

Access to Diabetes Treatment: Survival of Low-Income T1D Patients

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According to the American Diabetes Association, diabetes-afflicted patients in 2017 “incur[red] average medical expenditures of ~\$16,750 per year, of which ~\$9,600 [was] attributed to diabetes” (Association, 2018). In 2016, individuals with type 1 diabetes spent approximately \$5,705 on insulin alone due to rising insulin prices (Jean Fuglesten Biniek & William Johnson, 2019). From 2012 to 2017, the cost of insulin doubled, with the average prescription cost going from \$344 to \$666, which is almost a 300% increase in price from 2002. (Hargraves and Frost, 2017) Rising medical costs are prohibitive, especially in developing communities and low-income households. Diabetes is highest among individuals whose income is at or below the poverty line (Odutayo et al., 2017). Due to the higher prevalence of diabetes in low-income communities, where access to care is most constrictive, they warrant greater attention.

The three most prominent insulin manufacturers, accounting for 90% of the global insulin market, are known as the Big Three: Eli Lilly, NovoNordisk, and Sanofi Aventis. These companies have tended to raise insulin prices in lockstep together, with little to no indication of corresponding increases in production costs. The opacity of drug pricing lets them increase prices with little to no justification (Thomas, 2017). In patient care in the U.S., third parties, such as government, insurance companies, pharmacies, and pharmacy benefit managers (PBMs), increase costs and discount patient well-being. While the government contains many advocates for a reduction in insulin costs, they also regulate patents and FDA approvals of drugs. In exchange for developing new and innovative drugs, drug companies are given “patents and legal

exclusivities that delay the FDA approval of applications for generic drugs.” (FDA Center for Drug Evaluation and Research, 2019) Biosimilar and generic drugs typically sell at lower prices than brand specific drugs, but the government regulation of patent approvals impedes on the release of these affordable options to the market (Beyond Type 1, 2019).

Pharmacy benefit managers (PBMs) are also key players in the “selection, purchase, and distribution of pharmaceuticals.” As PBMs interact with patients, pharmacies, drug manufacturers, and health insurers, they can “influence which drug products are used most frequently and set terms for how much pharmacies are paid for their part in the process.” (Werble, 2017) Large PBMs such as CVS Health, Express Scripts, and OptumRX negotiate rebates negotiated from manufacturers, which lowers drug prices for consumers (Bishop & Dodge, 2019). Due to their large influence within the prescription drug market, they constantly face scrutiny as they can “drive up the costs of prescriptions without consumer awareness.” (Beyond Type 1, 2019)

These concerns are addressed on the federal level by the Congressional Diabetes Caucus (CDC), led by Diana DeGette, Democrat from Colorado, and Tom Reed, Republican from New York. The bipartisan effort aims to reduce the cost of diabetes management by reducing the cost of insulin. The CDC proposes to increase price transparency, promote competition between insulin makers, develop patent reforms, and streamline the process of FDA approval for biosimilar insulins (*Congressional Diabetes Caucus*, n.d.). The CDC works closely with the Diabetes Patient Advocacy Coalition (DPAC) is an advocacy striving to increase “affordable access to all medications, devices, and services to ensure healthy daily diabetes management.” DPAC calls for lower insurance and out-of-pocket expenses for patients with T1D. It also funds a variety of programs to alleviate the financial burden of diabetes on families, such as the

Affordable Insulin Project, which provides a plethora of resources for T1D families can use to access insurance coverage for insulin (DPAC, n.d.).

How do diabetics in low-income communities manage despite rising treatment costs? Diabetics utilize short-term measures to maintain their well-being despite insufficient access to affordable insulin and await long-term change to the drug pricing, purchase, and payment system in the U.S.

Review of Research

Social differences and income disparities are large factors in healthcare, adjusting life expectancy and specialty care for individuals in low-income communities. The U.S. has the largest income disparities in the world, with poor individuals being “five times as likely as those with incomes above 400 percent of the federal poverty level to report being in poor or fair health.” (Khullar & Chokshi, 2018, citing Braveman & Egerter, 2008) Rabi et al. (2006) conducted a study that demonstrated the “socio-economic gradient in diabetes prevalence,” which is heightened by rising insulin and other treatment costs today. Vest et al. (2013) investigated diabetes management in high-poverty settings, finding inadequate insurance and mistrust of the medical system impedes self-management of diabetes.

In 2012, half of all U.S. adults reported to have at least one chronic condition, with 7.5%-12.7% of diabetes-afflicted individuals (Chapel et al., 2017) Methods to lower the cost endured by these patients for chronic illnesses are widely investigated. From 2002 to 2013, the mean price of insulin tripled from \$4.34 per milliliter to \$12.92 per milliliter (Hua et al., 2016). A congressional study was led by CDC Leader Representative Diane Degette to investigate what Congress could do to lower the cost of insulin. This study revealed Congress should focus on

increasing competition within the marketplace, transparency of prices, and drug price fairness for consumers (Degette and Reed, 2018). Similarly, Vox conducted a study on the insulin-cost crisis, finding that though the U.S. only represents 15% of the global insulin market, it generates almost 50% of the global pharmaceutical industry's insulin revenue (Belluz, 2019).

Current Insulin Costs in the U.S.

Insulin goes through a lengthy and complex delivery system to reach patients from manufacturers. As investigated by the CDC, insulin is sold from manufacturers to wholesalers, which is then sold to pharmacies who dispense insulin to patients. Wholesalers benefit by selling insulin to pharmacies at a higher cost than the acquisition cost. The system of payment is also complex, involving many parties: patients, pharmacies, pharmacy benefit managers, and health insurers (fig. 1).

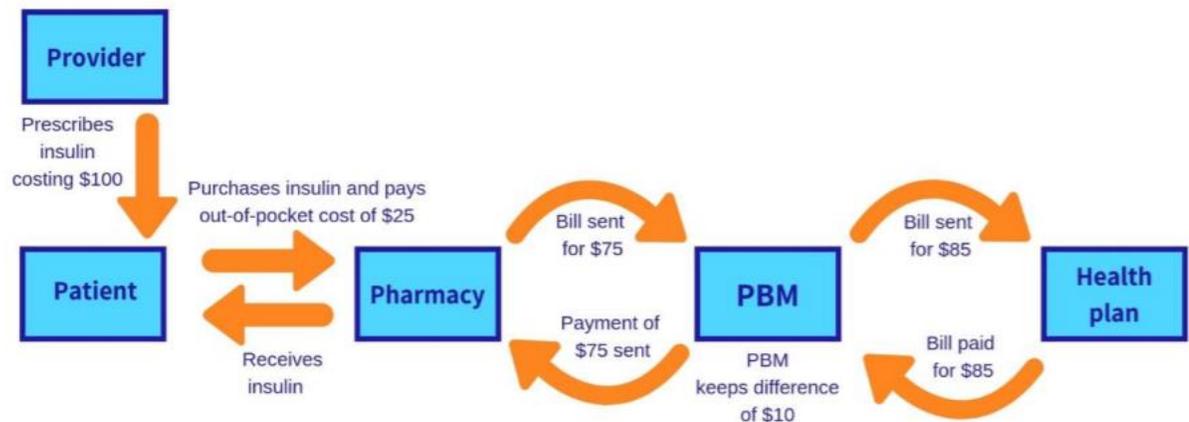


Figure 1. Example flow of payments for an insulin prescription costing \$100 (Degette and Reed, 2018).

During an investigation led by the Senate Finance Committee in February 2020, eight pharmaceutical companies in the US participated in a hearing to why prescription medication

costs were rising. The investigation focused on the effects that lower list prices would have on the drug pricing and delivery system. Many members of the Senate advocate that a reduction in list prices of insulin would lead to lower patient costs at pharmacies. However, drug manufacturers argued that list prices are rarely paid in full due to negotiations and rebates from PBMs. They believe that “lowering list prices alone will not necessarily result in lower out-of-pocket costs for most patients” due to adjustable insurance plans. Richard Gonzalez, CEO of AbbVie, defends higher prices in the U.S., claiming research and development opportunities would receive less financial support if “a market the size of the U.S. were to collapse to the lower end of [the] pricing model” (*Drug Pricing in America*, 2019).

During a hearing led by Representative Diane Degette, the Big Three insulin manufacturers and the Big Three PBMs participated in a discussion to specifically address the soaring costs of insulin and what each company is doing to alleviate the resulting toll diabetics patients must endure. Eli Lilly identified three classes of insurance coverage gaps: private insurance plans with high deductibles, the “donut hole” phase of Medicare part D, and uninsured patients. High deductibles are prohibitive, “requiring members to pay thousands of dollars before insurance coverage starts.” (Mason, 2019) For those with incomes too high to qualify for Medicaid but who cannot afford private insurance plans, the financial load is heavy. The steep increase in deductibles for private insurance plans “has worsened inequality, fueling anger and resentment” with “insurance premiums [taking] more and more of their paychecks and soaring deductibles [leaving] them with medical bills they can’t afford.” (Levy, 2019) For individuals in the high deductible phase of their insurance plan, Lilly automatically caps the prescription cost to \$95. During the “donut hole” phase of Medicare part D, once a predetermined amount has been spent on covered drugs, individuals are thereafter required to pay 25% of each prescription’s

cost. “90% of the people exposed to a prescription cost above \$100 for Humalog at a retail pharmacy were enrolled in Medicare Part D.” (Mason, 2019)

Lilly participates in several discount programs, such as Blink Health and Inside RX, and has even developed its own program Lilly Cares, when individuals without insurance or with Medicare part D are eligible to obtain free insulin (Mason, 2019). Novo Nordisk and Sanofi have also set up similar programs, such as Nordisk’s Patient Assistance Program, and Sanofi’s Insulin ValYou Savings Program (Tregoning, 2019; Langa, 2019). Though charitable, these temporary solutions do not address the flaws within the drug pricing system that drives up both the list price and consumer cost of insulin. Patients needing financial assistance for insulin costs also have difficulty qualifying for these programs (Varney, 2019). Lilly developed lower-priced versions of their insulin product, Humalog, to increase long-term insulin affordability. Lilly’s president, Mike Mason, advocates for change to the drug reimbursement system to reduce the number of individuals “forced to ration or skip doses for financial reasons” (Kueterman et al., 2020).

How are diabetics coping?

The hashtag #insulin4all is a campaign led by T1International, a global nonprofit that aims to improve access to proper healthcare for Type 1 diabetics around the world. This campaign publicizes the burden of the rising costs of diabetes healthcare (Farley, 2018).

Beginning as an awareness campaign, #insulin4all has transformed into a social movement.

Diabetics across the country share stories about the toll of inadequate access to insulin. Activists in this community blame “PharmaLogic” in the insulin price increase, claiming that regardless of supply and demand, pharmaceutical companies find reason to increase the price of the lifesaving drug (Elliott, n.d.). Activists also compare access to good quality insulin for diabetics with access

to good quality air for all humans. Cheaper insulins are typically not developed and processed as well as more expensive insulins, resulting “higher highs and lower lows of the blood sugar levels.” (Johnson, 2019)

When access to insulin is limited due to high cost, diabetics and their families take many routes to care for themselves despite little federal or state support. Some individuals turn to black market insulin, which can be off brand, second-hand, or even expired. Diabetics can also choose to purchase insulin internationally. Quinn Nystrom, a type 1 diabetic from Baxter, Minnesota, regularly leads a group to Canada to buy insulin at 90% less cost than in the US. All participants of the caravan spent a total of \$2,000 on insulin products, all of which would cost approximately \$24,000 in the U.S. (Varney, 2019). Companies such as CanadianInsulin.com also ship low-cost insulin to customers in the US. Though these methods cost less, the U.S. Food and Drug Administration (FDA) prohibits individuals from importing drugs into the US for personal use, as the drugs may not have been approved in the US (FDA, 2018).

Patients with diabetes without steady access to insulin sometimes choose to ration their insulin, taking smaller doses than needed or skipping doses altogether. Rationing insulin is dangerous, risking diabetic ketoacidosis (DKA). In DKA, ketone production by the liver rises, causing blood and urine toxicity that can be deadly (Gosmanov et al., 2000). Other physical outcomes of rationing insulin include “more severe hyperglycemia emergencies, more heart disease, more blindness, and more disability” (Mary Caffrey, 2019) In an international survey conducted by T1International in 2016, out of 1,478 type 1 diabetics, 18 percent of all respondents “reported having rationed insulin at least once in the previous year.” While many countries still lack financial support for diabetics, the U.S. “reported the highest percentage of insulin rationing of any high-income country surveyed.” The U.S. also contained the highest

percentage of individuals reporting blood glucose test rationing, lack of government assistance, and unaffordable costs. This study demonstrated the need for concrete measures to help diabetics on a national scale (T1International, 2019).

Rationing insulin has cost many lives, such as Alec Smith, a 26-year-old diabetic from Minnesota. Due to a high-cost insurance plan with a \$7,600 deductible and a \$450 monthly premium, Smith chose to remain uninsured and pay for his insulin as needed. He was quoted \$1,300 for a monthly supply of insulin, and chose to ration the rest of his supply, which led to his untimely death from DKA (Varney, 2019). Smith's parents, James Holt and Melissa Smith-Holt, publicized their son's story to ignite a national conversation on the high cost of insulin. Minnesota's legislature responded with the Alec Smith Emergency Insulin Act, which introduced an "insulin assistance account in the special revenue fund, requiring drug manufacturers to pay an insulin product fee... for emergency refills" for patients in need. Uninsured diabetics in Minnesota can acquire "insulin products and related supplies to avoid serious health complications." (Howard, 2019) The act compels pharmaceutical companies to help low-income diabetics get insulin. Emergency prescription refill laws in most states permit pharmacies to issue a maximum 72-hour supply of a drug to a patient in need without a doctor's prescription. Pharmacies cannot invoke the exemption to distribute drugs such as insulin that are unavailable in 72-hour supplies.

State-wide Congressional Efforts

Other state legislatures have made several attempts to alleviate the burden that high-cost healthcare has on diabetics. Colorado, Illinois, New Mexico, and Virginia were the first four states to introduce insulin price caps for individuals with health insurance, encouraging other

states to introduce similar legislation. However, each act has similar loopholes that minimize the impact of an insulin price cap. The act introduced in Colorado mandated that the out-of-pocket expenses that covered individuals must pay for insulin not “exceed one hundred dollars per thirty-day supply of insulin regardless of the amount or type of insulin needed to fill the covered person's prescription.” (Roberts et al., 2019) This act only addresses personal costs incurred by patients with health insurance coverage, neglecting uninsured individuals. The act also contains several loopholes that insurance companies and pharmacies exploit. This act only limits insulin expenses to \$100 per prescription, which leads to diabetics that have multiple monthly prescriptions being overcharged as they require more than one type of insulin to survive (Smith, 2020). Additionally, not all insured individuals benefit from this act, as many people utilize employee benefits to obtain health insurance. Melissa Knott, a mother of two diabetics, hoped to obtain a three-month supply of insulin for \$900 after passage of this act. However, her insurance company required her to pay \$5,600 as her “insurance plan fell into an exemption” because her employer partially funds her insurance coverage (Wingerter, 2020).

In Illinois, a similar bill was signed into law on January 24, 2020, capping insulin prices for insured individuals to \$100 per prescription (Office of JB Pritzker, 2020). This act will not come into effect until 2021, and only “20 percent of diabetics in Illinois will be affected by the bill.” Bill sponsors as well as Illinois Governor Pritzker recognize that the bill does not encompass the inherent problem of the high cost of insulin and is only a start to alleviating medical costs for all diabetics (Finke, 2019). This bill also faced scrutiny within the Illinois House Representatives, as patients may end paying the same amount annually due to subsequent adjustment of premiums and deductibles within insurance plans. Illinois State Representative Deanne Mazzochi believes that “getting generics on the market is the only way [to] make drug

products more affordable.” (Mazzochi, 2019) New Mexico introduced the lowest price cap at \$25, followed by Virginia with a price cap at \$50, making insulin semi-affordable for diabetics with health insurance. However, both of these bills face scrutiny similar to the Colorado and Insulin Bills, given that lowering cost-sharing payments will likely result in a rise in premium payments (Bunis, 2020; Masters, 2020).

National Efforts

Both the executive and legislative branches of government in the U.S. are actively working on introducing change in order to make insulin and other prescription drugs more affordable. In January 2020, the Trump administration introduced a notice of proposed rulemaking that would allow for the importation of some prescription drugs from Canada. This NPRM also provides guidelines for companies to import FDA-approved drugs that are manufactured and intended for sale abroad as a measure in providing “safe, effective, more affordable drugs to American patients” (HHS Secretary Alex Azar, qtd. in HHS, 2019).

Several bills have been introduced into the U.S. House and Senate to both increase insulin affordability and also decrease the prevalence of income disparities in healthcare. CDC leadership introduced the “Eliminating Disparities in Diabetes Prevention, Access, and Care Act” to increase research on diabetes in minority communities and federal efforts to address racial disparities in response to the disease (H.R.2651 - 114th Congress, 2015). Caucus leadership also worked towards improving Medicare benefits for diabetics, through both the Protecting Access to Diabetes Supplies Act and the Medicare CGM Access Act, which both aim to increase coverage to include continuous glucose monitoring (CGM) devices, insulin infusion pumps, and blood testing strips, all of which are covered by most private insurance companies

(Congressional Diabetes Caucus, n.d.; H.R.771 - 114th Congress, 2015; H.R.1427 - 114th Congress, 2015).

The Affordable Drug Manufacturing Act, sponsored by Senator Elizabeth Warren, Democrat from Massachusetts, and Representative Jan Schakowsky, Democrat from Illinois, addressed the lack of generic drugs available on the market. This bill would create the Office of Drug Manufacturing that can produce drugs that have met any of the following conditions: “there is already a patent for the medicine, no company is currently producing the drug; or only one or two companies produce the drug but the price is deemed a barrier to patient access.” (Jesse Rifkin, 2018) This bill was scrutinized as it didn’t address the causes behind escalating medical prices and imposed additional federal control over drug development, manufacturing, and distribution. Insulin Access for All Act of 2019 was introduced to eliminate cost-sharing payments in full for insulin as a covered prescription drug under both Medicare Part D and Medicaid (H.R.366 - 116th Congress, 2019). While many bills have been introduced in both the House and the Senate, these bills have not gained traction to enact change that can benefit the national diabetic population.

Conclusion

Chronic illnesses that require prescription medications include heart disease, stroke, cancer, diabetes, and chronic respiratory diseases (Beaglehole et al., 2011). Medically-necessary drugs that treat these chronic diseases are marketed as a luxury in the U.S., with constantly increasing prices with little justification. Drug manufacturers blame “high-deductible plans [that] should...exempt from their deductibles preventive medicines needed for chronic diseases.” (Ricks, 2019) Meanwhile, PBM’s argue that increases in list prices are the real drivers behind

rising drug costs (CVS Health, n.d.). As drug manufacturers, PBMs, and insurance companies continue to negotiate prices for life-saving drugs such as insulin, these companies ultimately profit from an increase in consumer costs which harms the well-being of patients in need.

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