



It's a Wonder Drug!

How Do We Pay For It?

FROM THE

YARDARM

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On June 7, 2021, the US Food and Drug Administration (FDA) provided accelerated approval to Biogen's Alzheimer's drug Aduhelm. Biotech company Biogen developed Aduhelm to treat the presumed underlying cause of Alzheimer's disease. Although accelerated approvals were designed for drugs still undergoing study if they addressed a critical unmet need, the approval of Aduhelm came as a shock. Seven months earlier, in November 2020, an advisory panel of outside neuroscience experts voted against approving Aduhelm by 10-0 with one abstention. The panelists did not believe there was sufficient proof of the drug's effectiveness in clinical trials.¹ While advisory panel recommendations are non-binding, the lopsided vote seemed to bury Aduhelm's prospects. The FDA's accelerated approval in June 2021 sent Biogen stock soaring, nearly doubling in that first week. The appreciation was spurred by projections of a potential \$10 billion revenue windfall for Biogen if only a small subset of Americans diagnosed with Alzheimer's were prescribed the medication. Part of the reason for the huge sales estimates was Aduhelm's annual price tag of \$56,000.

Euphoria surrounding Biogen abated when the Centers for Medicare and Medicaid Studies (CMS) indicated Aduhelm may not receive reimbursement. By June 2022, the one-year anniversary of Aduhelm's approval, Biogen shares had tumbled even lower than their pre-approval price. CMS was concerned about the same issues that had informed the advisory panel recommendation, but they also surely considered the effect on Medicare and Medicaid budgets. Approximately six million people in the US are living with Alzheimer's, but Aduhelm was only approved for those in the early stages of the disease – roughly 180,000 patients. At \$10 billion a year, Aduhelm would be the second most expensive drug in Medicare/Medicaid spending, after the blood thinner Eliquis.² Eliquis, however, has been proven to work.

While Aduhelm failed, remarkably effective medications for other health conditions with large patient populations have recently succeeded. Eli Lilly and Novo Nordisk both developed their own GLP-1, or semaglutide drugs, to treat type 2 diabetes. Novo markets their diabetes-specific treatment under the name Ozempic, and they branded the weight loss-specific dosage of the same medication, Wegovy. Lilly named their version of the semaglutide drug Mounjaro. Apart from providing more effective and convenient diabetes treatments, the drugs work well for weight reduction. They became so popular that even Elon Musk tweeted about Ozempic.³ Meanwhile, Lilly's Mounjaro has been found to be even more effective for weight loss than Wegovy. The drugs are much cheaper than Aduhelm; Ozempic costs around \$10,800 annually, Wegovy about \$16,000. However, it is important to consider that the potential patient population is enormous. Approximately 36 million Americans suffer from type 2 diabetes, and the National Institutes of Health (NIH) estimated that over 42% of the US adult population is obese.^{4,5} With 259 million Americans aged 18 or older, the NIH figures imply roughly 110 million are obese. How can insurance companies, the US government, or the US taxpayer afford the bill?

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In some cases, they have decided they can't. The University of Texas Health System announced that as of September 1, 2023, it will no longer cover Novo Nordisk's weight loss drugs. The UT System's outlays for the drugs were reaching \$5 million per month, an "unsustainable" amount, "due to the current rate of prescription drug expenditures." Although successfully treating Alzheimer's, diabetes, or obesity should lead to significant healthcare savings down the road, those savings "are not being realized due to the excessive cost the drug manufacturers charge for the weight-loss medication."⁶ While understandable from a financial perspective, the decision was premature from a medical standpoint; Wegovy has only been on the market for two years. Novo Nordisk released the results of a five-year, double-blind study of 17,600 patients in August of 2023, which reported a 20% reduction in major adverse cardiovascular events for people treated with Wegovy compared to a placebo.⁷ Both Eli Lilly and Novo Nordisk stock jumped on the data release, as investors realized it would be a lot harder to deny coverage for a drug that could prevent patients from dying of a heart attack than to deny coverage for "cosmetic" benefits such as weight loss.

Nonetheless, the problem remains – how can we pay for it? The savings will accrue over time, but the costs are upfront. If, for example, 110 million obese Americans were all prescribed Wegovy at \$16,000 a year, the annual tab would be \$176 billion. According to the Centers for Disease Control and Prevention (CDC), heart disease costs the US economy roughly \$219 billion per year.⁸ While Wegovy could ameliorate that expense over time, would it reduce the bill by 80%? Unlikely.

The United States has been described as an insurance company with an army. Reviewing the budget explains why. The US government spent \$6.3 trillion in fiscal year 2022. Mandatory spending accounted for \$4.1 trillion, including Social Security (\$1.2 trillion), Medicare and Medicaid (\$1.3 trillion), and various other guaranteed programs. Discretionary spending came to \$1.7 trillion, but that included \$751 billion for defense spending, which nobody considers discretionary. Another \$475 billion covered interest payments, which are as mandatory as can be unless you're looking to spark a global financial meltdown.⁹ Adding the military and interest expense to mandatory spending takes us to \$5.3 trillion of the \$6.3 trillion budget. Most of these categories are on a rising trajectory.

Adding \$100 billion for weight loss by 2030 certainly won't break the federal budget. But it would increase the Medicare and Medicaid budgets by 19% at the same time more boomers will be retiring, causing a surge in entitlement spending, while military challenges from Russia and China will undoubtedly lead to higher defense spending. At the same, the Congressional Budget Office (CBO) estimates that by 2030, the higher interest rate environment means interest payments will rise roughly 150% to \$1.2 trillion. Their numbers are likely optimistic.¹⁰

But when we consider the voting power of seniors, the generally bipartisan agreement on the importance of defense, and the financial market's insistence on the inviolability of US debt, we aren't left with many options.

Decrying the budget deficit and wailing in despair over how we will afford it are well-established pastimes, but Herb Stein's wisdom expressed in 1986 is worth recalling "If something cannot go on forever, it will stop."¹¹ An ever-increasing budget deficit as a share of gross domestic product (GDP) stands as one of those things. But when we consider the voting power of seniors, the generally bipartisan agreement on the importance of defense, and the financial market's insistence on the inviolability of US debt, we aren't left with many options. One option would be for US citizens to stop subsidizing drug discovery for the entire world. According to the Organisation for Economic Co-operation and Development (OECD), the US spends the most, per capita, on pharmaceuticals at \$1,432 per year, followed by Germany at \$1,042. In Norway, the UK, Portugal, Sweden, and Spain, spending ranges from \$400-600.¹² The Inflation Reduction Act allowed negotiation over the prices paid by the government for various drugs for the first time. We should not expect it to be the last.

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Scott Klimo, Chief Investment Officer, joined Saturna Capital in May 2012. He received his BA in Asian Studies from Hamilton College in Clinton, NY and also attended the Chinese University of Hong Kong and the Mandarin Training Center in Taipei, Taiwan. Mr. Klimo has over 35 years' experience in the financial industry, with the first several years of his career spent living and working in a variety of Asian countries and the past 20 years working as a senior analyst, research director, and portfolio manager covering global equities. Mr. Klimo is a Chartered Financial Analyst (CFA) charterholder and an avid cyclist. He is a supporter of various environmental organizations and served for several years on the Board of Directors of the Marin County Bicycle Coalition.

Footnotes

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⁵ Overweight & Obesity Statistics. National Institute of Diabetes and Digestive and Kidney Diseases. <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity>

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⁸ Health Topics – Heart Disease and Heart Attack. Centers for Disease Control and Prevention. <https://www.cdc.gov/policy/polaris/healthtopics/heartdisease/index.html>.

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¹⁰ Jakab, Spencer. The Scary Math Behind the World's Safest Assets. *The Wall Street Journal*. August 12, 2023. https://www.wsj.com/articles/the-scary-math-behind-the-worlds-safest-assets-a22069f9?mod=wsjhp_columnists_pos3

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¹² Pharmaceutical spending. Organisation for Economic Co-operation and Development. <https://data.oecd.org/healthres/pharmaceutical-spending.htm>

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