialty drugs are a large component of 340B Program expenditures.

As shown in Table 4 below, the national data show that 340B comprises a small share of the specialty market. Gross spending on 340B drugs – that is, what 340B covered entities would have spent absent the 340B Program – represents only 12.0 percent (\$18.1 ÷ \$150.8) of spending for all specialty drugs in 2015. The **total** 340B discount of \$6.1 billion represents 4.0 percent of specialty drug spending in 2015 (\$6.1 ÷ \$150.8). The baseline 340B discount of \$4.2 billion is 2.8 percent of specialty drug spending. The literature commonly cites the specialty drug market as a driver of overall drug spending, and given that the 340B discount is such a small part of the specialty drug market, these data suggest that 340B is not driving increases in overall drug spending.

³³ IMS Institute for Healthcare Informatics. *Medicines Use and Spending in the U.S. A Review of 2015 and Outlook to 2020*. April 2016.

³⁴ Quintiles IMS Institute. *Medicines Use and Spending in the U.S. A Review of 2016 and Outlook to 2021*. May 2017.

³⁵ Quintiles IMS Institute. *Medicines Use and Spending in the U.S. A Review of 2016 and Outlook to 2021*. May 2017.

The Size of the 340B Discount

Table 4. 340B Program Spending and Discounts Compared to Specialty Drug Spending, 2011-2015

	2011	2012	2013	2014	2015
Actual Spending on 340B Drugs ^a	\$6.4	\$7.0	\$7.1	\$9.0	\$12.0
Gross Spending on 340B Drugs ^b	\$9.7	\$10.6	\$10.7	\$13.6	\$18.1
Total Discounts for 340B Drugs ^c	\$3.3	\$3.6	\$3.6	\$4.6	\$6.1
Baseline Discounts for 340B Drugs ^d	\$2.2	\$2.4	\$2.5	\$3.1	\$4.2
Gross Spending on Specialty Drugs (Retail and Non-Retail)^e	\$82.0	\$88.0	\$97.3	\$124.1	\$150.8
Actual Spending on 340B Drugs as Percent of Specialty Drugs	7.8%	8.0%	7.3%	7.3%	8.0%
Gross Spending on 340B Drugs as Percent of Specialty Drugs	11.8%	12.0%	11.0%	10.9%	12.0%
Total 340B Discounts as Percent of Specialty Drugs	4.0%	4.1%	3.7%	3.7%	4.0%
Baseline 340B Discounts as Percent of Specialty Drugs	2.7%	2.7%	2.6%	2.5%	2.8%

Sources: ^aMedPAC (2011-2013); Drug Channels (2014); HRSA (2015)

^bThis is an estimate of what spending by 340B covered entities would have been, absent the 340B Program

^cCalculated using an average 34 percent discount for 340B drugs

^dDobson | DaVanzo analysis of MedPAC and HRSA 340B spending estimates

^eIMS Institute for Healthcare Informatics (Quintiles IMS Institute)

The 340B Program and Other Industry Spending

We next compare the discounts attributed to the 340B Program to other industry spending and costs. That is, we compare 340B expenditures to other rebates and discounts and other general industry costs such as advertising and patent expiries. We determine how the size of the discount provided by drug manufacturers to 340B covered entities compares to the size of other rebates and discounts, and examine the relationship between increasing drug prices and rebates and discounts. We then look at how the 340B discount compares to pharmaceutical industry spending in other areas, such as advertising and promotion, and finally how generic conversion affects drug manufacturers and drug prices.

Other Rebates and Discounts

Drug manufacturers provide rebates and discounts to a number of market entities other than 340B covered entities. Manufacturers provide discounts and rebates to negotiated health plans and to pharmacy benefit managers (PBMs); they offer cost sharing assistance directly to patients; and other governmental programs, such as the Medicaid Drug Discount Program, receive rebates. IMS estimates that in 2015, overall industry rebates and discounts reduced gross drug spending by 27 percent.³⁶ FiercePharma cites the Credit Suisse estimate of almost 36 percent for total rebates in 2015.³⁷ Given that the average 340B discount, including the larger discounts that can be required due to inflationary penalties and the lower best price requirement, is 34 percent, the size of the 340B discount is in line with the size of discounts and rebates offered to other market stakeholders. Moreover, as will be discussed below, the 340B discount represents a small portion of industry rebates and discounts, indicating that manufacturers are offering discounts elsewhere in the market that are just as large as 340B discounts, and many of them are voluntary.

Figures 1 and 2 illustrate the portion of rebates and discounts attributable to various market stakeholders. Figure 1 presents these rebates and discounts as a share of brand-name drug

³⁶ Ibid.

³⁷ Sagonowsky E. "Report: Price hikes are still driving pharma's earnings growth. Who's most at risk?" FiercePharma April 19, 2017. <http://www.fiercepharma.com/pharma/despite-scrutiny-price-hikes-still-driving-pharma-s-eps-growth-report>.

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rebates only, totaling \$106 billion, while Figure 2 presents these rebates and discounts as a share of total drug rebates (totaling \$170.2 billion). This information is also presented in Columns 2 and 3 of Table 5. These figures demonstrate the small size of the 340B discount in relation to rebates and discounts provided to other market entities.

As shown in columns 2 and 3 of Table 5, the total 340B discount was 5.7 percent of all brand-name drug rebates and 3.6 percent of total (brand name and non-brand name) discounts and rebates provided by drug manufacturers to market entities in 2015. The baseline 340B discount was 3.9 percent of brand-name drug rebates and 2.5 percent of total drug rebates (refer to the appendix for a discussion of the analytical methodology used to create this table). In this table, we apply the entire \$6.1 billion 340B discount to brand-name rebates, however, we note that this is a conservative estimate as some portion of this amount results from discounts to generic drugs. In addition, this \$6.1 billion includes the potentially avoidable inflationary penalties and best price discounts. As discussed previously, only \$4.2 billion is due to the statutorily-mandated baseline discount, which accounts for 2.5 percent of total discounts and rebates (Column 3 of Table 5).

Figures 1 and 2. Dollar Value and Percent Share of Rebates and Discounts for Market Stakeholders in 2015

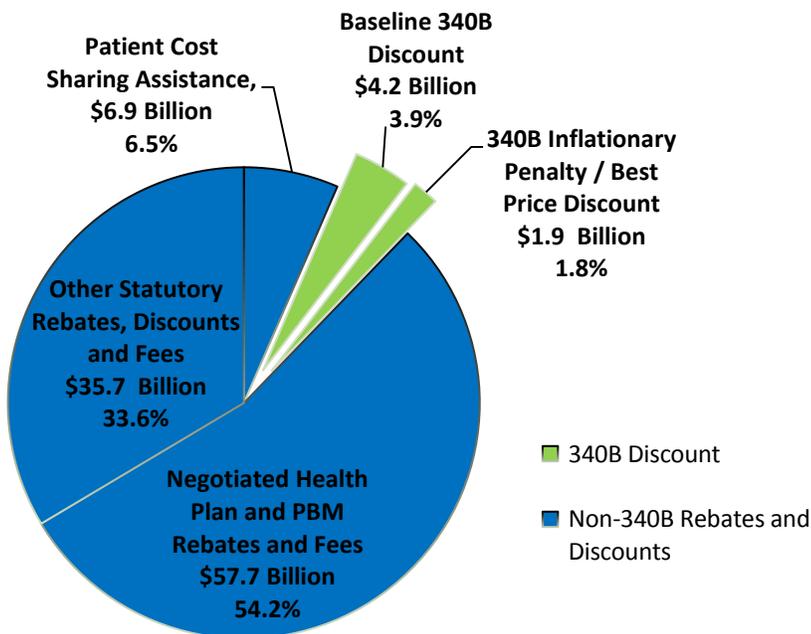


Figure 1. 340B Discounts as Share of Brand-Name Rebates and Discounts

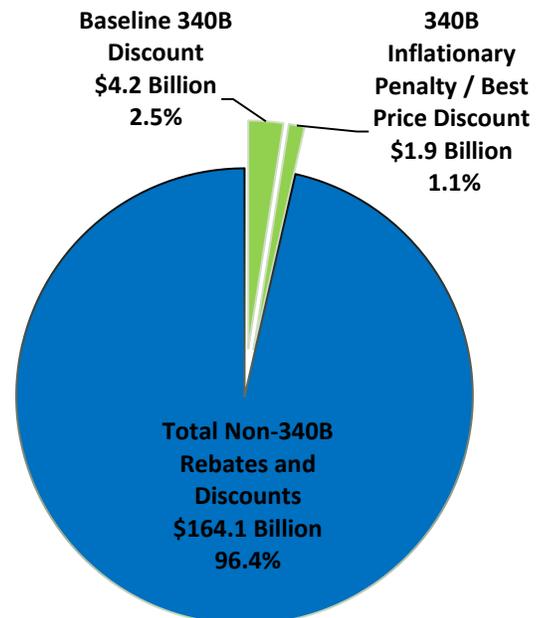


Figure 2. 340B Discounts as Share of Total Rebates and Discounts

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Table 5. Rebates for Brand Drugs and Non-Brand Drugs, 2015

Rebates, Discounts and Fees	Billions of Dollars (1)	Percent of Subtotal Rebates for Brand-Name Drugs (2)	Percent of Total Rebates and Discounts (3)
Market Rebates and Discounts for Brand-Name Drugs			
Negotiated Health Plan and PBM Rebates and Fees	\$57.7	54.2%	33.9%
Patient Cost Sharing Assistance	\$6.9	6.48%	4.1%
Statutory Rebates and Fees for Brand-Name Drugs			
340B Discounts	\$6.1	5.7%	3.6%
Baseline 340B Discount	\$4.2	3.9%	2.5%
Inflationary Penalty Add-On and Best Price Requirement	\$1.9	1.8%	1.1%
Other Statutory Rebates, Discounts and Fees*	\$35.7	33.6%	21.0%
Subtotal Rebates and Discounts for Brand-Name Drugs	\$106.4	100.00%	62.5%
Other Rebates and Discounts (e.g., Non Brand-Name Drugs)	\$63.8		37.5%
Total Rebates and Discounts	\$170.2		100.0%

* Includes the Medicaid Drug Rebate Program, Part D Coverage Gap Discounts, TRICARE Rebates, Federal Supply Schedule Discounts and Other Fees
Source: Dobson | DaVanzo analysis of Vandervele and Blalock table of gross brand drug expenditures by component.³⁸ See appendix for analytical methodology.

Table 5 also shows that the 340B discount is much smaller than negotiated health plan and PBM rebates and fees, which total \$57.7 billion and account for 33.9 percent of all rebates (54.2 percent of all brand-name rebates). It is smaller in size than all other government-sponsored programs combined. Because 340B discounts account for only about 3.6 percent of total rebates and discounts, they cannot be a major driver of overall industry rebates and discounts.

Not only do the data show that 340B discounts are so small that they could not justify drug price increases, but the data also show that drug price increases have more than offset the entire amount manufacturers provided in discounts and rebates. The previously cited article by FiercePharma, summarizing Credit Suisse analysis, reported that net price growth has remained consistent at 6 percent in recent years, and that net price increases in the U.S. resulted in \$8.7 billion net revenue for top pharmaceutical companies.³⁹ This means that, even after providing all discounts and rebates, drug manufacturers continued to generate

³⁸ Vandervele A., Blalock E. *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders*. Berkeley Research Group 2017.

³⁹ Sagonowsky E. "Report: Price hikes are still driving pharma's earnings growth. Who's most at risk?" FiercePharma April 19, 2017. <http://www.fiercepharma.com/pharma/despite-scrutiny-price-hikes-still-driving-pharma-s-eps-growth-report>.

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\$8.7 billion in income from price increases alone. In other words, price increases allowed drug manufacturers to recoup over \$106 billion in discounts and rebates for brand-name drugs and still increase their revenue by an additional \$8.7 billion. These estimates suggest that forces far larger than the 340B Program are at play in the industry.

Advertising and Promotion

The amount of money that drug manufacturers have been investing in advertising and promotion constitutes a significant part of their revenues, and exceeds the discounts that they provided to 340B covered entities by a wide margin. Although data specific to current U.S. expenditures for advertising and promotion are not readily available, a review of the literature has shown that in 2012, the U.S. pharmaceutical industry spent an estimated \$27.3 billion in marketing to consumers and health care providers, including \$3.1 billion (11 percent of the total \$27.3 billion) in direct-to-consumer advertising.⁴⁰ If we compare this to the size of the total 340B discount in 2015 (\$6.1 billion), manufacturers spent more than four times the amount of money on advertising than they provided in 340B discounts. Spending on advertising was more than six times the 340B baseline discount.

It is important to note that this comparison uses different years of data, and using a 2012 figure could underestimate advertising costs in 2015, as one would expect 2012 advertising costs to rise over time. Due to the paucity of information relating to U.S. advertising expenditures, we do not have similar figures for 2015. However, it has been reported that in 2015, spending on direct-to-consumer advertising in the U.S. rose to \$5.2 billion.⁴¹ As this figure is \$2.1 billion higher than that reported in 2012 (\$3.1 billion), it is reasonable to assume that the dollar difference between spending on total marketing and the size of the 340B discount has also grown. If we assume that direct-to-consumer advertising continues to represent 11 percent of total advertising and promotion spending, drug manufacturers would have spent \$45.8 billion on marketing in 2015, which is more than seven times larger than the total 340B discount and more than ten times larger than the baseline discount.

Patent Expiries

IMS reports that the expiry of patents for brand name drugs led to a \$14.2 billion spending loss for brand-name drugs in 2015.⁴² This is more than twice the size of the total 340B discount of \$6.1 billion and more than three times the baseline discount. This loss would have a greater impact on the industry than the 340B Program. This is consistent

⁴⁰ The Pew Charitable Trusts. *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*. November 11, 2013.

⁴¹ Robbins, R. "Drug makers now spend \$5 billion a year on advertising. Here's what that buys." March 9, 2016. <https://www.statnews.com/2016/03/09/drug-industry-advertising>.

⁴² IMS Institute for Healthcare Informatics. *Medicines Use and Spending in the U.S. A Review of 2015 and Outlook to 2020*. April 2016.

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with the literature, which consistently cites patent expiries as a factor in the change in drug spending but does not implicate the 340B Program.

In addition, it has been theorized that drug manufacturers may raise the prices of patent-protected drugs in order to maximize earnings prior to patent expiration.⁴³ They may also increase the prices of medications that remain under patent to make up for losses caused by blockbusters that have lost patent protection. It is also possible that manufacturers raise prices on a particular drug when competitors enter the market, either to match the price of the competitor or to make up for lost prescriptions.⁴⁴ This provides another example of factors unrelated to the 340B Program that may have a significant impact on drug prices and drug spending.

⁴³ DeRuiter J, Holston PL. "Drug Patent Expirations and the 'Patent Cliff'." U.S. Pharmacist June 20, 2012. <https://www.uspharmacis.com/article/drug-patent-expirations-and-the-patent-cliff>.

⁴⁴ Langreth R. "Drug Prices Defy Gravity, Doubling for Dozens of Products." <http://www.msn.com/en-gb/news/other/drug-prices-defy-gravity-doubling-for-dozens-of-products/ar-AAyc0A>.

Conclusion

We assessed the financial impact of the 340B Drug Pricing Program on the pharmaceutical industry and evaluated the plausibility of the claim that the 340B Program is a major cause of pharmaceutical price increases, cost shifting, and reductions in private sector research and medical discovery. Our evaluation indicates that the 340B Program cannot plausibly be a major driver of changes in overall U.S. drug expenditures, or a major cause of cost shifting by drug manufacturers to make up for the discounts provided under the Program. The 340B Program is a small part of the broader pharmaceutical industry, including a small part of overall drug spending, specialty drug spending, and the total amount of discounts and rebates offered by manufacturers.

The 340B discount represents only about 1 percent of net U.S. drug spending.

We examined the size of the 340B discount and found that the total 340B discount was about \$6.1 billion in 2015, or about 1.3 percent of the net U.S. drug market. The baseline 340B discount, excluding discounts resulting from inflationary penalties and lower best prices that are potentially avoidable by manufacturers, was about \$4.2 billion, or about 0.9 percent of net U.S. drug spending. It is not plausible that a segment of the industry of this small proportion can be a major factor in causing expenditure and price changes.

The 340B discount is a small share of total specialty drug spending. The literature commonly cites specialty drug growth as a driver of overall drug spending. The total 340B discount was only 4.0 percent of the specialty drug market in 2015, and the baseline 340B discount was 2.8 percent. Given that the 340B share of the specialty market is so small, it is unlikely that 340B is driving increases in specialty drug spending or the overall drug market.

The 340B discount is a small part of the total discounts and discounts provided to stakeholders. The total 340B discount accounts for 3.6 percent of total industry discounts and rebates, with the baseline 340B discount accounting for only 2.5 percent of total discounts and rebates. It is much smaller than negotiated health plan and PBM rebates and fees, which total \$57.7 billion and account for 33.9 percent of all rebates (54.2 percent of all brand-name rebates). Thus, 340B obligations are a small portion of the total discounts provided by manufacturers to other market entities and should not realistically be singled out as the cause of overall price increases or cost shifting.

Conclusion

Manufacturers offer discounts elsewhere in the market that are just as large as 340B discounts, and many of them are voluntary. The average 340B discount is in line with the average price reduction across all discounts and rebates. The fact that 340B discounts are such a small share of total discounts and rebates indicates that manufacturers offer discounts elsewhere in the market that are just as large as 340B discounts.

Price increases allow manufacturers to recover more than the total amount of all discounts and rebates, of which 340B discounts are a small share. While critics argue that rising drug prices are necessary to cover the discounts provided by the 340B Program, the analyses cited in this paper indicate that manufacturers more than make up for all of rebates and discounts they offer in total (of which the total 340B discount represents just 3.6 percent) by price increases, resulting in net revenue increases to manufacturers.

Spending by drug manufacturers in other areas dwarfs the discounts provided under the 340B Program. Spending on marketing to consumers and healthcare professionals is more than four times the size of the total 340B discount and more than six times the size of the baseline 340B discount. Losses due to patent expiries were more than twice the size of the total discount and more than three times the size of the baseline discount. Factors such as these must also be considered in any objective investigation of price increases and cost shifting.

The 340B Program is a small part of a large industry. This research indicates that singling it out as a major source of increases in prices and spending is unwarranted.

Appendix

Methodological Notes on Table 4:

- The discount amounts for brand-name drugs are borrowed directly from Vandervelde A., Blalock E. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders. Berkeley Research Group 2017.
- We estimate the total rebates and discounts to be \$170.2 billion, based upon the 27.14 percent overall rebate percentage as reported by IMS and the \$457 billion net U.S. spending reported by ASPE:

$$\frac{\$457}{(1 - 0.2714)} - \$457 = \$170.2$$

- We estimate that the difference between brand-name rebates and total rebates is \$63.8 billion. Due to a lack of data, we cannot allocate this to specific categories as with brand-name drugs.
- Although not presented as such, this amount would be divided between non-340B categories and would increase each one. As such, for non-340B categories, percentages of total rebates and discounts are underestimated.
- It is not underestimated for the 340B Program because we know the total 2015 340B discount to be \$6.1 billion.