The Impact on Diabetes of Restrictions on 340B Community Pharmacies

Since July 2020, eight drug companies have announced that they will no longer offer or will limit 340B discounts on outpatient prescription drugs sold to safety-net hospitals and dispensed through community pharmacies, despite government warnings that such actions violate the law. Several of these actions have been in effect for many months while others were put in place more recently. The companies are Eli Lilly, AstraZeneca, Sanofi, Novo Nordisk, Novartis, United Therapeutics, Boehringer Ingelheim, and Merck.

Most of these companies manufacture drugs used to treat diabetes, including but not limited to insulin.

KEY FINDINGS

- Eight drug manufacturers are limiting or prohibiting 340B discounts on outpatient prescription drugs dispensed through community pharmacies.
- Together, three of the companies have more than 90% of the American insulin market.
- In 2019, diabetes drugs manufactured by these companies accounted for 91% of all diabetes drug spending by Medicare Part D.
- 61% of Medicare Part D spending on all drugs made by these companies was for diabetes products.
- Due to significant price increases, nine out of the top 10 diabetes drugs made by these companies are more heavily discounted than other 340B drugs.
- Denying 340B discounts on nominally priced diabetes drugs dispensed by community pharmacies allows these companies to circumvent inflationary penalties and dramatically increases the cost of diabetes drugs to safety-net providers in the 340B program.

According to the Centers for Disease Control and Prevention (CDC), 34.2 million Americans are living with diabetes, representing 10.5% of all Americans. Prevalence of diabetes is disproportionately higher among Black, Hispanic, and American Indian/Alaska Native populations.[1] According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), high blood glucose leads to problems such as heart disease, stroke, kidney disease, eye problems, dental disease, nerve damage, and foot problems. Without medication to control their blood sugar, people with diabetes are at risk of premature death.[2] According to the American Diabetes Association, many people with diabetes are prescribed insulin,

[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report. 2020.
[2] National Institute on Diabetes and Digestive and Kidney Diseases. Health Information.

either because their bodies do not produce insulin (type 1 diabetes) or do not use insulin properly (type 2 diabetes).[3]

The total U.S. market for diabetes drugs reached [$49.4 billion] in 2019.[4] There are more than 20 types of insulin sold in the U.S., but three manufacturers – Eli Lilly, AstraZeneca, and Sanofi – capture more than 90% of the market. In addition to insulin, people with type 2 diabetes are often prescribed medications to reduce sugar production and block starches that increase blood sugar levels. [5]

Understanding the impact of these manufacturers' actions on insulin and other diabetes drugs is central to understanding the overall impact of these limits on safety-net providers and the low-income and rural patients they serve.

Methodology

340B Health analyzed data from Medicare Part D prescription drug claims to assess the impact of these actions by therapeutic class of drugs. Data on drug sales are largely proprietary, but each year the Centers for Medicare & Medicaid Services (CMS) releases a dataset that provides spending information for Medicare Part D drugs. Part D drugs are generally self-administered and include insulin and other diabetes medications. The Part D program includes about 70% of Medicare beneficiaries and represents more than $180 billion in spending on drugs before rebates and other price concessions.[6] Given its size and scope, the Part D dataset lends itself well to answering key questions about the impact of the manufacturer actions.

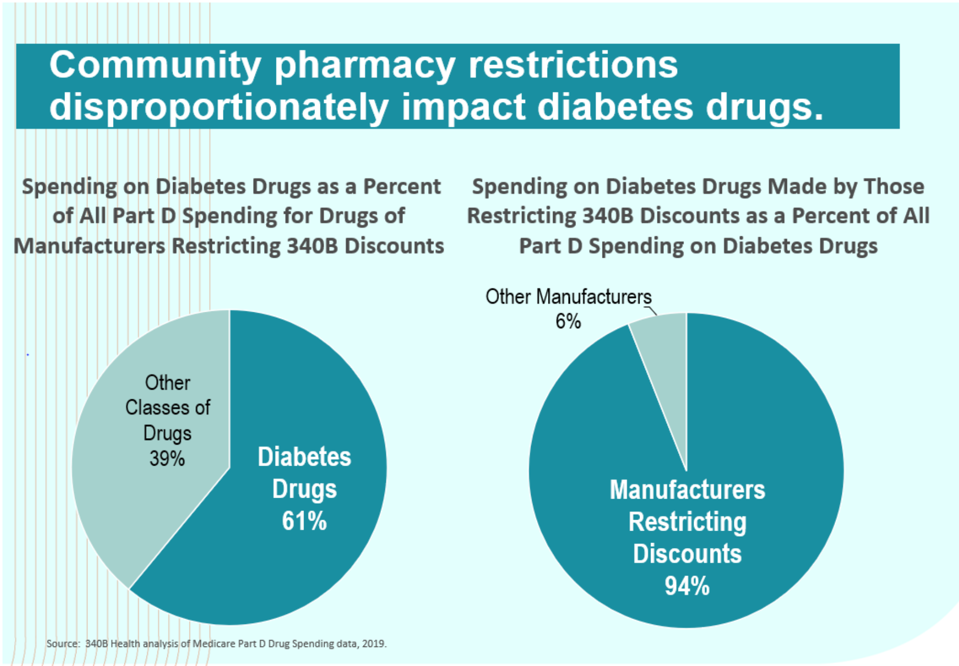
340B Health used the Part D dataset to identify the top-selling drugs manufactured by each of these companies to assess which therapeutic classes are most affected and to understand commonalities across drugs subject to these actions. 340B Health also reviewed secondary sources to identify trends in pricing behavior and the role of inflationary penalties, as well as public statements of manufacturers about the impact of these actions on their finances.

Findings

Diabetes Drugs Are Disproportionately Impacted

The impact of these restrictions has been the greatest for diabetes drugs. Based on 2019 spending in Medicare Part D, diabetes drugs represent 61% of all the Medicare Part D drug sales for these eight manufacturers. Diabetes products manufactured by these companies in turn represent 94% of all Part D spending on diabetes drugs.[7] A list of top diabetes drugs with Part D sales can be found in Appendix A.

[3] American Diabetes Association.
[4] Imarc, United States Diabetes Market Report: 2020 -2025.
[5] American Diabetes Association. 2021.
[6] Centers for Medicare & Medicaid Services. Medicare Part D Spending Dashboard & Data. 2015-2019.
[7] Analysis of Medicare Part D Dashboard. Data for 2019. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD



Diabetes Drugmakers Face Financial Penalties Due to Large Price Increases

The 340B drug pricing program requires manufacturers to discount name brand drug prices for safety-net hospitals, health centers, and clinics by a minimum of 23.1%. 340B discounts increase if manufacturers raise their prices by rates that exceed general inflation. Drugs with large or sustained increases over inflation eventually can have penalties that exceed the price of the drug. In such instances, the penalties are limited such that a drug price cannot fall below a penny per dose.[8] Published research finds this "inflationary penalty" provides an important constraint on drug price increases that spills over to non-340B purchases.[9] A recent report by the Senate Finance Committee provides examples of drug price increases for several top-selling affected drugs, illustrating why manufacturers of these drugs have been hit with inflationary penalties.

Due to manufacturers' pricing decisions, the prices of many diabetes drugs have increased dramatically in recent years. For example, the price of Eli Lilly's insulin products increased by 1200% between 1999 and 2019, from $21 for a one-month supply to $275.[10] Other major manufacturers – AstraZeneca and Sanofi – followed Lilly's lead and increased their prices in a pattern known as "shadow pricing."[11] As a result, of the top 10 diabetes drugs impacted by the manufacturer pricing actions, nine are "penny-priced" when sold to a 340B covered entity (See Appendix A).

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[8] Federal Register. 340B Drug Priding Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation. 1 May 2017.

[9] Dickson S. Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases. *JAMA Netw Open.* 2020;3(9):e2016388.

[10] Roberts Danielle. The Deadly Cost of Insulin. AJMC. 10 Jun 2019.

[11] Pflanzer Lydia. There's something odd about the way insulin prices change. 17 Sep 2016.

Examples of Drug Price Increases[12]

Manufacturer	Drug	Increase	Timeframe	Penny-priced?
Eli Lilly	Humalog 50-50 Kwikpen	64%	2013-2017	Yes
Eli Lilly	Humalog U-100 Kwikpen	86%	2013-2018	Yes
Sanofi	Lantus Solostar	250%	2005-2015	Yes
NovoNordisk	Levemir Flextouch	52%	5 years	Yes
NovoNordisk	Novolog Mix 70/30 Flexpen	70%	5 years	Yes

Current Manufacturer Actions Circumvent Inflationary Penalties and Raise Profits

Denying 340B discounts on these nominally priced diabetes drugs dispensed by community pharmacies allows these companies to circumvent inflationary penalties and dramatically increase the cost of diabetes drugs to safety-net providers in the 340B program. These actions also serve to increase revenue and profits for the manufacturers during a time of record profits in the midst of the COVID-19 pandemic.

Some manufacturers have publicly acknowledged they are profiting from these actions. In an April 27, 2021, financial report, Eli Lilly said "lower utilization in the 340B segment, primarily for the diabetes portfolio," contributed to the company's first-quarter 2021 revenue growth of 16%.[13] The company said its 340B actions have created "about two to three points tailwind here in the U.S. on pricing for the full year."[14]

Similarly, in a 2020 interview, Merck's chief commercial officer said its major diabetes drug, Januvia, is a significant part of its 340B market segment. [15] Due to pricing behavior, Januvia is "penny-priced." Merck imposed community pharmacy restrictions on Sept. 1, 2021.

Denial of 340B Discounts is Negatively Affecting Patient Care

Health care professionals at 340B hospitals report that the actions of these drug companies are compromising their ability to provide high-quality care to many of their patients. An endocrinology clinic treating complex diabetes patients in Peoria, Ill., reported that it has had to change patients' prescriptions for insulin multiple times as each of the major manufacturers adopted limits on discounts for drugs dispensed in community pharmacies (see below).

A small rural hospital serving St. Marys, Kan., announced plans to close its emergency room and lay off several of its senior staff due, in part, to the losses incurred as a result of the denials of 340B discounts.[16] Small rural hospitals have been hit particularly hard due to the fact that, on average, they rely on partnerships with community pharmacies to generate more than 50% of their 340B savings.[17]

[12] Senate Finance Committee. Insulin: Factors Driving the Cost of a Century Old Drug. 2021.
[13] Eli Lilly. Lilly Reports Strong Fourth-Quarter and Full-Year Financial Results. 29 Jan 2021.
[14] Eli Lilly and Company's Management on UBS Global Healthcare Virtual Conference. 26 May 2021.
[15] Thomson Reuters. MRK – Q12020 Merck and Co Inc Earnings Call. 28 April 2020.
[16] WIBW. Community HealthCare System in St. Marys to close emergency room doors, adjust services. 28 Apr 2021.
[17] 340B Health Annual Survey. 2020.

Conclusion

This research indicates that the higher discounts required of diabetes drug manufacturers correlate with the decisions of several companies to deny or limit discounts for drugs dispensed in community pharmacies. The impact of those actions on safety-net hospitals, health centers, and clinics and the patients they serve is substantial and will continue to grow the longer the companies persist in their policies. Efforts by the federal government to halt these behaviors are crucial to the care of low-income and rural patients.

The Health Resources & Services Administration (HRSA), which oversees 340B, has warned six of these companies that they are violating the 340B law and ordered them to restore discounts and repay overcharges.[18] HRSA also said it could impose civil monetary penalties on manufacturers that "knowingly and intentionally" overcharge for 340B covered drugs. Rather than complying, those six companies have gone to court to block the government from enforcing those orders. Subsequently, two drug companies – Boehringer Ingelheim (BI) and Merck – imposed limits on 340B discounts. BI manufactures Jardiance, and Merck sells Januvia.

Reversing these manufacturer actions is imperative to reinstate 340B discounts for a critical class of drugs and restore some level of pricing discipline to the market for diabetes drugs. While these actions are bolstering profits of pharmaceutical manufacturers, they are hurting safety-net and rural health care providers and the patients they serve.

MANUFACTURER ACTIONS DISRUPT PATIENT CARE

UnityPoint Health Methodist Hospital is a 340B hospital in Peoria, Ill. It operates a large endocrinology clinic for patients with complex diabetes. UnityPoint relies on a partnership with a Walgreens pharmacy located within the hospital to provide patients with access to advanced forms of insulin and other needed drugs and supplies at affordable prices. These patients include those with type 1 diabetes, those that are highly insulin resistant, and others with various comorbidities. Many of these patients are uninsured or underinsured including those that fall into the Medicare coverage gap. In 2020, uninsured and underinsured diabetes patients saved $1.2 million on medications obtained through the use of this Walgreens partner pharmacy.

According to Anne Webster, a nurse practitioner at the clinic, manufacturers began cutting off access to 340B discounts in community pharmacies beginning in the summer of 2020. Many patients had to switch immediately to older, less concentrated, and less expensive forms of insulin that offered worse glycemic control. The volume of insulin that needed to be injected also was much greater, leading to other potential problems. Some patients had to go from using an insulin pen two times a day to injecting themselves by syringe four to six times per day.

[18] Department of Health & Human Services. Letter to Manufacturers, 17 May 2021.

Appendix A:
Top Diabetes Drugs by Part D Medicare Spending
2019

Brand Name	Manufacturer	Total Part D Spending
Januvia*	Merck Sharp & D	$3,535,983,474.00
Lantus Solostar*	Sanofi-Aventis	$2,495,768,701.50
Trulicity	Eli Lilly & Co.	$2,273,120,392.90
Novolog Flexpen*	Novo Nordisk	$1,844,090,301.60
Levemir Flextouch*	Novo Nordisk	$1,622,206,516.90
Victoza 3-Pak*	Novo Nordisk	$1,527,143,435.80
Jardiance*	Boehringer Ing.	$1,447,765,688.20
Humalog Kwikpen U-100*	Eli Lilly & Co.	$1,218,126,350.70
Tradjenta*	Boehringer Ing.	$1,187,579,077.40
Lantus*	Sanofi-Aventis	$1,158,911,973.10

*Penny-priced
Source: Analysis of Medicare Part D Dashboard. Data for 2019. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD