Hearing before the Senate Committee on Health, Education, Labor and Pensions

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Chairman Sanders, Ranking Member Cassidy, and Members of the Committee, thank you for the opportunity to participate in today's hearing. I appreciate the chance to speak about Novo Nordisk's decades of work developing glucagon-like peptide 1 agonists, or "GLP-1s." These include semaglutide, the GLP-1 active ingredient in our FDA-approved products Ozempic® and Wegovy®.

These innovative medicines are part of a groundbreaking drug category with the potential to improve and extend the lives of millions of Americans.

Our company is grateful for Chairman Sanders's recognition that "scientists at Novo Nordisk deserve great credit for developing these drugs." As a company committed to improving the health and quality of patients' lives, Novo Nordisk is proud of the extensive research and development that our scientists have devoted toward enabling patients to receive innovative medicines that drive safe and effective therapeutic outcomes. Without fanfare or guarantee of success, Novo Nordisk researchers worked tirelessly for decades toward discovering and developing molecules that can treat and prevent some of the most persistent and costly public health challenges in the United States and around the world. The work of these scientists, researchers, and personnel has not only made Novo Nordisk the industry leader in treating diabetes and obesity, but it has also radically altered the medical management of these complicated and devastating chronic diseases and opened the door to new possibilities and avenues of inquiry for other serious chronic diseases—including heart, kidney, liver, and Alzheimer's diseases.

Their collective work embodies our company's core values and illustrates the power of our unique ownership structure, which is unlike any other major pharmaceutical company in the world. The Novo Nordisk Foundation, one of the largest charitable foundations in the world, is the controlling shareholder of Novo Nordisk. This structure was intended to build and sustain an enterprise that would take risks for the benefit of patients, invest in early science, and spend the time and resources needed to investigate and develop research that could one day unlock a cure for diabetes and other serious chronic diseases.

Under the Foundation's stewardship, this is exactly what Novo Nordisk has done—allowing us to prioritize long-term scientific efforts over short-term financial gain. In 2023 alone, Novo Nordisk spent $4.2 billion on diabetes and obesity research and development—a 37 percent increase from the previous year, and 50 percent more than the diabetes and obesity research and development budget of the entire National Institutes of Health. Our research and development

("R&D") spending has more than doubled since 2020, and we recently spent billions on our new U.S. research and development hub in Lexington, Massachusetts. Novo Nordisk intends to continue increasing the amount of our investment in R&D as a percentage of our total sales, meaning we will devote more to discovering new therapies and cures each year. I was humbled to see that Novo Nordisk was ranked the most innovative pharmaceutical company in the world just a few months ago.[1]

We welcome the opportunity to provide clarity on challenges in the U.S. health care system. Notably, the system enables hundreds of millions of Americans to access medicines, including Novo Nordisk medicines, at costs of between $25 and $50 per month. However, the complexities of the system unfortunately reduce access and affordability for many Americans. We are eager to work with this Committee to address these systemic issues so that everyone who can benefit from our medicines is able to get them.

In the meantime, Novo Nordisk is doing our part. Since Ozempic® was first introduced in 2018, the *net* price—the amount that Novo Nordisk is actually paid for our medicines—has declined by about 40 percent in the U.S. Today, Ozempic® is the lowest cost once-weekly GLP-1 medicine on the market in the United States. The net price of Wegovy® has similarly declined since its launch less than three years ago.

Currently, more than 80 percent of U.S. patients with insurance coverage for Ozempic® or Wegovy® are paying $25 or less for each prescription, and 90 percent of U.S. patients pay $50 or less. Under current market conditions, we expect that net prices will continue to decline for both Ozempic® and Wegovy®.

This testimony provides significant information on a number of issues that that are central to today's hearing: (I) a snapshot of the medical and financial toll that type 2 diabetes and obesity take on America, (II) details on Novo Nordisk's groundbreaking GLP-1 medications, Ozempic® and Wegovy®, (III) an overview of Novo Nordisk's decades of effort and investment to discover and develop these drugs and bring them to American patients, (IV) insight into how Novo Nordisk's unique ownership structure enabled it to pursue these groundbreaking medications when virtually no one else would, and (V) how Novo Nordisk is working to address patient affordability and access within the confines of the complex U.S. healthcare system.

I. The True Cost of Type 2 Diabetes and Obesity

Type 2 diabetes and obesity are chronic diseases that put an enormous strain on patients suffering from them; families across America; the entire U.S. healthcare system; and the economy as a whole. To fully understand the impact that GLP-1 medications can have, it is important to understand the toll and scale of these diseases.

Type 2 diabetes mellitus is a disease that occurs when the body stops responding normally to insulin, the important hormone that helps transform blood sugar into energy, leading to high blood sugar. Unfortunately, there is a tendency to confuse and muddle the distinctions between

[1] Matthew Herper, *Analysis of pharmaceutical R&D ranks Novo Nordisk and Johnson & Johnson above their peers*, Stat News (May 16, 2024), https://www.statnews.com/2024/05/16/pharma-research-development-rankings/.

type 1 and type 2 diabetes—both are very serious diseases, but they are distinct. Patients with type 1 diabetes must take insulin every day, and need to manage their disease with real-time glucose monitoring.[2] Type 2 diabetes is a progressive and insidious disease that worsens over time.[3] While some patients with type 2 diabetes may not require insulin injections in the same way as those living with type 1 diabetes, living with type 2 diabetes also exacts a serious toll. Patients routinely suffer from headaches, exhaustion, thirst, and depression.[4] Moreover, without proper and stable treatment, these symptoms can quickly advance to even more serious complications.

As one expert has observed, in diabetes hospitals, "[p]eople come in with amputated limbs and compromised cognitive functions and heart problems or they can barely move—they're miserable and depressed."[5]

Some of the most serious potential complications include high blood pressure, high cholesterol, heart disease, gastroparesis, kidney disease, stroke, amputations, blindness, and nerve damage.[6] Many of these complications have shared risk factors such that having one of them can compound or worsen others. And, unfortunately, complications from type 2 diabetes are disproportionately likely to be experienced by communities of color.[7]

The Centers for Disease Control and Prevention ("CDC") estimates that 38 million Americans are living with diabetes today, and as many as 36 million of these patients have type 2 diabetes.[8] An additional 98 million Americans are prediabetic and at risk for developing type 2 diabetes.[9] And around the world, there are more than a billion people who are either living with diabetes or are prediabetic and at risk of developing the disease.[10]

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[2] *About Type 1 Diabetes*, CDC (accessed May 22, 2024), https://www.cdc.gov/diabetes/about/about-type-1-diabetes.html.

[3] Vivian A. Fonseca, *Defining and Characterizing the Progression of Type 2 Diabetes*, Diabetes Care (Nov. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811457/.

[4] *E.g.*, Divya Gopisetty et al*., How Does Diabetes Affect Daily Life? A Beyond-A1C Perspective on Unmet Needs*, Clinical Diabetes (April 1, 2018), https://diabetesjournals.org/clinical/article/36/2/133/32827/How-Does-Diabetes-Affect-Daily-Life-A-Beyond-A1C; Christopher J. Bulpitt et al., *Association of Symptoms of Type 2 Diabetic Patients With Severity of Disease, Obesity, and Blood Pressure*, Diabetes Care (Jan. 1, 1998), https://diabetesjournals.org/care/article/21/1/111/19852/Association-of-Symptoms-of-Type-2-Diabetic.

[5] Matt Reynolds, *What the Scientists Who Pioneered Weight-Loss Drugs Want You to Know*, Wired (June 12, 2023), https://www.wired.com/story/obesity-drugs-researcher-interview-ozempic-wegovy/.

[6] Paraskevi Farmaki et al., *Complications of the Type 2 Diabetes Mellitus*, Curr. Cardiology Rev. (Nov. 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7903505/.

[7] J. Sonya Haw et al., *Diabetes Complications in Racial and Ethnic Minority Populations in the USA*, Curr. Diab. Rep. (Jan. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7935471/.

[8] *National Diabetes Statistics Report*, CDC (accessed May 22, 2024), https://www.cdc.gov/diabetes/php/data-research/index.html; *see Statistics About Diabetes*, Am. Diabetes Ass'n (accessed May 22, 2024), https://diabetes.org/about-diabetes/statistics/about-diabetes.

[9] *Statistics About Diabetes*, *supra* note 8.

[10] *See IDF Diabetes Atlas, 10th edition 2021*, Int'l Diabetes Found. (accessed May 9, 2024), https://diabetesatlas.org/data/en/world/

Obesity is also a serious chronic metabolic disease with important genetic and environmental inputs, as the American Medical Association recognized in 2013.[11] Obesity has been classified as a global health epidemic by both the CDC and the World Health Organization,[12] and more than 40% of American adults—over 100 million people—are now living with obesity,[13] with that number expected to continue to grow if we fail to successfully prevent and treat this disease.

Obesity also increases the risk of many other health problems, including type 2 diabetes, cardiovascular disease, strokes, several cancers, chronic kidney disease, and early death.[14] Hundreds of thousands of Americans die from obesity-related conditions every year.[15]

Adding to the physical costs of this chronic disease, individuals living with obesity face serious mental health risks as well. Throughout our society, individuals suffering from obesity suffer from a false-yet-persistent social stigma that obesity is a moral failing or a lack of willpower. Living in the shadow of this stigma can negatively impact social relationships, educational performance, professional outcomes, and long-term mental health.[16] This narrative has permeated public discourse for decades and has unfairly stigmatized patients for what we now know is a complex, chronic, and treatable disease.

There is no question that diabetes and obesity cause tangible harms in the lives of tens of millions of Americans, spawn myriad related diseases, and take a heavy financial toll on the U.S. healthcare system and on society. The American Diabetes Association estimates that type 2 diabetes alone costs American society $413 billion annually, with $307 billion in direct medical costs and $106 billion in indirect costs like lost productivity, unemployment due to chronic disability, and premature death.[17] The economic toll of the obesity epidemic is even greater. The *annual* impact of obesity and overweight on the American economy exceeds $1.7 trillion each year, including $481 billion in direct healthcare costs and $1.24 trillion in lost economic

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[11] Sara Berg, *With U.S. obesity rate over 40%, 3 treatment keys for doctors*, Am. Med. Ass'n (July 20, 2023), https://www.ama-assn.org/delivering-care/public-health/us-obesity-rate-over-40-3-treatment-keys-doctors.

[12] *See Causes of Obesity,* CDC (accessed May 22, 2024), https://www.cdc.gov/obesity/basics/causes.html; Rohana Haththotuwa, Chandrika Wijeyaratne & Upul Senarath, *Worldwide epidemic of obesity*, Obesity & Obstetrics, (accessed May 22, 2024), https://www.sciencedirect.com/science/article/abs/pii/B9780128179215000011.

[13] *Overweight & Obesity Statistics*, Nat'l Institute of Diabetes & Digestive & Kidney Diseases (accessed May 23, 2024), https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity.

[14] Steven J. Atlas et al., *Medications for Obesity Management: Effectiveness and Value*, Inst. for Clinical & Econ. Rev. (Aug. 31, 2022), https://icer.org/wp-content/uploads/2022/03/ICER_Obesity_Evidence_Report_083122.pdf.

[15] Zachary J. Ward et al., *Excess mortality associates with elevated body weight in the US and demographic subgroup: A modelling study*, The Lancet (April 28, 2022), https://doi.org/10.1016/j.eclinm.2022.101429.

[16] Zara Abrams, *The burden of weight stigma*, Monitor on Psychology, Am. Psych. Ass'n (March 1, 2022), https://www.apa.org/monitor/2022/03/news-weight-stigma; *see also* Gina Kolata, *We Know Where New Weight Loss Drugs Come From, But Not Why They Work*, N.Y. Times (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.

[17] Emily D. Parker et al., *Economic Costs of Diabetes in the U.S. in 2022*, Diabetes Care (Jan. 2024), https://doi.org/10.2337/dci23-0085.

productivity.[18] Obesity is also a leading cause of cardiovascular disease, which is the leading cause of death in the United States—and which costs over $315 billion annually in direct medical costs.[19]

Obesity also places an extraordinary strain on patients' personal finances, as those with diagnosed obesity incur more than twice the out-of-pocket health care costs of patients without an obesity diagnosis.[20] Studies also show that total per patient healthcare spending rises substantially as patient body mass index ("BMI") increases. Even within the subset of patients living with obesity (those with a BMI above 30), total healthcare spending for patients in the highest BMI group (40+) is more than double that of patients in the 30-34 BMI group.[21]

The World Obesity Federation expects the economic costs from excess weight and obesity to reach three percent of global GDP each year by the middle of the next decade; this is similar to the global impact of COVID-19 in 2020.[22] Absent therapeutic intervention, the global cost of obesity-related complications is expected to rise to over $4 trillion by 2035—higher than the entire gross domestic product of nearly every individual country in the world.[23] The price of treating complications that arise from these diseases continues to be astronomical, and it's a price that American taxpayers have had to bear for many years—including directly through Medicare.

It is apparent that any drug therapies able to reduce the prevalence of these expensive and deadly diseases will provide enormous personal, economic, and societal value to individuals, families, and communities across the country. Researchers at the University of Southern California have projected that insurance coverage of the new generation of effective weight-loss therapies would save the Medicare program as much as $245 billion in the first decade alone, with savings accruing mostly to Medicare Part A by reducing the number of inpatient hospital stays and the corresponding demand for highly skilled nursing care.[24] The same study concluded that the overall

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[18] Hugh Waters & Marlon Graf, *America's Obesity Crisis*, Milken Institute 1 (Oct. 2018), https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB.pdf.

[19] *See Heart Disease Facts*, CDC (accessed May 22, 2024), https://www.cdc.gov/heart-disease/data-research/facts-stats/; *see also* RTI International, *Cardiovascular Disease: A Costly Burden For America – Projections Through 2035*, American Heart Association and American Stroke Association 10 (2017), https://www.heart.org/-/media/Files/About-Us/Policy-Research/Fact-Sheets/Public-Health-Advocacy-and-Research/CVD-A-Costly-Burden-for-America-Projections-Through-2035.pdf.

[20] Imani Telesford et al., *How have costs associated with obesity changed over time*?, Peterson-KFF Health System Tracker (accessed May 22, 2024), https://www.healthsystemtracker.org/chart-collection/how-have-costs-associated-with-obesity-changed-over-time/.

[21] *See* Brigit Kyei-Baffour et al., *Health Spending Varies for Patients Likely to Have Obesity*, Avalere (Nov. 3, 2023), https://avalere.com/insights/health-spending-varies-for-patients-likely-to-have-obesity.

[22] *See* World Obesity Fed'n, *Press Release: Economic impact of overweight and obesity to surpass $4 trillion by 2035* (March 2, 2023), https://www.worldobesityday.org/assets/downloads/World_Obesity_Atlas_2023_Press_Release.pdf.

[23] *Id.* Of the nearly 200 countries in the world, only four—the United States, China, Japan, and Germany—report a gross domestic product higher than $4 trillion. *GDP (current US$)*, World Bank (accessed May 24, 2024), https://data.worldbank.org/indicator/NY.GDP.MKTP.CD.

[24] *See* Alison Sexton Ward et al., *Benefits of Medicare Coverage for Weight Loss Drugs*, USC Schaeffer Center White Paper Series (April 18, 2023), https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/.

cumulative social benefit would be even greater, reaching nearly $1 trillion over the next ten years.[25] And a recent analysis by Goldman Sachs concluded that increased utilization of GLP-1 medications could add as much as an additional 1 percent to U.S. gross domestic product over the next four years due to a reduction in health problems like heart attacks, strokes, and diabetes.[26] One study estimates that for each Medicare patient able to receive anti-obesity treatment, the Medicare system would see $6,800 to $7,200 of cost savings over 10 years from reduced usage of ambulatory care and prescription drugs—again, that's per patient.[27] Therefore, apart from the essential human impact, drugs that could meaningfully address the diabetes and obesity epidemics also have the potential to be fiscally transformative. That means discussions about the cost of treatment must necessarily start with the value, tangible and intangible, as well as the savings, that GLP-1 medications provide.

II. Novo Nordisk's Groundbreaking GLP-1 Medications

Novo Nordisk's GLP-1 medications, including Ozempic® and Wegovy®, have the potential to transform the lives of countless people living with diabetes, obesity, and other chronic diseases.

In developing these drugs, Novo Nordisk has pioneered something revolutionary. Our groundbreaking class of GLP-1 medications, including our latest achievement—semaglutide—meaningfully treats and manages these chronic diseases, with proven positive health outcomes for comorbidities and related conditions. As the *New York Times* said: "Every so often a drug comes along that has the potential to change the world. Medical specialists say the latest to offer that possibility are the new drugs" like Ozempic® and Wegovy®.[28] And as the *Financial Times* put it, this medication has "enormous potential to boost public wellbeing and slash healthcare costs throughout the world."[29]

Ozempic® was approved by the Food and Drug Administration ("FDA") in 2017 for the treatment of type 2 diabetes. It increases the body's production of insulin, a hormone that lowers blood sugar levels, and reduces production of glucagon, which increases blood sugar levels.[30] As the *New York Times* reported this year, Ozempic® is "changing diabetes treatment," as many patients "have been able to lower their insulin doses after starting Ozempic[®], and some have

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[25] *Id.*

[26] Matthew Fox, *The more Americans who take Ozempic, the faster the US economy could grow, Goldman Sachs says*, Business Insider (April 26, 2024), https://www.businessinsider.com/us-economy-faster-growth-ozempic-glp-1-weight-loss-drugs-2024-2.

[27] Fang Chen et al., *Ten-year Medicare budget impact of increased coverage for anti-obesity intervention*, J. Med. Econ. (Aug. 19, 2019), https://pubmed.ncbi.nlm.nih.gov/31378108/.

[28] Kolata, *supra* note 16.

[29] Financial Times Editorial Board, *The promise of anti-obesity drugs*, Financial Times (Sept. 6, 2023), https://www.ft.com/content/a6e0ccbd-66b4-4e5d-9a9a-002b95b0d19f.

[30] Manoj Kumar Mahapatra, Muthukumar Karuppasamy & Biswa Mohan Sahoo, *Semaglutide, a glucagon like peptide-1 receptor agonist with cardiovascular benefits for management of type 2 diabetes*, R. Endocrine & Metabolic Disorders (2021), https://ncbi.nlm.nih.gov/pmc/articles/PMC8736331/.

been able to go off insulin entirely."[31] And while the first GLP-1 agonists were introduced to treat patients with diabetes by promoting insulin production, studies indicated that they also regulate the body's response to food, creating a sensation of fullness and reducing the desire to continue eating.[32]

As Novo Nordisk's scientists dug deeper into the innovation that created Ozempic®, they uncovered a new possibility: a treatment that could bend the curve on the global obesity epidemic. According to prominent medical experts in the U.S., any such medication would be a "holy grail" of medicine.[33] I will detail Novo Nordisk's extensive efforts to identify and prove both the efficacy and the safety of this treatment later in my testimony.

In clinical trials, adults taking Wegovy® lost an average of about 15 percent of their body weight[34]—meaning a person who began the trial weighing 232 pounds lost an average of about 35 pounds. Wegovy® was approved by the FDA in 2021 as a treatment for obesity,[35] and the medicine was first sold in the U.S. that June, two full years before it was made available anywhere else in the world—even in Denmark, the global headquarters of Novo Nordisk. As of today, the United States is one of only a handful of countries where Wegovy® is sold.

To be clear: While Ozempic® and Wegovy® share the same molecule, they are not the same. Rather, Wegovy® and Ozempic® are different products, approved separately by the FDA based on their own respective clinical development programs, with different indications, dosages, prescribing information, titration schedules, formulations, and delivery devices. As such, they are not interchangeable. To understand their efficacy and in order to seek and secure FDA approval to treat different diseases and populations, Novo Nordisk conducted separate clinical trials and significantly invested in research for both diabetes and obesity.

Novo Nordisk has not merely opened the door to transforming the treatment paradigm around type 2 diabetes and obesity. We continue to make significant investments in the science to learn more. Indeed, we conducted additional large-scale clinical trials involving tens of thousands of people in dozens of countries around the world that proved semaglutide can not only effectively

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[31] Dani Blum, *How Ozempic Is Changing Diabetes Treatment*, N.Y. Times (May 13, 2024), https://www.nytimes.com/2024/05/13/well/live/insulin-ozempic-diabetes.html; *see also* Paresh Dandona, Ajay Chaudhuri, and Husam Ghanim, *Semaglutide in Early Type 1 Diabetes,* N. Engl. J. Med. (2023) https://www.nejm.org/doi/full/10.1056/NEJMc2302677.

[32] John Blundell et al., *Effects of once-weekly semaglutide on appetite, energy intake, control of eating, food preference and body weight in subjects with obesity*, Diabetes, Obesity & Metabolism (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5573908/; *see also* Susan Cornell, *A review of GLP-1 receptor agonists in type 2 diabetes: A focus on the mechanism of action of once-weekly agents*, J. Clinical Pharm. & Therapeutics (2020), https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/jcpt.13230; Jean-Pierre Gutzwiller et al., *Glucagon-like peptide-1 promotes satiety and reduces food intake in patients with diabetes mellitus type 2*, Am. J. Physiology (May 1999), https://pubmed.ncbi.nlm.nih.gov/10233049/.

[33] *E.g.*, Eric Topol, *The New Obesity Breakthrough Drugs*, Ground Truths (Dec. 10, 2022), https://erictopol.substack.com/p/the-new-obesity-breakthrough-drugs.

[34] *Novo Nordisk receives FDA approval for Wegovy™ to treat adults with obesity based on unprecedented efficacy for a prescription medicine in clinical trials*, Novo Nordisk (June 4, 2021), https://www.novonordisk-us.com/media/news-archive/news-details.html?id=62113.

[35] *Id.*

treat obesity—in the SELECT trial, semaglutide was also shown to reduce the risk of major adverse cardiovascular events like heart attacks and strokes in adults with established cardiovascular disease and either obesity or overweight by 20%. Semaglutide is the only weekly GLP-1 medication on the market that is FDA-approved to reduce the risk of these major adverse cardiovascular events—which are the number one cause of death in the United States.[36] The FLOW trial showed semaglutide to reduce the progression and mortality of kidney disease in adults with diabetes and chronic kidney disease by 24%, and that the risks of major cardiovascular events and death from any cause were significantly lower in the semaglutide group than in the placebo group.[37]

These drugs can result in significant and sustained health improvement and have the potential to be transformative for the millions of Americans struggling with type 2 diabetes and obesity. As one expert has said, "[o]besity is associated with 200 other obesity-related diseases. . . . If we treat this one disease, we can potentially impact the health of so many patients in many different ways."[38] The panoply of benefits and applications for GLP-1 medications like semaglutide is not yet known, and scientists are exploring its potential to treat a range of serious conditions. Our researchers are continuing to learn more about the diseases of diabetes and obesity, and what impact GLP-1s may have on other disease states. For example, we have trials underway examining the use of semaglutide for treatment of liver disease and Alzheimer's disease, and there are some studies by others that show that GLP-1s may have the ability to treat or improve Parkinson's or various forms of addiction.[39] We are investing substantial resources, time, and

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[36] *See* Seth S. Martin et al., *2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association*, Circulation, A Journal of the American Heart Association (Jan. 2024) https://www.ahajournals.org/doi/10.1161/CIR.0000000000001209; *see also* FDA Office of Media Affairs, *FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight*, U.S. Food & Drug Administration (Mar. 8, 2024), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or.

[37] The landmark SELECT study, funded by Novo Nordisk, demonstrated that semaglutide reduced the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) by 20% in adults with overweight or obesity and established cardiovascular disease. This trial involved more than 17,000 adults across 41 countries and 800 investigator sites. *See Company announcement No 50 / 2023*, Novo Nordisk (Aug. 8, 2023), https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=166301. Additionally, Novo Nordisk's FLOW study demonstrated a 24% reduction in kidney disease progression and mortality in adults with type 2 diabetes and chronic kidney disease. Like the SELECT study, this trial was funded by Novo Nordisk and involved thousands of patients across hundreds of investigator sites in 28 countries. *See Company announcement No 20 / 2024*, Novo Nordisk (March 5, 2024), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=167028; *Ozempic® (semaglutide) injection 1 mg demonstrated reduction in risk of kidney disease-related events in Phase 3 FLOW trial presented at the 84th Scientific Sessions of the American Diabetes Association*, Novo Nordisk (June 24, 2024), https://www.novonordisk-us.com/media/news-archive/news-details.html?id=168527.

[38] Benjamin Mueller, *Obesity Treatment Relieves Heart Failure Symptoms, Drugmaker's Study Finds*, N.Y. Times (Aug. 25, 2023), https://www.nytimes.com/2023/08/25/health/weight-loss-drug-heart-failure.html.

[39] *See R&D Pipeline*, Novo Nordisk (accessed May 23, 2024), https://www.novonordisk.com/science-and-technology/r-d-pipeline.html; *see also* Nat'l Inst. on Alcohol Abuse & Alcoholism, *Semaglutide shows promise as a potential alcohol use disorder medication* (March 13, 2024), https://www.niaaa.nih.gov/news-events/research-update/semaglutide-shows-promise-potential-alcohol-use-disorder-medication; Wassilios G. Meissner, et al., *Trial of Lixisenatide in Early Parkinson's Disease*, N. Engl. J. Med. (April 2024) https://www.nejm.org/doi/pdf/10.1056/NEJMoa2312323.

dollars into these studies—and while it will be years before many of them yield conclusive findings, our researchers are optimistic about identifying even more ways in which these medicines can change and potentially save lives.

All of these findings make plain that the development of GLP-1 drugs like Ozempic® and Wegovy® has been a monumental step forward for public health. GLP-1 drugs were named the 2023 Breakthrough of the Year by *Science* magazine, and experts describe them as "medical breakthroughs" on par with advancements like gene therapy and the mRNA technologies that produced COVID vaccines.[40] In April, Dr. Lotte Bjerre Knudsen—the Novo Nordisk scientist who led the company's work on liraglutide, the company's pioneering first GLP-1 medicine—was awarded a 2024 Breakthrough of the Year Award from the American Association for the Advancement of Science ("AAAS").[41] Just last week, Dr. Knudsen was honored with the Lasker-DeBakey Clinical Medical Research Award—often referred to as one of America's Nobel Prizes.[42] And as researchers around the world continue to explore uses and applications of GLP-1 therapies, I am humbled to note that the work of our scientists and their contemporaries has been heralded as so groundbreaking that it could be considered for a Nobel Prize.[43]

III. Novo Nordisk's Massive Investment to Create These Groundbreaking Medications and Bring Them to Market

On average, it takes 10 to 15 years to develop a new drug from initial discovery through regulatory approval.[44] However, the journey to develop these medications and bring both Ozempic® and Wegovy® to market required a much longer than average sustained investment by Novo Nordisk. Since the early 1990s, our scientists encountered many roadblocks and observed competitors pulling the plug on their research, or simply refusing to invest in GLP-1 medications at all. But year after year, we persisted.

Dr. Knudsen, now our chief scientific adviser, was in the vanguard of Novo Nordisk's GLP-1 work as a frontline researcher beginning in the 1990s. She knew that GLP-1 was a short-lasting gut hormone that was rapidly broken down by other enzymes, unable to last long enough within the human body to serve as a medicine. Despite this, she still believed that GLP-1 had the potential to stimulate insulin and alter appetites. It took years of work before Dr. Knudsen and her team were finally able to alter the GLP-1 molecule to "hide" it from those enzymes—but even still,

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[40] Jennifer Couzin-Frankel, *Obesity meets its match: Blockbuster weight loss drugs show promise for a wider range of health benefits*, Science (Dec. 14, 2023), https://www.science.org/content/article/breakthrough-of-the-year-2023.

[41] Meagan Phelan, *Innovators Who Fought to Unlock GLP-1 Drug for Obesity Awarded Mani L. Bhaumik Breakthrough of the Year Award*, American Association for the Advancement of Science (April 4, 2024), https://www.aaas.org/news/innovators-glp-1-obesity-bhaumik-breakthrough.

[42] Gina Kolata and Stephanie Nolen, *Research That Led to Obesity Drugs Wins Major Medical Prize*, N.Y. Times (Sept. 19, 2024), https://www.nytimes.com/2024/09/19/health/2024-lasker-awards-ozempic-wegovy-glp-1.html; *see also Lasker Awards*, NIH (accessed Sept. 21, 2024) (Lasker Awards are "America's Nobels"), https://www.nih.gov/about-nih/what-we-do/nih-almanac/lasker-awards.

[43] *See* Megan Molteni & Elaine Chen, *GLP-1 drugs are transforming diabetes, obesity and more. Could a Nobel be next?*, Stat News (Sept. 30, 2023), https://www.statnews.com/2023/09/30/weight-loss-ozempic-nobel-prize-science/

[44] *Research & Development Policy Framework*, PhRMA (accessed May 16, 2024), https://phrma.org/policy-issues/Research-and-Development-Policy-Framework.

they couldn't get past human kidneys, which flushed it out from the bloodstream within minutes. But instead of giving up, our scientists dedicated their efforts to find a way to protect GLP-1 from this degradation process. Along the way, the project faced obstacles, including questions about whether there was a viable medicine to be had at all, and it was very nearly cancelled.

But our researchers prevailed, and over the course of many more years, Dr. Knudsen and her team finally succeeded—finding a way to further disguise GLP-1 in reservoirs of a naturally-occurring protein called albumin, allowing it to stay in the bloodstream for hours and even slip across the brain-blood barrier to bind to neurons in the part of the brain responsible for food intake.[45] And then, through the course of *yet another decade*, her team worked tirelessly to transform these insights into actual, usable medication—resulting in liraglutide, Novo Nordisk's pioneering once-daily GLP-1 medicine.

Many in the pharmaceutical industry believed that liraglutide would represent the pinnacle of potential achievement in the GLP-1 medicine category. Some suggested that we could have stopped there, given the molecule's promise. Indeed, others suggested that we would have *no choice* but to stop there, because it would be *impossible* to create a GLP-1 medicine that could last in the body for any longer—after all, natural GLP-1 itself has a half-life of less than two minutes, and it took many years to develop a medicine with a half-life that could be measured in hours. But another team, led by Drs. Jesper Lau, Thomas Kruse, and Paw Bloch, resolved to begin a new wave of innovation. They were determined to create a novel, even more potent GLP-1 drug—one that would stay in the bloodstream for days, and that could be injected *weekly* instead of every 24 hours.[46] After several more years, and after facing down and overcoming many new obstacles, they did just that. These scientists created the revolutionary semaglutide compound, with a half-life of 165 hours—more than ten times longer than the half-life of liraglutide, and with even more powerful effects.[47]

Throughout the decades, Novo Nordisk constantly pushed this research forward, funding study after study to understand whether these drugs worked and could be used to improve the lives of those with chronic diseases. We even continued funding expensive new trials after the drugs had already been approved by the FDA, because we wanted to find out if there were even more ways they could help patients. The landmark SELECT study that demonstrated semaglutide's effect on those suffering from established cardiovascular disease and either obesity or overweight was the largest clinical trial in Novo Nordisk history, enrolling more than 17,000 patients across 41 countries and 800 investigator sites. The median pivotal clinical trial alone costs more than $40,000 per enrolled patient.[48] Each time that we believe we have identified a potential new

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[45] *See* Lotte Bjerre Knudsen & Jesper Lau, *The Discovery and Development of Liraglutide and Semaglutide*, Frontiers in Endocrinology (April 12, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6474072/pdf/fendo-10-00155.pdf.

[46] *See, e.g.*, *id.*; Jesper Lau et al., *Discovery of the Once-Weekly Glucagon-Like Peptide 1 (GLP-1) Analogue Semaglutide*, J. Med. Chem. (2015), https://pubs.acs.org/doi/10.1021/acs.jmedchem.5b00726.

[47] Jesper Lau et al., *supra* note 46.

[48] Thomas J. Moore et al., *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, JAMA Internal Medicine (Nov. 1, 2018), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2702287.

indication for semaglutide, we must fund another set of large studies to prove that the drug is safe and effective for that purpose.

The total investment that we have made in the treatment of these chronic diseases through our revolutionary category of GLP-1 medications is difficult to comprehensively quantify. The company's spending dates back to the early 1990s—predating our existing finance system—and sprawls across many categories of expenses. But even under an extraordinarily conservative approximation, we have invested *well over $10 billion dollars* to develop our groundbreaking GLP-1 medicines without knowing if any of the work would result in safe and effective medication that could be provided to the general public.[49] We undertook more than 100 phase II and III clinical trials for our GLP-1 medicines over the course of more than three decades, collecting more than 135,000 person-years of data.[50]

Moreover, these figures do not capture the full picture and cost of what it took to get to where we are today—because for every drug that works, there are nine that fail.[51] That is, for every medication that advances all the way to human testing, 90% still fail during phase I, II, and III clinical trials.[52] And of the one-in-ten medications that do make it to the market, only a minority actually turn a profit.[53] Nevertheless, we continued with studies, trials, and lines of research over the years when both academia and the pharmaceutical industry showed little interest in exploring these treatments—all for a stigmatized disease wrongly considered to be the result of patients' moral failure,[54] and when no success was guaranteed.

Just a few years ago, we invested more than $150 million in a growth hormone deficiency drug that never saw commercial success. We recognize that failures like this are the cost of taking big risks to find innovative new therapies. But this means that drugs that succeed, like Ozempic® and Wegovy®, bear a heavy burden. They must return the investment in not only themselves, but in each of the far more numerous drugs that failed—and fund the next breakthrough.

This is the cycle that enables companies like Novo Nordisk to continually reinvest in the future, enabling continued innovation focused on improving patients' lives. In fact, despite having approved treatments on the market for over a decade, Novo Nordisk has only made a profit on medication for obesity in the past two years.

Novo Nordisk also continues to invest in innovations that make it easier for patients to take their medications. For years, Novo Nordisk has worked to create ever more innovative injection

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[49] Novo Nordisk emphasizes that this is an extremely conservative estimate, and the true expense required to develop these medicines likely substantially exceeds this amount.

[50] Each "person-year" is a year of data contributed by an individual participant in a study.

[51] Duxin Sun et al., *Why 90% of clinical drug development fails and how to improve it?*, Acta Pharmaceutica Sinica B (Feb. 11, 2022), https://pubmed.ncbi.nlm.nih.gov/35865092/.

[52] *Id.*

[53] John A. Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, Health Economics (Aug. 2010), https://pubmed.ncbi.nlm.nih.gov/19655335/.

[54] Kolata, *supra* note 16 ("'There was very little interest in the industry in doing this,' said Dr. [Richard] Di Marchi, now at Indiana University. 'Obesity was not thought to be a disease. It was looked at as a behavioral problem.'").

pens, combining patient insight with engineering excellence, making drug delivery as simple and painless as possible to help overcome this fear. Each of these inventions increased dosing accuracy, portability, ease of use, and improved quality of care while reducing patient pain.[55]

While all of these research and development expenses are essential elements of the cost of these drugs, none of them are accounted for in the often-cited Yale study published in *JAMA*. That study was intended to estimate the hypothetical *future* costs of producing generic versions of GLP-1 medications like semaglutide. As the authors of the study make clear, the study's calculation of profitability included neither the cost of researching and developing Novo Nordisk's GLP-1 medications, nor the significant costs of developing the first-in-the-world manufacturing facilities to meet demand.[56]

Producing these medications at the scale needed to meet current (and rising) demand is complicated and expensive, as Novo Nordisk knows well. Our company was founded to bring insulin to the people of Europe, but manufacturing complex peptide treatments like insulin is extraordinarily difficult to do—and we spent the first five decades after insulin's discovery trying to find a way to scale production sufficiently to serve all patients who could benefit from it. Semaglutide is also a complex peptide, and, today, we are once again hard at work trying to solve the same challenge: increasing production capacity and closing the gap between supply and demand.

Since just the beginning of last year, Novo Nordisk has committed to spending over $30 billion on expanding our manufacturing capacity—more than double our company's entire net profit in 2023. The overwhelming majority of this investment is being directed towards GLP-1 medication production. We announced our most recent investment of $4.1 billion to expand our production facility in North Carolina just this past June, which we predict will ultimately create 1,000 good-paying jobs—in addition to the more than 3,000 construction jobs that the expansion will create.[57] That investment comes on top of the $6 billion already committed there, and the thousands of jobs we have already created in the state.[58] And just a few months ago, Novo Nordisk spent $11 billion to acquire three manufacturing sites in Indiana, Italy, and Belgium from Catalent,

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[55] *See, e.g.*, Jakob Oest Wielandt et al., *FlexTouch: A Prefilled Insulin Pen with a Novel Injection Mechanism with Consistent High Accuracy at Low- (1 U), Medium- (40 U), and High- (80 U) Dose Settings*, J. Diabetes Sci. Tech. (Sept. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3208880/; Thomas Sparre et al., *Development of an Insulin Pen is a Patient-Centric Multidisciplinary Undertaking: A Commentary*, J. Diabetes Sci. Tech. (May 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9158249/.

[56] *See* Melissa J. Barber et al., *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, JAMA Network Open 10 (March 27, 2024), https://shorturl.at/hzAQV.

[57] *See* Annika Kim Constantino, *Novo Nordisk to build $4.1 billion North Carolina facility to boost output of Wegovy, Ozempic*, CNBC (June 24, 2024), https://www.cnbc.com/2024/06/24/novo-nordisk-nc-facility-wegovy-ozempic-output.html.

[58] *Novo Nordisk announces 4.1 billion USD investment to expand US manufacturing capacity*, Novo Nordisk (June 24, 2024), https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=168528; *Who we are: North Carolina*, Novo Nordisk (accessed Sept. 8, 2024), https://www.novonordisk-us.com/about/who-we-are/north-carolina.html.

one of the largest drug manufacturing contractors in the world.[59] This is in addition to our announcements in late 2023 that we would invest $8 billion in manufacturing facilities in France and Denmark to increase production.[60]

We continue to evaluate potential additional investments in expanding manufacturing capacity, and intend to maintain elevated levels of capital expenditures—more than $7 billion each year—through at least 2026. We are making these investments so that we can manufacture enough GLP-1 medications to meet the need for them. If we are unable to build out sufficient production capacity to supply enough semaglutide, it would deprive many patients of revolutionary therapies for their diseases—to the overall detriment of society.

Our multibillion-dollar investments in North Carolina have created jobs for thousands of Americans at more than double the average local income, and North Carolina is the only place outside of Denmark where we manufacture the active pharmaceutical ingredient (API) semaglutide. The company also owns facilities in New Hampshire and California; in total, Novo Nordisk employs more than 8,000 people across the United States.[61]

Novo Nordisk has made all these investments while reducing our carbon footprint. In 2020, we achieved our goal of using 100% renewable energy across all global production, including in the U.S., where our North Carolina facility is completely powered by a nearby, purpose-built, 105-megawatt solar farm.

And while we continue to invest to build our capacity to serve patients, we are concerned that others may be exploiting patients and putting their safety at risk. Certain foreign manufacturers are claiming to provide "semaglutide." To be clear, Novo Nordisk manufactures the only FDA-approved semaglutide. In fact, testing has shown that many of these non-FDA approved products often contain high levels of impurities that can pose significant harm to patients. Data from the FDA shows that there have been over 500 reports of adverse events associated with these unapproved products, including **more than 300 serious events, over 100 hospitalizations, and 10 deaths**.[62] The total number of adverse events from these unapproved compounded "semaglutide" products alone is now more than twice the number of adverse events that the FDA

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[59] *Press Release: Novo Nordisk to acquire three fill-finish sites from Novo Holdings A/S in connection with the Catalent, Inc. transaction*, Novo Nordisk (Feb. 5, 2024), https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=167017; Novo Holdings and Catalent, *Press Release: Novo Holdings to Acquire Catalent*, Business Wire (Feb. 5, 2024), https://www.businesswire.com/news/home/20240204431488/en/Novo-Holdings-to-Acquire-Catalent.

[60] *Press Release: Novo Nordisk invests more than 16 billion Danish kroner in expansion of production facilities in Chartres, France*, Novo Nordisk (Nov. 23. 2023), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166350; *see also Press Release: Novo Nordisk invests more than 42 billion Danish kroner in expansion of manufacturing facilities in Kalundborg, Denmark*, Novo Nordisk (Nov. 10, 2023), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166342.

[61] Novo Nordisk, Annual Report 2023, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2024/novo-nordisk-annual-report-2023.pdf.

[62] *See generally* FDA Adverse Event Reporting System (FAERS) Public Dashboard, U.S. Food & Drug Administration, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

received for all compounded drugs in 2022 combined.[63] While we support the use of compounding pharmacies for their intended purpose—to combine ingredients to create a medication tailored to the unique needs of an individual patient—neither Congress nor the FDA intended for compounding pharmacies to sell large volumes of compounded drugs across state lines and as an alternative to FDA-approved medicines.[64] We strongly oppose compounding of non-FDA approved "semaglutide" products that puts patients at risk, especially given that risk has been associated with serious adverse events, hospitalization, and death. We hope Congress will look into the risks from these companies that are deceiving the public and putting patient safety at risk.

IV. How Novo Nordisk's Unique Corporate Structure Enabled GLP-1s—And So Much More

Novo Nordisk is uniquely positioned to take the long view. Unlike any other major drug company, our controlling shareholder is a charitable foundation, and our mission is to *defeat* diabetes and serious chronic diseases. Our structure comes from the foresight and values of our founders. It began when a husband and wife from Copenhagen, August and Marie Krogh, a professor and physician respectively, visited the United States in 1922 and learned that people with diabetes were being treated with insulin. Mrs. Krogh was a physician who herself had type 2 diabetes, but she also treated patients with type 1 diabetes in her practice. After meeting with the two Canadian researchers who discovered insulin, including Dr. Frederick Banting, Mr. and Mrs. Krogh received permission to bring that innovative therapy back to Denmark. Chairman Sanders has rightfully praised Dr. Banting for his commitment to ease suffering and save human lives. The Kroghs shared Dr. Banting's commitment, and we hold true to their values today through the unique structure they pioneered.

The controlling shareholder of Novo Nordisk is the Novo Nordisk Foundation—a charitable foundation that traces its roots to our founders over 100 years ago. The Foundation is owned by no one; instead, it is governed by an independent Board of Directors that is legally obligated to govern it in accordance with the mission laid out in its bylaws. As a result, Novo Nordisk cannot be acquired or subjected to a hostile takeover, freeing us from the pressures of daily stock market fluctuations.

The Foundation's overriding vision is to improve people's health and the sustainability of society and the planet. Since its inception, it has pursued a dual mission of supporting philanthropic purposes—more precisely scientific, humanitarian, and social causes—and ensuring a stable basis for the companies in the Novo Group. It is chartered under Danish law to ensure that the companies it owns (1) make a significant difference in improving the way people live and work, and (2) conduct their activities in a financially, environmentally, and socially responsible way.[65] The Foundation has never strayed from that approach.

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[63] *Id*.

[64] *See FDA's Human Drug Compounding Progress Report: Three Years After Enactment of the Drug Quality and Security Act*, U.S. Food & Drug Administration (Jan. 2017), https://www.fda.gov/media/102493/download.

[65] *See generally Charter for companies in the Novo Group*, Novo Nordisk Foundation (accessed May 22, 2024), https://novonordiskfonden.dk/en/who-we-are/goal-and-values/charter/.

This principled and persistent approach—including a laser-like focus on treating and defeating diabetes and related chronic diseases—enabled Novo Nordisk to continue to invest in unlocking the potential of GLP-1s, even as other companies shied away.

Novo Nordisk is the single largest private funder of diabetes research and education in the world, thanks in part to investments made through the Foundation. **We spent $4.2 billion on diabetes and obesity research and development in 2023 alone—50 percent more than the diabetes and obesity R&D budget of the entire National Institutes of Health**.[66] That investment in research and development will only continue to grow, as we intend to increase the amount of our investment in R&D as a percentage of our total sales—meaning billions more for discovering new therapies and cures each year. And last year, we reached more than 40 million patients globally with our diabetes medications, a 12% increase from the year before.[67] We have 10 new potential diabetes treatments in the research pipeline, and we will never give up on our efforts to find a cure.[68]

The Novo Nordisk Foundation has awarded thousands of grants worth approximately $5 billion over the last five years alone towards three focus areas: health, sustainability, and the life science ecosystem—including more than $1.3 billion in grants in 2023.[69] Many of the Foundation's efforts are directed to work in partnership with institutions in the United States, including:

- The Pandemic Antiviral Discovery initiative to catalyze discovery and early development of antiviral medicines for future pandemics, in partnership with the Gates Foundation,
- The Novo Nordisk Foundation CO2 Research Center to discover solutions to capture and recycle carbon dioxide from the atmosphere, in partnership with Stanford University,
- The Novo Nordisk Foundation Quantum Computing Programme to create a working quantum computer, in partnership with MIT,
- The Pioneer Center for Landscape Research in Sustainable Agricultural Futures, paving the way for a green transition in the agriculture industry, in partnership with Colorado State University, and

[66] Novo Nordisk spent $4.8 billion on R&D in 2023, with 87 percent of that total allocated to diabetes and obesity care. Annual Report 2023, *supra* note 61, at 56. The NIH reported spending of $2.8 billion on these categories in 2023. NIH Research Portfolio Online Reporting Tools, *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NIH (March 31, 2023), https://report.nih.gov/funding/categorical-spending#/ ($1.3 billion for diabetes, $1.2 billion for obesity, and $269 million for childhood obesity in 2023).

[67] Novo Nordisk, Annual Report 2023 at 15 and 90, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2024/novo-nordisk-annual-report-2023.pdf.

[68] *Id.* at 27.

[69] *Annual Impact Report 2023: Societal Impact of the Novo Nordisk Foundation*, Novo Nordisk Foundation vi (2024), https://novonordiskfonden.dk/app/uploads/Novo-Nordisk-Foundation-2023-Annual-Impact-Report.pdf.

- The Novo Nordisk Foundation Center for Genomic Mechanisms of Disease at Broad Institute of MIT and Harvard, to pave the way for better diagnostics, improved treatments, and the development of precision medicine by exploring human gene regulation in connection with common complex diseases.

The Novo Nordisk Foundation also funds the BioInnovation Institute ("BII"), an international incubator founded in 2018 that helps inventors and scientists build new companies focused on improving human and planetary health.[70] Nearly 90 start-ups working to improve human and planetary health have launched from the BII in the last six years.[71]

This work is funded through Novo Nordisk's dividends and buybacks.[72] When we are fortunate enough to discover a successful treatment in the fight against chronic diseases, our profits fuel the Novo Nordisk Foundation to further deliver on its charitable mission in support of better health and a sustainable environment for the U.S. and the world.

V. Novo Nordisk's Commitment to Patient Access

We agree that, when innovative medicines like Ozempic® and Wegovy® have transformative effects on public health and address massive drivers of health care costs, American patients should benefit from these savings. But the modern U.S. health care system is a complex ecosystem with many players, and we do not control what patients pay for their medications. Unfortunately, the U.S. system has created unintended consequences that can harm patients and interfere with affordable access to prescription drugs.

The U.S. healthcare system is dominated by middlemen who play a key role in both patient access and costs—the vertically-integrated healthcare conglomerates made up of insurers, pharmacy benefit managers ("PBMs"), specialty pharmacies, and opaque group purchasing organization contractors ("GPOs"). As a *New York Times* investigation found this summer, these conglomerates and their PBMs "operate in the bowels of the health care system and cloak themselves in such opacity and complexity that many people don't even realize they exist" while "driving up drug costs for millions of people, employers and the government" and "extract[ing] billions of dollars in hidden fees" from pharmaceutical companies.[73]

Today, the three biggest PBMs control prescription drug access for more than 80 percent of the market, exercising near-total control over the ability of hundreds of millions of Americans to get the medicines they need at affordable prices, and each of these PBMs is owned by one of

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[70] BioInnovation Institute Foundation, *BII Impact Report*: *A year in review*, BioInnovation Institute 1, 4 (2024), https://bii.dk/wp-content/uploads/Impact_Report_2023_FINAL_WEB-2.pdf.

[71] *Id.* at 7.

[72] *See Annual Impact Report 2023*, *supra* note 69, at 4-5.

[73] *See* Rebecca Robbins & Reed Abelson, *The Middlemen: The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, N.Y. Times (June 21, 2024), https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.

the largest health insurance companies in the United States.[74] As the Federal Trade Commission found in July: these "dominant PBMs can often exercise significant control over which drugs are available" and "at what price."[75]

Last year, these three PBMs appeared before this Committee and explained that they negotiate lower drug prices for their "customers."[76] The PBMs' customers, however, are often their own corporate parent healthcare conglomerates—not American patients. In practice, this means that PBMs negotiate large undisclosed payments from drug manufacturers that lower the price of medicines, called "rebates," that they then provide to their corporate affiliates, rather than applying those dollars to lower the cost actual patients pay for their medications at the pharmacy counter.[77] And while PBMs negotiate low net prices for their corporate parents, those insurers design their plans such that nearly half of all patients' out-of-pocket spending for brand medication is based on the full list price, with the insurer collecting the difference.[78] Meanwhile, the PBMs continue to create further complexities to enrich themselves and their corporate parents, including through the creation of offshore rebate aggregator entities which—as one PBM executive put it—are intended to "create a fee structure that can be retained and not passed on to a client."[79] It also includes the creation of offshore "private labeling" entities: new companies that enter exclusive deals to procure medicines that other generic manufacturers are already making—but that the PBMs can then include on their own formularies at higher prices, pocketing the profits.[80]

Overall, we pay 75 cents of every dollar of medicine we sell back into this complex system in rebates, discounts, and fees—meaning the "net" price Novo Nordisk ultimately receives for the medicines it sells is far below the published "list" price. And while the rebates we pay to PBMs and insurers as a share of each dollar earned have increased dramatically over the last decade, this has not resulted in a proportionate reduction in out-of-pocket costs for patients at the pharmacy counter. Instead, as the *New York Times* investigation concluded, PBMs "steer patients toward pricier drugs, charge steep markups on what would otherwise be inexpensive medicines and extract billions of dollars in hidden fees."[81]

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[74] United State Federal Trade Commission Office of Policy Planning, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drugs Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[75] *Id*. at 3.

[76] *Examining the Need to Make Insulin Affordable for All Americans: Hearing before the S. Comm. On Health, Educ., Lab., and Pensions,* 118th Cong. 60 (May 10, 2023) (statement of Heather Cianfrocco, CEO of OptumRx), https://www.congress.gov/118/chrg/CHRG-118shrg54476/CHRG-118shrg54476.pdf.

[77] *See, e.g.*, *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines*, PhRMA (Nov. 2017), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Follow-the-Dollar-Report.pdf.

[78] Andrew Brownlee & Jordan Watson, *The Pharmaceutical Supply Chain, 2013–2020*, Berkeley Research Group (Jan. 7, 2022), https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/.

[79] *Pharmacy Benefit Managers*, *supra* note 74 at 22.

[80] *Id.* at 27–29.

[81] *See* Robbins et al., *supra* note 73.

As an independent study found last year, the gap between list prices and net prices persists even for the newest generation of GLP-1 medications like Ozempic® and Wegovy®.[82] In fact, the net price of Ozempic®—the amount that Novo Nordisk is actually paid for the medicine—has declined by about 40 percent since its introduction in the U.S., and the net price of Wegovy® has similarly declined since its launch less than three years ago.

Because of this complexity in the U.S. healthcare system—with PBMs asking that more money be paid to them in the form of rebates, discounts, and fees each year—unilateral manufacturer cuts to list prices do not consistently alleviate the cost burden on patients, and may in fact create harmful unintended consequences.

Indeed, last year, we announced that we would voluntarily reduce the list price of several of our insulin products in January 2024, including our Levemir® basal insulin, by as much as 75 percent. At that time, I personally cautioned the Committee that reducing list prices could actually harm patients if it resulted in PBMs dropping medications from their "formularies"—because formularies control what prescription drugs are covered by patient insurance and dictate which products patients have access to under their prescription plans.[83] Unfortunately, that is precisely what happened. In 2023, before we lowered the price of Levemir®, it was available on formulary to *90 percent* of U.S. patients with coverage from commercial insurance or Medicare. In 2024, after Novo Nordisk dropped the price, Levemir® was available on formulary to just *36 percent* of those patients. Ultimately, Levemir®'s loss of access to the vast majority of patients in the U.S. was a fundamental consideration in our decision to discontinue the medication.[84]

In short, manufacturer list price cuts may actually have the opposite of the intended effect on patient choice, costs, and access. Thus, to effectively address what patients actually pay at the pharmacy counter for their prescriptions, it is essential to consider the role each actor in the system plays—as this Committee recognized when it called the heads of the three dominant PBMs to testify in May of 2023, alongside myself and the CEOs of Sanofi and Eli Lilly. This is why we have committed to work on *systemic changes* to address these true drivers of cost, and why we have concerns about oversimplifying the full and complex reality of the American healthcare system. Moreover, we are concerned that oversimplification can also turn well-meaning policies into significant unintended consequences that negatively impact patients.

For instance, any such changes must not harm or weaken the incentives for innovation in the American prescription drug ecosystem. Manufacturers are willing to invest significant resources and money in risky moonshots that often take 10 to 15 years to potentially yield any results in no small part because of the strong intellectual property protections the U.S. provides if they succeed. Those incentives also often enable the American people to access groundbreaking therapies like Ozempic® and Wegovy® before anyone else in the world—indeed, the United States

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[82] Benedic N. Ippolito & Joseph F. Levy, *Estimating the Cost of New Treatments for Diabetes and Obesity*, American Enterprise Institute, 2-3 (Sept. 2023), *https*://www.aei.org/wp-content/uploads/2023/09/Estimating-the-Cost-of-New-Treatments-for-Diabetes-and-Obesity.pdf?x91208.

[83] *Examining the Need*, *supra* note 76, at 84 (statement of Lars Fruergaard Jørgensen, CEO of Novo Nordisk).

[84] Of course, Levemir® is no longer under patent, and any biosimilar manufacturer is welcome to create and market a generic version of the insulin.

was the first country to get access to these groundbreaking therapies and remains one of a handful of countries where Wegovy® is sold.

Policymakers considering changes should also take care to ensure that Americans continue to benefit from access to many different choices of medicine. Today, patients in the United States have access to 85% of all of the new medicines launched since 2012. In Europe, by contrast, patients have access to less than 40% of the new medicines launched during the same time period, on average.[85] It is important that American patients and their health care professionals continue to have the ability to choose the therapy that is right for them.

The U.S. system must also continue to benefit from the forces of competition, which are already at work in the GLP-1 market. Today, Novo Nordisk faces significant competition in the GLP-1 market from multiple market participants, including from U.S. pharmaceutical company Eli Lilly. Even more GLP-1 medications are expected to come to market in the coming months and years from several different manufacturers, with analysts predicting that as many as 13 new offerings will progress toward approval over the next five years.[86] At the same time, Novo Nordisk's compound patent on its first GLP-1 medications based on the liraglutide molecule—Victoza® for diabetes and Saxenda® for obesity—has already expired, and one manufacturer launched a generic version of Victoza® this past June.[87]

In due course, as provided by federal law, other manufacturers will be able to produce generic versions of Ozempic® and Wegovy® without having to invest in additional research and development. This will likely have substantial effects on the market. As the FDA has said, "[w]ithin a year of the first generic approval, we often see prices fall by more than 75 percent compared to the brand price."[88] Indeed, we expect substantial competition at the time of generic entry.

The U.S. system also now has a dedicated statutory channel for addressing drug prices in the Medicare program through the Inflation Reduction Act ("IRA"). Based on its duration in the market, and assuming it meets the other statutory criteria established by Congress, Ozempic® is eligible for price negotiation with Medicare under the IRA in less than a year. The federal government is the largest single purchaser of prescription drugs in the world, and those negotiations will likely exert a substantial effect on prices in the commercial insurance market as

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[85] PhRMA, Global Access to New Medicines Report 45 (April 2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

[86] Abigail Beaney, *Obesity: Six trials to watch over the next 12 months*, Clinical Trials Arena (June 20, 2023), https://www.clinicaltrialsarena.com/features/obesity-trials-to-watch/; *see also* Marc Iskowitz, *Why the obesity drug market is about to get a lot more crowded*, Medical Marketing and Media (April 26, 2024), https://www.mmm-online.com/home/channel/why-the-obesity-drug-market-is-about-to-get-a-lot-more-crowded/.

[87] *Teva Announces Launch of Authorized Generic of Victoza® (liraglutide injection 1.8mg), in the United States*, Teva Investor Relations (June 24, 2024), https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2024/Teva-Announces-Launch-of-Authorized-Generic-of-Victoza-liraglutide-injection-1.8mg-in-the-United-States/default.aspx.

[88] Ryan Conrad & Kristin Davis, *Estimating Cost Savings from New Generic Drug Approvals in 2021*, U.S. Food & Drug Admin. 3 (Sept. 2023), https://www.fda.gov/media/172608/download?attachment.

well. At the same time, competing GLP-1 products from Eli Lilly will not be subject to government price-setting under the IRA for another ten years.

As a result of the various market pressures described above—as well as the fact that the net prices of Ozempic® and Wegovy® have already substantially decreased (for Ozempic®, by about 40 percent) since their introduction—any study with cost estimates premised on the idea that our GLP-1 medications will be priced the same ten years from now as they are today in the U.S. are not credible. Such assertions and conclusions run afoul of the general experiences of bringing a biopharmaceutical product to market, and contradict the actual market realities already observable for Ozempic® and Wegovy®.

Novo Nordisk will continue working to ensure that Americans are able to affordably access these groundbreaking medications in the existing system. Our company has already undertaken important affordability initiatives for patients with type 2 diabetes who cannot afford the price of their GLP-1 medicine, including offerings that reduce the price at the pharmacy counter to as little as $25 for a one-month supply of Ozempic® for patients with commercial insurance facing large co-pays—for example, because they have not satisfied their insurance plan's deductible yet. Our Patient Assistance Program provides free Ozempic® to patients in need who are uninsured or receive insurance through Medicare and whose household income falls below 400% of the federal poverty line (approximately $120,000 for a family of four).[89] Since 2019, we have saved nearly 7 million American patients more than $1.7 billion towards our semaglutide products through our Savings Card and e-Voucher programs.

Ultimately, however, the most wide-reaching way that we are working to address patient access and affordability in the United States is by convincing PBMs and insurers to put these new therapies on insurance formularies. This requires us to pay substantial rebates and discounts to the PBMs, and these efforts are working. Currently, Ozempic® is covered by 99 percent of U.S. commercial insurance plans. And Wegovy®, a much newer medication, is already covered by approximately half of all commercial insurance plans, as well as 21 state Medicaid plans, the Department of Veterans Affairs, the Indian Health Service, military healthcare, and plans for federal employees—with the majority of patients with insurance coverage for Wegovy® paying $25 or less per 28-day supply.

Unfortunately, the same prejudicial stigma that attaches to people living with obesity has reared its head in the national debate about whether these same patients should have their medication covered by basic commercial insurance or Medicare. This would be unthinkable for patients living with any other serious chronic disease.

Novo Nordisk is confident that even more insurers will cover our GLP-1 medications in the coming months and years. Plan sponsors will not be able to ignore the cost savings and lifetime benefits accruing to patient health that make the medications a tremendous value. We remain confident that Medicare will ultimately see this value as well. As Milliman found in a February

[89] *See* NovoCare, *Patient Assistance Program*, Novo Nordisk (accessed April 30, 2024), https://www.novocare.com/diabetes/help-with-costs/pap.html.

2024 report, Medicare stands to see cost savings of as much as $5.8 billion over ten years from covering anti-obesity medicines like Wegovy®.[90]

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Novo Nordisk is proud of the work that our scientists, researchers, and personnel have done to advance innovation and to improve the lives of people with chronic diseases, including diabetes and obesity. And I am proud to be here today to represent them. We are humbled to see how Ozempic® and Wegovy® have already helped so many Americans, and we agree that affordable access to these important treatments is essential for patients in Medicare, Medicaid, and the commercial markets. Novo Nordisk remains committed to working with policymakers to advance solutions that support access and affordability for all patients.

I look forward to answering your questions and engaging in meaningful discussions on these important topics.

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[90] Maddie Cline et al., *Milliman Report: Impact of Anti-Obesity Medication Coverage in Medicare Part D*, Milliman 1, 7 (Feb. 23, 2024), https://www.milliman.com/-/media/milliman/pdfs/2024-articles/3-6-24_impact-of-covering_anti-obesity-medications-in-medicare-part-d.ashx (even in the most conservative, high-uptake scenario modeled by Milliman, Medicare would see increased costs of 75 cents per member per month).