



Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic



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Executive Summary

Pharmaceutical companies have relentlessly raised drug prices, and prices for insulin are no exception. For many of the more than 30 million Americans living with diabetes, insulin is an essential medicine that helps the body process glucose derived from food.¹ Without glucose (and the insulin necessary to process it), the human body cannot function properly. In the words of one diabetes patient, “We either buy insulin or we die.”²

Three pharmaceutical companies—Sanofi, Novo Nordisk, and Eli Lilly—dominate the insulin market, producing over 80% of the global insulin supply.³ These companies have taken advantage of limited market competition by steadily increasing insulin prices, even though experts estimate insulin could be profitably produced for \$7 to \$11 per patient per month.⁴ Little generic competition exists in the insulin market—further contributing to increased prices. While insulin manufacturers have raked in millions in profits, insulin patients have suffered. At least twelve Americans have died as a result of rationing insulin in the past three years, and roughly one in four patients with diabetes have reported skipping doses or rationing their intake due to the high price of the drug.⁵ Taxpayers, too, bear the burden of high prices.

Patients, caregivers, and advocates have raised alarms about the life-threatening insulin drug price increases. In response to this public pressure, manufacturers have announced measures that they claim will help reduce patients’ out of pocket drug costs—including the introduction of so-called “authorized generics.” Unlike true generics, which are produced by competing companies, authorized generics are the same drug sold by the original manufacturer at a slightly discounted price.⁶ In March 2019, for example, Eli Lilly—the manufacturer of the rapid-acting insulin Humalog—announced that it would produce an authorized generic version of Humalog, “Insulin Lispro.” In the announcement, Eli Lilly claimed that:

Reinforcing our commitment to lower out-of-pocket costs for people who need insulin, Eli Lilly and Company...[will be] providing people with diabetes an insulin option that will have a list price 50 percent lower than the current Humalog list price... [W]e’re eager to bring forward a low-priced rapid-acting insulin... Vials and pens of the lower-priced insulin have been manufactured, and Lilly will now work with supply chain partners to make them available in pharmacies as quickly as possible.⁷

Eli Lilly also indicated that “pharmacists will be able to substitute Insulin Lispro Injection for Humalog” because they are “the same insulin.”⁸

In the months after Eli Lilly’s announcement, however, anecdotal reports raised questions about the availability of the authorized generic “Insulin Lispro” in local pharmacies.⁹ To assess the impact of authorized generics, like “Insulin Lispro,” on patients’ access to insulin, the Offices of U.S. Senator Elizabeth Warren and U.S. Senator Richard Blumenthal conducted a national telephone survey of pharmacies to determine if they had access to and were providing patients with the lower-cost authorized generic version of Humalog insulin. The investigation found that, contrary to the promises made by Eli Lilly, the vast majority of patients who seek to use this less expensive drug are not able to obtain it at their local pharmacy. Specifically, a 50-state survey of 190 chain and 196 independent pharmacies reveals that:

- **Eli Lilly’s authorized generic insulin, “Insulin Lispro,” is not widely available in pharmacies across the country.** In 83% of pharmacies surveyed, the less expensive, authorized generic promised by Eli Lilly was not in stock and available for consumers. In 14 states, not one of the up to eight surveyed pharmacies had the generic version of the drug in stock; in 17 states, the drug was only available in one surveyed pharmacy. And in most cases (69%), pharmacies that did not have the generic drug in stock indicated that they

could not order the drug, even if the consumer did not need it immediately.

- **Pharmacies are unaware of and not adequately informing consumers about the availability of Eli Lilly’s authorized generic insulin.** In many cases, consumers cannot get the generic version of a drug if they do not know to ask for it – and they rely on pharmacies to inform them when generics are available. But this survey revealed that, even when pharmacies have the authorized generic version of Humalog, they do not proactively offer it to consumers. Only half of the limited number of pharmacies that had the authorized generic in stock offered it as a first option for consumers. In total, only 15% of pharmacies offered the authorized generic without prompting.
- **Eli Lilly has not taken meaningful steps to increase patient access to insulin.** The results of the survey suggest that Eli Lilly’s introduction of a lower-cost alternative has not translated to lower-costs for patients, who are not able to access the authorized generic. Eli Lilly has failed to take consequential steps—such as simply lowering the list price of Humalog, as it has in foreign markets¹⁰—to provide lower-cost access to this important diabetes drug.

Introduction

Pharmaceutical companies have relentlessly raised prices on critical lifesaving drugs for years, charging consumers thousands of dollars for drugs they cannot live without. Nearly one in four Americans taking prescription drugs “report difficulties affording their medications,”¹¹ and according to a recent poll conducted by the Kaiser Family Foundation, at least three in ten adults reported skipping drug doses, delaying filling prescriptions, or taking less of a drug than prescribed to save money.¹²

Drug prices for insulin are no exception. Insulin, a hormone produced in the pancreas, helps the body

process glucose derived from food. Glucose is the body’s “main source of energy”; without glucose (and the insulin necessary to process it), the human body cannot function properly.¹³ Diabetes is a disease that prevents the body from producing or adequately processing insulin—resulting in high blood-glucose levels and associated health problems. For many of the more than 30 million Americans living with diabetes, insulin is an essential medicine.¹⁴ In the words of one diabetes patient, “We either buy insulin or we die.”¹⁵

Insulin was first discovered almost 100 years ago when the drug’s inventors famously sold the patent for \$1 because they felt it was unethical for a person to profit from a life-saving discovery.¹⁶ Today, diabetes patients can rely on multiple different types of insulin—from rapid-acting insulin that “begins to work about 15 minutes after injection” to ultra-long-acting insulin that “reaches the blood stream in 6 hours”¹⁷—to manage their disease. This variety, however, has not translated into lower costs. Three pharmaceutical companies—Sanofi, Novo Nordisk, and Eli Lilly—dominate the insulin market, producing over 80% of the global insulin supply.¹⁸ These companies have taken advantage of limited market competition by steadily hiking insulin prices, even though experts estimate insulin could be profitably produced for \$7 to \$11 per patient per month.¹⁹ The cost of insulin has increased by over 1,200% since the 1990s,²⁰ and patient spending on insulin nearly tripled from 2002 to 2013²¹—then nearly doubled again between 2012 and 2016.²² Little generic competition exists in the insulin market, further contributing to increased prices.

While insulin manufacturers have raked in millions in profits, diabetes patients have suffered. At least twelve Americans have died as a result of rationing insulin in the past three years, and roughly one in four patients with diabetes have reported skipping doses or rationing their intake due to the high price of the drug.²³ Taxpayers, too, bear the burden of high prices. In 2017, before rebates, Medicare Part D spending on

Humalog—a rapid-acting insulin lispro injection manufactured by Eli Lilly—amounted to \$595 million, while Medicaid spending was \$499 million—a total of over \$1 billion.²⁴

Patients, caregivers, and advocates have raised alarms about the life-threatening rise of insulin drug prices. In September 2018, protestors gathered in Indianapolis to demonstrate at the offices of Eli Lilly. In November 2018, demonstrators similarly protested outside of the Sanofi offices in Cambridge, Massachusetts.²⁵ State governments are also taking notice of high insulin prices. In 2018, Minnesota’s Attorney General sued insulin manufacturers for alleged price gouging.²⁶ In May 2019, Colorado passed a law capping monthly insulin co-pays at \$100.²⁷ Meanwhile, the U.S. Congressional Diabetes Caucus issued a report on the financial burdens faced by diabetes patients,²⁸ and federal lawmakers continue to consider legislative fixes to the high cost of prescription drugs, including insulin.

In response to public pressure, manufacturers have announced measures that they claim will help reduce patients’ out of pocket drug costs—including the introduction of so-called “authorized generics.” Unlike real generic drugs—which are developed and produced by a competing company and sold at significantly lower prices—authorized generics are “the exact same drug product as the branded product,” just “marketed without the brand name on its label.”²⁹ Authorized generics are typically marketed by the manufacturer of a brand-name drug, or by another company with the brand company’s explicit permission.³⁰ Brand-name companies can use authorized generics to extend their effective monopoly.³¹ A 2011 Federal Trade Commission report concluded that, while authorized generics can “modestly reduce drug prices,” they can also “affect decisions by generic competitors to challenge patents on drugs with low revenues”—and have been used by brand-name companies as a tool to delay generic market entry.³² Recently, analysts have suggested that a surge in authorized generic development (there are

now roughly 1,200 approved authorized generics in the U.S.) “may help explain why relatively few true generics are reaching the market.”³³

In March 2019, Eli Lilly announced that it would produce an authorized generic version of Humalog after the company had raised the list price of a 10-ml vial of Humalog by 685% from \$35 in 2001 to \$275 today.³⁴ On average, patients use two to four vials per month, meaning that patients without insurance face costs of over \$1,000 per month without rebates, discounts, or insurance.³⁵ Eli Lilly promised to sell its authorized generic at “a list price 50 percent lower than the current Humalog list price.”³⁶ The company also promised that it would “work with supply chain partners to make them available in pharmacies as quickly as possible”³⁷ and indicated that “pharmacists will be able to substitute Insulin Lispro Injection for Humalog” because they are “the same insulin.”³⁸ The product went live in May 2019.³⁹ In September 2019, Novo Nordisk announced plans to market authorized generics of its products—starting in January 2020—at 50% of the list price.⁴⁰ Sanofi, meanwhile, announced a fixed-price, \$99-per-month “Insulin Valyou Savings Program” for customers, who can now receive up to 10 boxes of certain Sanofi products each month.⁴¹ It then lowered prices for Ademlog, its follow-on insulin lispro product similar to Humalog.⁴²

Investigation Overview and Methodology

Manufacturers, particularly Eli Lilly, have made bold claims about the extent to which their drug savings programs will benefit patients. When the company announced that its authorized generic was “available for order in pharmacies” in May 2019, for example, Eli Lilly heralded “[t]he availability of Lilly’s Insulin Lispro Injection” as “important progress that helps more people afford their insulin.”⁴³

In the months after Eli Lilly’s announcement, however, anecdotal reports raised questions about the availability of the authorized generic “Insulin

Lispro” in local pharmacies.⁴⁴ Then, in August 2019, an independent analysis of a sample of U.S. prescription drug claims found that the “majority of fills” for insulin lispro products were “still for Humalog,” not the authorized generic—raising further questions about whether patients actually have access to this lower-priced product.⁴⁵

The Offices of U.S. Senator Elizabeth Warren and U.S. Senator Richard Blumenthal conducted a national telephone survey of pharmacies between July and September 2019 to determine if they had access to and were providing patients with the lower-cost authorized generic version of Humalog insulin. The purpose of the survey was to shed light on whether the use of authorized generics in the insulin marketplace could bring real relief for patients—or, whether additional steps were necessary to reduce patient costs.

Staff contacted pharmacies from 204 counties across the country and asked about the availability of insulin lispro injections. Staff chose counties using data from the CDC’s Diabetes Interactive Atlas, which provides county-by-county estimates of the prevalence of adults diagnosed with diabetes for 2009. Out of 3,220 counties with CDC data on diabetes, staff chose four counties from each state (counties in the 25th, 50th, 75th, and 100th percentile of in-state population with diabetes). Staff also included pharmacies in Puerto Rico and in the District of Columbia. For each of the 204 counties in total, staff selected two pharmacies for participation at random—one chain pharmacy and one independent pharmacy. For counties without either a chain or independent pharmacy, staff substituted pharmacies within reasonable proximities of the county. Twenty pharmacies were not contacted either because there was no pharmacy within close proximity of the chosen county, the chosen pharmacy refused to participate in the survey, or staff were otherwise unable to contact the chosen pharmacy. In total, staff contacted 386 pharmacies for the survey.

Staff contacted the chosen pharmacies by phone to inquire about the availability of Humalog insulin. The objectives of the calls were to determine the answers to the following questions:

- When asked about the pharmacy’s availability and uninsured price of insulin lispro, did the pharmacy pro-actively indicate the availability of the lower-cost authorized generic Humalog alternative, “Insulin Lispro”? Or was the authorized generic only offered after being specifically requested?
- Did the pharmacy have Eli Lilly’s authorized generic, “Insulin Lispro,” in stock and available for patients at the pharmacy location?
- What was the price of the authorized generic, “Insulin Lispro,” and the price of the Humalog sold at the pharmacy?

Findings

An analysis of the call results suggests that, despite Eli Lilly’s promise to “work with supply chain partners to make lower priced insulin available in pharmacies as quickly as possible,” “Insulin Lispro” is not widely available to patients. Instead, significant barriers exist for patients seeking a lower-cost alternative to brand-name insulin.

- **Eli Lilly’s authorized generic, “Insulin Lispro,” is not widely available in pharmacies across the country.**

Staff calls confirmed that the authorized generic version of the drug was significantly less expensive than the brand-name drug. On average, a box of five “Insulin Lispro” pens cost \$316.31, and a 10ml vial of “Insulin Lispro” cost \$175.62, compared to \$618.69 for five Humalog pens and \$321.86 for a 10ml vial of Humalog. However, the survey also revealed that this less expensive product—despite Eli Lilly’s promises—was not widely available to patients.

When asked about the availability of Eli Lilly’s authorized generic, “Insulin Lispro,” specifically, many pharmacists or pharmacy staff expressed confusion regarding the request, and admitted to being unaware that an authorized generic version was available. Furthermore, when they were told about and asked specifically about the availability of the generic, only 17% of pharmacies contacted (66 of 386 total) said that the authorized generic was available in stock and ready for pick-up. Twenty percent of independent pharmacies surveyed had the authorized generic available, while only 14% of chain pharmacies surveyed had the authorized generic available.

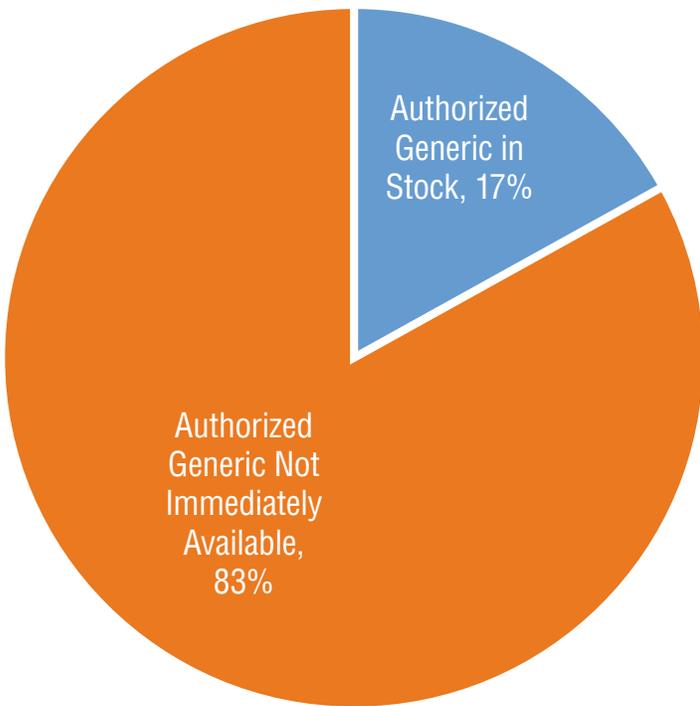


Figure 1: 83% of Pharmacies Did Not Have Eli Lilly’s Authorized Generic in Stock

The drug was often not available even via special order. Only 31% (98 of 320) of pharmacies that did not have the authorized generic drug in stock said that at least one form of the drug was available to order: 60 independent pharmacies and 38 chain pharmacies.

Ultimately, 58% of pharmacies were unable to offer patients access to the authorized generic, either immediately in stock or via special order.

- **Pharmacies are unaware of and not adequately informing consumers about the availability of Eli Lilly’s authorized generic insulin.**

In many cases, consumers cannot obtain a generic version of a drug if they don’t know to ask for it because they rely on pharmacies to inform them when cheaper alternatives are available. But this survey revealed that, even when pharmacies have the authorized generic of Humalog, they do not necessarily offer it to consumers. Only half of the limited number of pharmacies that had the generic in stock offered it as a first option for consumers.

Out of 386 pharmacies contacted, only 15% proactively offered the generic version as a cheaper alternative to the brand-name product, and only 13% had it in stock. Among that subset of 13%, representing 66 pharmacies that did have the generic drug available in stock at the pharmacy, 34 (or more than one half) failed to offer the cheaper generic alternative when questioned about the price and availability of Eli Lilly’s Humalog. Six in ten independent pharmacies with the generic in stock offered the drug without prompting, and four in ten chain pharmacies with the generic in stock offered the drug without prompting.

When asked specifically about the authorized generic drug, some pharmacists or pharmacy staff indicated that they were unaware of the availability of a generic at all; others offered brand-name versions of different diabetes drugs, suggested that callers try a different store, or stated that the drug was not listed by their vendor. These responses suggest that a large proportion of pharmacists and pharmacy staff are unaware that a lower-priced authorized generic alternatives exist, or that, if they were aware, did not offer it to customers.

• **Eli Lilly has not taken meaningful steps to increase patient access to insulin.**

When Eli Lilly announced the launch of “Insulin Lispro,” the manufacturer claimed, “Lilly will continue to work with health plans, wholesalers, employers and the government to work toward permanent solutions that will help every person with diabetes afford their medicines.”⁴⁶ And according to an Eli Lilly spokesperson, the company recognizes that its lower cost alternative is “not a panacea.”⁴⁷ In fact, the results of the phone survey suggest that Eli Lilly has avoided the one, true “permanent solution” it has the ability to offer: simply lowering list prices for Humalog.

Though drug manufacturers like Eli Lilly often justify high drug prices by the need to fund research and development, some experts believe that research and development is usually “paid for in the first years of life of a drug.”⁴⁸ In the case of Humalog, it has been 20 years since Eli Lilly first began marketing the drug and the price has risen from \$21 per vial in 1996 to approximately \$300 per vial today.⁴⁹ The lower-cost authorized generic is simply the same Humalog drug priced as it was in 2012.⁵⁰ These high prices have allowed Eli Lilly to boast consistently high earnings, including its latest reports of \$5.48 billion in Q3 of 2019—beating expectations by 3.5%.⁵¹ Meanwhile, Eli Lilly sells Humalog at a steep discount in foreign markets, including a mere \$32 per vial in Canada.⁵²

Ultimately, Eli Lilly has failed to take consequential steps—such as simply lowering the list price of Humalog—to provide lower-cost access to this important diabetes drug. Eli Lilly appears to have also failed to take basic steps, such as educating patients and pharmacists about the authorized generic or working with supply chain partners to properly stock pharmacies, in order to make the lower cost version more accessible. Its authorized generic, rather than expanding access to low-cost insulin, appears instead to be a public relations move intended to ease scrutiny on the rising price of insulin.

Conclusion

The findings of this report reveal that, despite Eli Lilly’s public promise about the availability of a less expensive, authorized generic version of its brand-name insulin drug, the vast majority of pharmacies do not offer access to this drug. So far, the company has failed to address the legitimate health and budget problems faced by patients who are unable to afford their brand-name products.

The findings also raise questions about the ability of authorized generics to deliver real savings to consumers. Ultimately, Congress must take steps to enact systemic change to reduce costs of drugs nationwide. Among other steps, Congress should pass legislation allowing the government to negotiate fair prices for prescription drugs offered through the Medicare program. It should permit wholesalers, pharmacies, and patients to safely import affordable drugs from countries like Canada. It should take steps to promote the development of generic drugs and should implement the Affordable Drug Manufacturing Act, a bill introduced by Senator Warren that would allow the federal government to develop generic drugs—including insulin—in cases where the market has failed. Finally, it must address the high costs that patients face when purchasing prescription drugs and pass legislation to reduce or eliminate patients’ out of pocket expenses.

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