



Leading Manufacturers Cut Insulin Product Prices in the U.S.

(Sources: Staff Articles for CNN Health, NPR, Scrip Intelligence, and Wall Street Journal)

All three of the largest insulin product manufacturers have announced price caps on their top-selling drugs for all U.S. patients with commercial insurance. Sanofi was the last to make the announcement, joining Eli Lilly and Novo Nordisk, bringing costs more in line with a US\$35 cap on copays under the Medicare Part D, a requirement of the U.S. Inflation Reduction Act, passed by the U.S. Congress in 2022.

Sanofi said in its statement about the pricing change of *Lantus* (insulin glargine) and copay cost cap that the company believes “no one should struggle to pay for their insulin.” These changes are on top of Sanofi’s June 2022 launch of an unbranded *Lantus* biologic at 60% below the list of the branded product. Additional measures are needed because the company said, “the health system was unable to take advantage of it due to its structural challenges.” Sanofi also noted the *Lantus* price cutting and copay cost-lowering actions need to be “coupled with broader change to the overall system to actually drive savings for patients at the pharmacy counter.” The company’s out-of-pocket cost cap for insured patients is in addition to a US\$35 cap on copays for Sanofi insulins that it implemented for uninsured US patients last year. The prices changes will take effect in January of 2024.

Eli Lilly CEO David Ricks made similar pleas in a media briefing when the company announced plans to cut the cost of its *Humalog* (insulin lispro) and *Humulin* insulins in the fourth quarter of 2023 and for an authorized generic version of the drug by 1 May 2024. It will also reduce the cost of *Rezvoglar*, its interchangeable biosimilar for *Lantus*. In addition, effective immediately, Lilly will cover the difference between patient copays and a US\$35 cap on out-of-pocket costs for its insulins.

Novo Nordisk announced that it will implement a 65%-75% list price cut on *Levemir* (insulin detemir) *Novolin*, *Novolog*, and *Novolog Mix* effective 1 January 2024. The company already has an unbranded version of its long-acting insulin *Tresiba* (insulin degludec) on the market at a 65% discount to the brand, so it will not cut the list price for *Tresiba*. It also already offers copay programs through various retail pharmacies to keep out-of-pocket costs for its insulins at US\$25-US\$35 per vial for commercially insured patients.

Insulin is a declining business for drugmakers. However, as novel diabetes medicines have become a more common means for controlling the disease. *Lantus* (insulin glargine 100 units/mL) is Sanofi’s most prescribed insulin product and generated €2.26 billion in 2022 net sales, while *Toujeo* (insuline glargine 300 units/mL) net sales totaled €1.11 billion last year. Even so, *Lantus* sales fell 27.6% in the fourth quarter, dragged down by a 56.7% decline in the U.S. where both the eroding basal insulin market

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In Brief...

◆ Pharmaceutical giant **Pfizer** has agreed to buy **Seagen**, a biotech company, for US\$43 billion in cash (US\$229 per share) making it one of largest pharma deals in history. The price includes debt, as the biotech company was not turning a profit. In 2022, the total losses for Seagen were US\$610 million, despite revenues of US\$2billion. Seagen makes an antibody drug conjugate (ADC), a targeted cancer treatment that attacks cancer cells with toxins. Separately, Pfizer announced that the **U.S. Food and Drug Administration’s (FDA) Vaccines and Related Biological Products Advisory Committee** voted that available data is adequate to support the safety and effectiveness of its respiratory syncytial virus (RSV) bivalent vaccine candidate *PF-06928316* or *RSVpreF*. The vaccine candidate is under review for the prevention of acute respiratory disease and lower respiratory tract disease caused by RSV in patients ages 60 and older.

◆ Five months after claiming U.S. rights to **Provention Bio, Inc.’s** type 1 diabetes therapy *Tzield* (*teplizumab*), as well as an exclusive right of first negotiation to commercialize the drug in international markets, **Sanofi** has agreed to acquire the company for US\$2.9 billion. In November, the **U.S. Food and Drug Administration (FDA)** gave approval for *Tzield*, a CD3-directed antibody, for use in patients aged eight and over who currently have stage 2 type 1 diabetes in order to delay the onset of stage 3 of the disease. Stage 2 of the disease indicates glucose intolerance but are still presymptomatic, whereas stage 3 has manifested in typical clinical symptoms and patients eventually require insulin injections for life.

◆ After the exit of **AbbVie** and **Eli Lilly** from the U.K.’s *Voluntary Scheme for Branded Medicines Pricing and Access*, **Viatrix** may be the next to step out, warning that it will stop selling some of its essential medicines in the U.K. unless the British government makes changes to the program. The 2019 agreement sets a limit on the

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Insulin Products (cont.)

and removal from payer formularies pushed sales volumes lower, according to the company. *Toujeo* sales increased 13.9% in Q4, driven by ex-U.S. sales volume.

These price changes come amid another challenge facing the diabetes drug market that has become an issue. There is a significant increased demand for other diabetes treatment drugs including *Ozempic (semaglutide)*, and Lilly's *Mounjaro* and *Trulicity* since both have emerged as popular weight-loss aids, though drug regulators haven't approved them for such use. This has resulted in drug shortages for those who require these necessary medications for their originally intended treatment of type 2 diabetes. It is also causing a significant increase in the pricing, making them unaffordable as well.

Telehealth and social media are playing a significant role in driving demand for these medications. Digital health companies make medications like *Ozempic* easier to get by providing prescriptions online. Many advertise quick and easy — sometimes same-day — access.

"Anecdotally, it's almost easier to get medication [via digital health companies]," said Dr. Disha Narang, endocrinologist and director of obesity medicine at Northwestern Medicine, Lake Forest Hospital. "But not always the safest." People who put in average weights on the online intake forms were still offered the antidiabetic drug, Narang told CNN.

In part because of *Ozempic's* popularity, the prescription weight loss drug market has grown significantly, according to MarketData Enterprises, an independent market research and consulting firm. The market surpassed forecasters' expectations for 2022 and is expected to become a nearly US\$2 billion industry in 2023.

Philanthropist Bill Gates Thinks AI Will Revolutionize Healthcare For World's Poorest

(An article by Ana Faguy for Forbes Magazine)

Former Microsoft CEO and philanthropist Bill Gates called artificial intelligence the "most important advance" in technology since the development of computers and smartphones in a blog post Tuesday, arguing AI bears both opportunities and responsibilities as it can help improve access to healthcare and education globally, but acknowledged developers still need to work out some shortcomings.

"[AI] will change the way people work, learn, travel, get health care, and communicate with each other," Gates said. "Entire industries will reorient around it. Businesses will distinguish themselves by how well they use it."

Gates pitched the advances in AI as a way to improve productivity in the workplace, help reduce global preventable deaths among children and improve inequity in American education by bettering students' math skills.

AI will reduce the workload on healthcare workers, completing tasks for them like filing insurance claims and drafting notes from doctor's visits, Gates predicted.

Gates also sees AI as a way to reduce the death rate for young children—five million children under the age of five die every year—particularly in poor countries, where AI could help

patients determine whether they need to seek treatment and AI-linked devices like ultrasound machines could help healthcare workers be more productive.

One of the Gates Foundation's priorities will be ensuring advancements in AI are used to help the poorest people in the world, including those who struggle with health problems like AIDS, TB and malaria, Gates said.

AI could also revolutionize education in the next five to ten years by creating tools that understand an individual's interests and learning style and tailoring educational content to those needs, but he cautioned that tools need to be equally accessible to all schools.

While the comments are Gates' soundest endorsement of the future of AI, they are not his first comments on the developing technology. In a previous interview last month, Gates described AI advancements as "pretty stunning" and compared them to the developments of the PC and the internet.

At the end of last year, Gates also said his foundation was working to develop an ultrasound tool for the developing world using AI software. The probe, which Gates said could help reduce the number of deaths during the neonatal period, would be plugged into a mobile phone or tablet and can distinguish whether the pregnancy is high risk or whether the mother could need a C-section delivery. If the technology is helpful in places where it's currently being tested—Kenya and South Africa—Gates said it could be widely available in two to three years.

In Brief (cont.)

National Health Service's annual drug spending and requires pharma companies to refund any sales beyond established thresholds. Since healthcare costs have skyrocketed during the pandemic, the clawback rate has jumped from 5% in 2019 to 26.5% in 2023.

- ◆ Scientists at the **National Institutes of Health** and **Massachusetts General Hospital** in Boston have uncovered a potential new approach against liver cancer that could lead to the development of a new class of anticancer drugs. The discovery is of a molecule that kills cells in a rare liver cancer when the molecule is converted by an enzyme in these liver cancer cells, creating a toxic anticancer drug. The study was of cholangiocarcinoma, a type of liver cancer that affects the bile duct.

- ◆ With a number of countries in Europe adopting policies perceived to be harmful to innovation by the pharma industry, Bayer AG may opt to not launch new medicines in some parts of the continent. *Stefan, Oelrich*, Bayer's pharma chief, said during an interview with *Scrip*, "Europe is a topic that is near and dear to our heart [and] we're in constant dialogue with policymakers on how to create a more innovation-friendly environment...sometimes that works better, sometimes it doesn't." He added that the company is concerned that the commercial market conditions and the incentives to invest in Europe do not at this point compare to the U.S. marketplace.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Scrip Intelligence, and World Pharma News)