State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Insurance Department

TANJI J. NORTHRUP
Interim Insurance Commissioner

December 30, 2020

Senator Allen M. Christensen, Senate Chair
Representative Brad M. Daw, House Chair
Health and Human Services Interim Committee
350 North State Street
Salt Lake City, Utah 84114

Utah Code § 31A-22-626.5 requires that the Utah Insurance Department produce a study on the affordability of insulin.

Enclosed is the Utah Insurance Department's report, *Affordable Insulin Study*, which provides information and data on the statutory requirements of Utah Code § 31A-22-626.5. While the Department was unsuccessful in obtaining a grant for funding of this study, we were still able to produce it through the assistance of an unpaid intern. The report was due on or before October 30th, 2020 and we apologize for the delay in providing this information.

I hope this report is useful to the committee. If you or other members of the committee have any questions or concerns with the report, please contact Shelley Wiseman, the Health & Life Insurance Division, Director, at 801-537-9293 or swiseman@utah.gov.

Sincerely,

Tanji J. Northrup,
Interim Insurance Commissioner

State of Utah
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Affordable Insulin Study

The *Affordable Insulin Study* was prepared by Daniel Sloan of the Health & Life Insurance Division for the Utah Insurance Commissioner pursuant to Utah Code § 31A-22-626.5. Publication date: December 30, 2020.

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The Utah Insurance Department would like to acknowledge and thank Daniel R. Sloan, a graduate student from Brigham Young University, who conducted the research for this report and was responsible for writing the Affordable Insulin Study. Daniel freely volunteered his assistance and it is because of his contributions that the legislative requirements in HB207 Insulin Access Amendments have been met.

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Introduction

For millions of Americans living with diabetes, insulin is a lifesaving drug that helps them manage their diabetes and live fulfilling, healthy lives. Insulin and insulin products are readily available in the United States and have helped countless people feel healthier and manage a disease that, just a few decades ago, often led to physical limitations and even early death. For many, though, the price of insulin has become too high and has placed undue financial burdens on insulin users and their families. Some insulin users have made the choice to ration their insulin intake to save money. Rationing has led to health complications and, tragically, even death. The high cost of insulin is something governments feel increasingly compelled to address, as evidenced by several executive orders issued by the federal government during summer 2020 to lower prescription drug costs.[1]

This study, commissioned by the 2020 Utah State Legislature through passage of HB207, Insulin Access Amendments, investigates current and historical trend information about the wholesale acquisition cost (WAC) of insulin; the cost to produce insulin; explanations for increases in insulin costs; expenditures of drug manufacturers in marketing insulin; manufacturers' net profits from insulin; portion of drug manufacturers' total net profits that is composed of insulin net profits; financial assistance currently available to individuals who use insulin through patient prescription assistance programs; value to individuals who use insulin benefits (including coupons provided directly to individuals who use insulin and programs to assist individuals who use insulin in paying co-payments and coinsurance); the costs to drug manufacturers of the programs described in Utah Code Subsection 31A-22-626.55(h); total value of benefits manufacturers provide in the form of rebates for insulin to health plans for pharmacy benefit managers in Utah;

[1] The White House, 2020.

and additional information to aid the Legislature in developing policy to reduce insulin prices in Utah.[2]

Insulin is a lifesaving drug included on the World Health Organization's (WHO) List of Essential Medicines, which are medicines the WHO indicates should always be available and available at an affordable price. Over the last ten years, insulin prices tripled in the United States, and out-of-pocket costs per prescription have doubled. One survey distributed to patients with Type 1 (T1) or Type 2 (T2) diabetes with insulin prescribed in the last six months and who had visited the Yale Diabetes Center found that 51 patients (25.5% of survey respondents) had underused insulin because of costs. Patients with cost-related underuse were more likely to have lower incomes than others. Similarly, one-quarter of patients at an urban diabetes center reported cost-related insulin underuse. (This was associated with poor glycemic control.) A third of patients who experienced cost-related underuse did not discuss these issues with a clinician but decided to ration their insulin themselves.[3]

Current and historical trend information about the wholesale acquisition cost of insulin

The cost of insulin has steadily increased over the last several years. In 2016, individuals with Type 1 (T1) diabetes spent $5,705 per person on insulin, a $2,841 increase per person from 2012 when gross insulin spending per person was $2,864. During this same period, daily insulin usage for T1 users only rose 3% while prices increased significantly more. (Prices also rose for all insulin-related products between 2012-2016.)[4] Diabetes was the costliest chronic disease in the nation in 2017, costing the U.S. healthcare system $327 billion. Between 2012-2018, insulin

[2] Utah State Legislature, 2020.
[3] Herkert, Vijayakumar, and Luo, 2019.
[4] Biniek and Johnson, 2019.

increased an average of 14% annually; and accounted for 31% of a T1 diabetic's healthcare costs, up from 23% in 2012.[5]

One aspect of the cost of diabetes is the wholesale acquisition cost (WAC). The WAC is a manufacturer's list price for a drug to direct purchasers or wholesalers in the United States and does not include any discounts or rebates as part of the price calculation.[6] The average WAC for insulin has steadily risen over the last decade, from about $6/mL for short-acting insulin (vials) in 2012 to over $11/mL in 2016, 183%. For rapid-acting insulin (pens), the rise was even steeper, from about $16/mL in October 2012 to about $31/mL in October 2016, 194%.[7]

The cost to produce insulin

Diabetes cost the United States healthcare system $327 billion in 2017, making diabetes the most expensive chronic disease in the nation. Much of this is due to the increased insulin prices over the last decade. But why are insulin prices going up and what is the cost for insulin producers? Insulin is a century-old drug, but only three insulin-producing companies have a patent to produce insulin. Price varies over time, but a recent study found that the cost of production for one vial of insulin averages between $2.28 and $3.42. The cost for most insulins is higher, averaging between $3.69 and $6.16.[8]

Explanations for increases in insulin costs

There are a number of reasons for the rise in insulin costs. A substantial portion of the rise in costs comes from higher prices for new products, not necessarily a rise in prices on existing products. Additionally, rebates offered by manufacturers can also contribute to the rise in insulin

[5] Hayes and Farmer, 2020.
[6] California Office of Statewide Health Planning and Development.
[7] Insulin Access and Affordability Working Group, 2018.
[8] Silverman, 2018.

costs. Pharmacy benefit managers (PBMs) create substantial revenue via rebates on brand-name drugs from insulin manufacturers. Competing drug manufacturers vie for top-tier allocation of their products (i.e., insulin) via pharmacies, which in turn drives larger rebates leading to higher list prices of insulin. Insulin rebates average between 30-50%, significantly higher than rebates for other drugs.[9]

Expenditures of drug manufacturers in marketing insulin

There are only three insulin manufacturers providing insulin to the United States: Eli Lilly, Novo Nordisk, and Sanofi. All three of these companies do not publicly disclose how much of their budget is focused on marketing insulin. However, there is publicly available data about how much some of the companies spend on advertising and marketing overall. Eli Lilly spent $864 million on advertising in the United States in 2019, nearly $100 million more than the previous year (2018). Expenditures on advertising in 2019 were the highest for Eli Lilly since 2012-2013, when Eli Lilly spent more than $913 million in each year on advertising.[10]

Manufacturers' net profits from insulin (including the portion of total net profits from insulin net profits)

The three manufacturers of insulin in the United States—Eli Lilly, Novo Nordisk, and Sanofi—each has different net profits. While there is not publicly available data on how much of their net profits come from insulin, the following information details their annual net profits overall. Eli Lilly's net profit (income) was $4.538 billion in 2019, an increase of over a billion dollars from 2018 ($3.151 in 2018). This is an increase of 47.21%.[11] Novo Nordisk had a vastly

[9] Hayes and Farmer, 2020.
[10] Guttmann, 2020.
[11] The Wall Street Journal.

larger net profit in 2019 with $38.951 billion, an increase of only about 0.84% from the previous fiscal year.[12] Sanofi had a much smaller net profit in 2019 with $2.907 billion, net income growth of -32.69% from the previous year ($4.319 billion).[13] The table below details the annual net profit (income) of the three insulin manufacturers. All information is from *The Wall Street Journal* and all numbers is stated in millions.

	2019	**2018**	**2017**	**2016**	**2015**
Eli Lilly	$4,638	$3,151	($204)	$2,738	$2,408
Novo Nordisk	$38,951	$38,628	$38,130	$37,925	$34,860
Sanofi	$2,907	$4,319	$3,773	$4,395	$4,411

Financial assistance currently available to individuals who use insulin through patient prescription assistance programs

Patient assistance programs (PAPs) can help patients who are without insurance or who have had an alteration in their drug coverage. According to a congressional study, all three brand-name insulin manufacturers have PAPs, although two of them operate PAPs through 501(c)(3) foundations. PAPs vary based on insurance coverage and eligibility can be different depending on the person, but overall access to PAPs is available via manufacturers to all insulin patients in need.[14] These programs also benefit the uninsured and those who are on Medicare Part D, helping patients receive insulin free of charge.[15]

[12] The Wall Street Journal.
[13] The Wall Street Journal.
[14] Congressional Diabetes Caucus.
[15] Orrange, 2018.

Value to individuals who use insulin benefits

Value to patients using insulin benefits can also come through coupons provided directly to individuals who use insulin and through programs assisting individuals who use insulin in paying co-payments and coinsurance. Coupons are available through groups such as goodrx.com, and some of the three main insulin manufacturers offer vouchers for a "free, but limited, sample of insulin."[16] Additionally, Eli Lilly, Novo Nordisk, and Sanofi Aventis all offer copay cards to both patients with insurance and without, which can lead to reduced out-of-pocket costs.[17] These measures—coupons and assistance with copays—can help reduce the cost of insulin for both insured and uninsured patients. While the costs to drug manufacturers of the programs described above can't be known without data from the manufacturers, these programs can reduce their revenues over time.

The total value of benefits manufacturers provide in the form of rebates for insulin to health plans or pharmacy benefit managers

Rebates have contributed greatly to the expanding gap between the net and list prices of insulin. As one study noted:

> Manufacturers negotiate with a PBM for discounts from the list price to have their medications placed on a lower cost-sharing tier and/or to avoid constraints on utilization on the PBM's client formulary. In this process, manufacturers agree to fees and price concessions…The rate of increase in these rebates has accelerated to approach approximately half of the list price of insulin…This gives PBMs considerable leverage in any rebate-discount negotiation with stakeholders.[18]

[16] Orrange, 2018.
[17] Lee, 2020.
[18] Insulin Access and Affordability Working Group, 2018.

Rebates have grown substantially in the last several years and, in some cases, account for over 40% of U.S. gross sales.[19] In his April 2019 testimony before a congressional subcommittee, the executive vice president of North American and president of Novo Nordisk, Doug Langa, stated that the demand for rebates has increased yearly, with rebates and other discounts accounting for $.68 of every dollar of Novo Nordisk sales in the U.S.[20] As of this writing, data specific to Utah was not publicly available.

Recommendation

There are many differing opinions on what governments can do to address the problem of costly insulin. People of good intent on every side of the issue have different views on what will be most beneficial and what type of government intervention is appropriate in a free market economy. The Utah State Legislature should continue to monitor the cost of insulin in the State of Utah and the impact on consumers and business entities. Creating a regulatory climate that promotes competition and fosters innovation should aid in bringing down the costs of insulin.[21]

Summary

Insulin is a lifesaving drug that helps millions with diabetes live fulfilling, healthy lives, something that was not possible just decades ago. The availability of insulin is a lifesaver for many. Unfortunately, the high price of insulin has placed massive financial burdens on insulin users and their families, leading to economic hardship and even tragic loss of health and life.

[19] Insulin Access and Affordability Working Group, 2018.
[20] Congressional testimony, C-Span, 2019.
[21] Civica Rx, a not-for-profit drug company affiliated with Intermountain Healthcare, is one such company working to lower drug prices.

The price of insulin has increased 14% annually between 2012-2018, with individuals with T1 diabetes spending $5,705/person on insulin. Gross insulin spending per person increased $2,841 between 2012 and 2016, while producing insulin just costs between $2.28 and $3.42 per vial. There are a number of reasons for the rise in insulin costs, much of it coming from higher prices for newer products (rather than rising prices on existing products). Another reason is that rebates offered by manufacturers can also contribute to the rise in insulin costs. PBMs create revenue via rebates on brand-name insulins, leading drug manufacturers to via for top-tier allocation of their insulins in pharmacies, which drives even larger rebates and higher list prices of insulin. Patient assistance programs (PAPs) can help patients without insurance and are available to all insulin patients via the manufacturers.

Ultimately, many people have differing views on how government can help address the increase of insulin costs. The Utah State Legislature can continue to monitor the situation to help increase innovation while also providing aid to those struggling with the burden of high-priced insulin.

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Statutory Requirements

Utah Code § 31A-22-626.(5) requires that the Utah Insurance Department produce a study on the affordability of insulin. The statutory requirements for this evaluation are shown below:

(1) As used in this section, "insulin" means a prescription drug that contains insulin.

(2) The department shall obtain funding through grants to fund a study on insulin costs.

(3) If the department obtains the funding described in Subsection (2), the department shall, on or before October 30, 2020, complete a study on the cost of insulin manufacturing and factors that determine the price of insulin.

(4) The department shall use public, readily available data accessible to the department to conduct the study described in Subsection (3).

(5) The study described in Subsection (3) shall investigate:

(a) current and historical trend information about the wholesale acquisition cost of insulin;

(b)the cost to produce insulin;

(c) explanations for increases in insulin costs;

(d) expenditures of drug manufacturers in marketing insulin;

(e) manufacturers' net profits from insulin;

(f) the portion of a drug manufacturers' total net profits that is composed of insulin net profits;

(g) financial assistance currently available to individuals who use insulin through patient prescription assistance programs;

(h) value to individuals who use insulin benefits including:

(i) coupons provided directly to individuals who use insulin; and

(ii) programs to assist individuals who use insulin in paying co-payments and coinsurance;

(i) costs to drug manufacturers of the programs described in Subsection (5)(h);

(j) total value of benefits manufacturers provide in the form of rebates for insulin to health plans or pharmacy benefit managers in Utah; and

(k) additional information that the department determines will aid the Legislature in developing policy to reduce insulin prices in Utah.

(6)

(a) On or before October 30, 2020, the department shall submit a final report on the study described in Subsection (3) to the Health and Human Services Interim Committee and the Business and Labor Interim Committee.

(b) The department's report may include recommendations on legislation for:

(i) increased drug pricing transparency; and

(ii) programs that would meaningfully reduce the cost of insulin.

(c) The final report shall include references to all sources of information and data used in the report and study, except the department may not disclose information that is proprietary or protected under state law or federal law or regulation.