Prices of Diabetes Drugs for Seniors and the Uninsured in the United States and Abroad

Illinois's 14th Congressional District

Staff Report
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EXECUTIVE SUMMARY

More than 30 million people in the United States, including more than one in four seniors, have diabetes. Patients with diabetes rely on prescription drugs, including insulin, to help manage their conditions.

Over the past two decades, manufacturers have systematically and dramatically raised the prices of their insulin products by more than tenfold—often in lockstep. These high prices lead many people to ration or stop taking their medications, which can result in serious health complications and even death, as the Committee heard in direct testimony earlier this year.

The prices of diabetes medications—and insulin in particular—are far higher in the United States than they are overseas, in part because certain federal programs lack the authority to negotiate directly with drug manufacturers.

In order to assess the impact of the high prices of diabetes medications on seniors and uninsured patients, this report was prepared by the staff of the House Committee on Oversight and Reform for the 14th Congressional District of Illinois.

Costs to Seniors and Medicare

This report estimates that there are approximately 15,000 Medicare beneficiaries in the district who have been diagnosed with diabetes. The 50 most popular brand-name diabetes medications used by these beneficiaries are available at significantly lower prices in other countries. For example, the cost of these drugs to the Medicare program in the district are 4.9 times the cost in Australia, 3.6 times the cost in the United Kingdom, and 2.7 times the cost in Canada.

Costs to Uninsured Patients

This report estimates that there are 36,000 uninsured residents in the district. These patients often bear the entire burden of their high prescription drug prices and pay significantly more than patients pay overseas for the same drugs. This report finds that uninsured diabetes patients in the district who purchase Novolog Flexpen—a popular brand of insulin—pay 23 times more than they would in Australia, 15 times more than they would in the United Kingdom, and 13 times more than they would in Canada.

I. HIGH PRICES OF DIABETES DRUGS IN THE UNITED STATES

More than 30 million people in the United States, including more than one in four seniors, have diabetes.[1] Diabetes is a life-threatening disease that disproportionately affects communities of color. It is associated with serious health problems, including heart disease and stroke, kidney failure, and blindness.[2] In 2017, diabetes contributed to the death of 277,000 Americans—and was the primary cause of death for 85,000 of those individuals.[3]

In 2017, diagnosed diabetes cost the United States an estimated $327 billion—including $237 billion in direct medical costs and $90 billion in productivity losses.[4]

Diabetes drugs, including insulin and oral medications that regulate blood sugar levels, play a critical role in helping people with diabetes manage their condition and reduce the risk of diabetes-related health complications.

Insulin—used by approximately 7.5 million Americans to treat their diabetes—was discovered nearly a century ago by Canadian researchers Frederick Banting, Charles Best, J.B. Collip, and J.J.R. Macleod, who assigned their patent to the University of Toronto with the goal of making the medication widely available.[5]

Insulin was initially produced from animals, and the development of synthetic forms of insulin from human genes in the 1990s—called "analogs"—improved the medication's efficacy. Analog insulin products manufactured by three companies—Sanofi, Eli Lilly, and Novo Nordisk—now account for 96 percent of the insulin market in the United States.[6] Even though analog insulin has been on the market for nearly 30 years, it has no meaningful generic competition.[7]

Price Increases for Diabetes Drugs

Over the past two decades, manufacturers have systematically and dramatically raised the prices of their insulin products by more than tenfold—often in lockstep. These prices dwarf manufacturing costs. One study found manufactures could charge as little as $7 to $11 per month for insulin and still make a profit.[8]

Although insulin is the most well-known diabetes medication, diabetes patients are often prescribed other oral drugs to use in place of or alongside insulin. Many of these non-insulin products used to regulate blood sugar levels are brand drugs that lack generic alternatives.

In recent years, the high prices of diabetes drugs have placed a tremendous strain on diabetes patients as well as the federal government, which provides diabetes medications to more than 43 million Medicare beneficiaries.

Because Medicare lacks the authority to negotiate directly with drug manufacturers, Medicare beneficiaries pay significantly more for their drugs than patients abroad. Patients who are uninsured or underinsured and must pay for their drugs out of pocket bear an even greater cost burden.[9]

Effects of Price Increases on Families and Taxpayers

The high prices of diabetes drugs lead some beneficiaries to ration or stop taking their medications, which can result in serious health complications and even death, as well as significantly higher costs to the American taxpayers.

The first witness who testified before the Oversight Committee in the 116th Congress was Antroinette Worsham, whose daughter died after rationing her insulin because of its cost. When Ms. Worsham appeared before the Committee on January 29, 2019, she stated, "My older daughter, Antavia, was diagnosed at the age of 16 and only lived 6 years with this disease, due to the high cost of insulin."[10]

Her testimony echoed previous studies on this issue. One found approximately a quarter of patients with type 1 and type 2 diabetes had rationed their insulin in the previous year.[11] Another found that avoidable expenditures associated with rationing or not taking diabetes medication costs the Medicare program $2 billion annually.[12]

Other experts who testified before the Committee agreed:

- Dr. Alicia Georges, a registered nurse and the national volunteer president of AARP, testified: "It is hardly surprising that our members consistently tell us that they cannot afford the medications they need, and are forced to make difficult choices as a result."

- Dr. Aaron Kesselheim, practicing physician and professor of Pharmacoeconomics at Harvard Medical School, testified that "increasing drugs prices can make important breakthroughs unaffordable to patients." He proposed: "To improve competitive price negotiation during the market exclusivity period, we could authorize Medicare to create a program wide formulary and negotiate drug prices."

- Dr. Avik Roy, physician and health policy expert, testified, "Nobody forces drug companies to charge high prices." He added that "in the absence of competition, manufacturers often charge the highest prices they can."[13]

- Dr. Gerard Anderson, professor of health policy and management at Johns Hopkins University, testified, "In the U.S., branded drug companies are much more likely to increase prices than lower prices." He concluded: "In other countries, the prices of branded drugs tend to go down."

II. ESTIMATED EFFECTS OF HIGH DIABETES DRUG PRICES IN THE UNITED STATES

This report examines the prices paid for the top 50 brand-name prescription diabetes drugs taken by seniors and disabled beneficiaries on Medicare drug plans and uninsured individuals in the 14th Congressional District of Illinois. It concludes that these prices far exceed the prices of these drugs in Australia, the United Kingdom, and Canada.

Costs to Seniors and Medicare

In the 14th Congressional District of Illinois, there are an estimated 15,000 seniors and disabled Medicare beneficiaries who have been diagnosed with diabetes.[14] In this district, the top 50 diabetes medications cost the Medicare program and beneficiaries approximately $13.9 million in 2016.[15]

These same drugs are available at significantly lower prices in other countries.

- The costs to Medicare for the top 50 drugs are 4.9 times higher than the costs of the same drugs in Australia. If Medicare had paid what Australia pays for these drugs, the costs to the program in this district would have been 72 percent lower, saving approximately $10 million.

- The costs to Medicare are 3.6 times higher than the costs of the same drugs in the United Kingdom. If Medicare had paid what the United Kingdom pays for these drugs, the costs to the program in this district would have been about 70 percent lower, saving approximately $9.7 million.

- The costs to Medicare for the top 50 drugs are 2.7 times higher than the costs of the same drugs in Canada. If Medicare had paid what Canada pays for these drugs, the costs to the program in this district would have been 52 percent lower, saving approximately $7.2 million.

Because Medicare beneficiaries may be responsible for a significant part of their drug costs until they reach catastrophic coverage limits, Medicare beneficiaries in the district also would have realized substantial savings if these drugs were made available at the lower prices charged in foreign countries. For example:

- A Medicare beneficiary in the district with a 25 percent co-insurance requirement could incur up to approximately $1,320 in out-of-pocket costs for an annual supply of Novolog Flexpen.[16]

- These costs could be reduced by up to 94 percent at Australian prices (a savings of approximately $1,240 for the beneficiary), 91 percent at UK prices (a savings of approximately $1,200 for the beneficiary), and 89 percent at Canadian prices (a savings of approximately $1,180 for the beneficiary).

Costs to Uninsured Patients

The estimated 36,000 uninsured individuals in the district pay even higher prices for their drugs as compared to patients in other countries.[17]

- Uninsured diabetes patients in the district pay on average $493 for a monthly supply of Lantus Solostar—a popular brand of insulin—as compared to $33 in Australia, $51 in the United Kingdom, and $70 in Canada (a 15, 10, and 7 times difference, respectively).

- Uninsured diabetes patients in the district pay on average $632 for a monthly supply of Novolog Flexpen—another popular insulin brand—as compared to $28 in Australia, $42 in the United Kingdom, and $47 in Canada (a 23, 15, and 13 times difference, respectively).

Although some uninsured and underinsured diabetes patients may be eligible for coupons and other patient assistance programs, these programs can be difficult to access and are not guaranteed.

CONCLUSION

The high prices of prescription diabetes drugs in the United States place a significant economic burden on both taxpayers and patients, including Medicare beneficiaries and uninsured patients in the 14th Congressional District of Illinois. Substantial savings could be realized if Medicare and uninsured patients paid the same prices that patients overseas pay for their drugs.

METHODOLOGY

This staff report draws on data from the Part D Prescriber Public Use File made available by the Centers for Medicare and Medicaid Services (CMS), which includes prescription data for both Medicare Part D plans and Medicare Advantage drug plans; data from retail price aggregator GoodRx; and data from public health service formularies in Australia, Canada, and the United Kingdom.

Because neither CMS nor drug manufacturers make complete pricing data publicly available, certain assumptions are made to estimate Medicare spending, beneficiary costs, and potential savings. Those assumptions are described below.

The number of Medicare beneficiaries in each State or District that have been diagnosed with diabetes is derived from data made publicly available by CMS on the Medicare Current Beneficiary Survey and the Medicare Enrollment Dashboard and by the Centers for Disease Control and Prevention on the United States Diabetes Surveillance System.

The number of uninsured individuals in each State or District is based on data from the 2017 American Community Survey, which is compiled by the Census Bureau.

The number of doses of the top 50 branded diabetes drugs that have been prescribed is drawn from the Part D Prescriber Public Use File.

Total Medicare spending on the top 50 branded diabetes drugs is drawn from the Part D Prescriber Public Use File and reflects amounts paid by Medicare drug plans, Medicare beneficiaries, government subsidies, and any other third-party payers.[18] This total spending is reduced by 53 percent to reflect estimated rebates provided by manufacturers for diabetes medications. The 53 percent figure is drawn from a 2018 report published by the Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry's trade organization. This figure is a conservative estimate, and actual rebates may be lower—the average rebate estimated by the Medicare Trustees in 2018 was 25.3 percent.[19]

Because CMS suppresses some local data to protect individual privacy, underreporting of total Part D payments occurs at the local level. To account for this underreporting, correction factors are applied to the number of prescriptions filled and the costs incurred by Medicare, respectively. This correction factor is based on the state-level rate of suppression and assumes that state-level suppression rates are consistent in each of the state's congressional districts.

A crosswalk provided by the Missouri Census Data Center is used to match zip codes with their respective congressional districts. Provider location is the closest proxy to beneficiary location, but some beneficiaries may live in different congressional districts from the one in which their prescriptions were issued.

Medicare beneficiary out-of-pocket costs are estimated using the Medicare Part D standard benefit, which includes a 25 percent co-insurance payment for beneficiaries in the initial coverage period. Because co-insurance is based on a drug's list price, the 25 percent calculation

is applied to the pre-rebate Medicare price to determine the amount paid by the beneficiary. This 25 percent figure is also applied to the foreign price to determine the amount that the beneficiary would pay if overseas prices applied in the United States.

The retail price paid by uninsured patients (excluding coupons or other discounts) is calculated by taking the average of retail prices listed at three sample pharmacies in three zip codes in each congressional district. This data is publicly available on the GoodRx website.

Overseas prices are obtained using publicly available pricing data for public health service formularies in Australia, Canada, and the United Kingdom.

A manual review of each country's formulary is conducted to match the top 50 diabetes drugs covered by Medicare with those covered abroad. Australia's formulary matches 41 of the 50, Canada's formulary matches 37 of the 50, and the United Kingdom's formulary matches 46 of the 50. In making international comparisons, only products that have a U.S. match are used to determine potential savings to Medicare. For instance, in comparing prices available to patients in the United Kingdom, the average cost in the United States is calculated using data for only the 46 identical medications available in both countries. When a foreign country covers multiple formulations of a single drug, the most expensive formulation of the drug is selected to provide a conservative estimate.

Prices for certain diabetes medications available to patients in Canada are reported on a per-unit basis. For these medications, the price-per-unit is scaled to match the 30-day equivalent prescription fills reported to Medicare.

All currencies are converted using exchange rates effective January 1, 2019.

ENDNOTES

[1] Centers for Disease Control and Prevention, *National Diabetes Statistics Report, 2017* (online at www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf).

[2] A. Deshpande et al., *Epidemiology of Diabetes and Diabetes-Related Complications*, Physical Therapy (Nov. 2008) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3870323/).

[3] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, Diabetes Care (May 2018) (online at http://care.diabetesjournals.org/content/early/2018/03/20/dci18-0007).

[4] *Id.*

[5] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations* (June 2018) (online at http://care.diabetesjournals.org/content/41/6/1299.full-text.pdf); C. Feudtner, *Bittersweet: Diabetes, Insulin, and the Transformation of Illness* (2003); J. Greene and K. Riggs, *Why is There No Generic Insulin? Historical Origins of a Modern Problem*, New England Journal of Medicine (Mar. 2015) (online at www.nejm.org/doi/full/10.1056/NEJMms1411398).

[6] Congressional Research Service, *Insulin Products and the Cost of Diabetes Treatment* (Nov. 2018) (online at https://fas.org/sgp/crs/misc/IF11026.pdf).

[7] Senate Special Committee on Aging, Testimony of Jeremy Greene MD, PhD, Professor of Medicine and the History of Medicine, Johns Hopkins University, *Hearings on Insulin Access and Affordability: The Rising Cost of Treatment*, 115th Cong. (May 8, 2018) (online at www.aging.senate.gov/imo/media/doc/SCA_Greene_05_08_18.pdf).

[8] Congressional Research Service, *Insulin Products and the Cost of Diabetes Treatment* (Nov. 2018) (online at https://fas.org/sgp/crs/misc/IF11026.pdf).

[9] Insulin manufacturer Eli Lilly recently announced it would begin selling an authorized generic version of its branded insulin product Humalog at a list price of $137.35 per vial as "another option" for "people with high-deductible insurance plans, the uninsured, or people in the coverage gap of Medicare Part D." Eli Lilly and Company, *Lilly to Introduce Lower-Priced Insulin* (Mar. 4, 2019) (online at https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin).

[10] Committee on Oversight and Reform, *Hearing on Examining the Actions of Drug Companies in Raising Prescription Drug Prices* (Jan. 29, 2019)

[11] D. Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, Journal of the American Medical Association (Jan. 2019) (online at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499).

[12] IHS Markit, *Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare* (May 14, 2018) (online at https://cdn.ihs.com/www/pdf/IHSM-RebateSharingReport-10May2018.pdf).

[13] *Id*.

[14] Centers for Medicare and Medicaid Services, Medicare Current Beneficiary Survey (online at www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/) (accessed Mar. 17, 2019); Centers for Medicare and Medicaid Services, Medicare Enrollment Dashboard (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/Dashboard.html) (accessed Mar. 17, 2019); Centers for Disease Control and Prevention, U.S. Diabetes Surveillance System (online at https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html) (accessed Mar. 17, 2019).

[15] Assuming a 53 percent rebate provided by manufacturers to lower drug prices. This figure is a conservative estimate published by the Pharmaceutical Research and Manufacturers of America, and actual rebates may be lower—the average rebate estimated by the Medicare Trustees was 25.3 percent in 2018. Centers for Medicare and Medicaid Services, *2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (2018) (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf).

[16] Assuming a 25 percent co-insurance rate in a standard Medicare Part D prescription drug plan. Kaiser Family Foundation, *An Overview of the Medicare Part D Prescription Drug Benefit* (online at www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/).

[17] Census Bureau, *2017 American Community Survey* (online at www.census.gov/acs/www/data/data-tables-and-tools/data-profiles/2017/).

[18] Centers for Medicare and Medicaid Services, *Medicare Provider Utilization and Payment Data: Part D Prescriber* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/PartD2016.html) (accessed Mar. 14, 2019).

[19] Centers for Medicare and Medicaid Services, *2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (2018) (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf).