



# The Pharmacist Activist

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**“Wait for the Lord; be strong and take heart and wait for the Lord.”** Psalm 27:14

Editorial

## Are the GLP-1s the Drugs that will Cause the Collapse of the Already Unsustainably Costly Drug Development and Distribution System? **THE U.S. CAN'T AFFORD THE GLP-1s!**

If you are not familiar with the relationship between the venom of Gila Monsters and the actions and development of the glucagon-like peptide-1 (GLP-1) receptor agonists, I urge you to locate the story and read it. It is a remarkable example of what can be accomplished with the integration of curiosity, observation, research, and clinical trials.

The GLP-1s were initially studied and determined to be effective in the treatment of patients with type 2 diabetes. Exenatide (Byetta) was the first GLP-1 to be approved and marketed. It is administered subcutaneously twice a day. Research programs were focused on the development of longer-acting GLP-1 analogs/formulations that could be administered less frequently. In addition to an extended-release formulation of exenatide (Bydureon) that is administered subcutaneously once a week, new analogs such as liraglutide (Victoza; administered once a day) and dulaglutide (Trulicity; administered once a week) were approved and marketed.

The rapidly increasing use of the GLP-1s in patients with diabetes quickly revealed that the drugs provided additional

benefits. Among these was that the drugs could reduce the risk of occurrence of problems in patients with cardiovascular diseases that are also commonly experienced in patients with diabetes. The labeled indications for several of the agents were expanded to include this benefit. Also of great interest were the observations and experience that use of these medications caused substantial weight loss that exceeded that attainable with any other medications.

The approval of semaglutide injection (Ozempic – Novo Nordisk) in 2017 corresponded with the sharp increase in the interest and studies of this and other GLP-1s in reducing excess body weight in patients who were overweight or obese and had diabetes or other weight-related comorbid conditions. Extensive media publicity greatly increased consumer awareness.

In 2022, tirzepatide (Mounjaro – Lilly) was approved for the treatment of patients with diabetes. In addition to its GLP-1 receptor agonist action, tirzepatide is also a glucose-dependent insulinotropic polypeptide (GIP) receptor agonist. Semaglutide (Ozempic) and tirzepatide (Mounjaro) are ad-

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ministered subcutaneously once a week. The properties of the two agents are general similar, but there are also differences and they are not interchangeable. Nevertheless, some PBMs and other organizations with formularies have deceptively overlooked the differences and negotiated a better price with one of the two companies and placed its drug on the preferred list on their formulary. Why don't the Boards of Pharmacy, the FDA, and other regulatory agencies take action when organizations steer patients and prescribers to the use of a drug that is similar, but different, than the one initially prescribed?

The GLP-1s frequently cause gastrointestinal adverse events (20%-40%) and their use is initiated with a low dosage that is titrated upwards to reduce the frequency and severity of these effects. Almost overlooked in the excitement regarding the value of these agents is that they all include a boxed warning in their labeling regarding the risk of thyroid C-cell tumors. The GLP-1s are also implicated in certain other adverse events and drug interactions. The labeled indication for each of the agents includes a provision such as it is to be used in combination with a reduced-calorie diet and increased physical activity.

### **THE COSTS ARE UNCONSCIABLE!**

The list prices for the GLP-1s are more than \$1,000 for a one-month supply. The initial list prices, which are periodically increased, were established when the drugs were initially approved for the treatment of patients with diabetes. Typically used in combination with other antidiabetic agents, their unique mechanism of action and effectiveness have resulted in their being prescribed for millions of patients with diabetes. Even before their approval for weight loss, semaglutide and tirzepatide became revenue "blockbusters" for their manufacturers, Novo Nordisk and Lilly, respectively, who are fierce competitors for the dominant position in the marketplace. But a much greater economic impact was looming!

Tens of millions of Americans are overweight or obese. The increasing publicity about the unprecedented effectiveness of the GLP-1s in reducing excess body weight resulted in huge public demand for the off-label prescribing of these agents (regardless of whether individuals had diabetes) or access through other means, legal and illegal. Chaos ensued!

- Demand far exceeded supplies and manufacturer shortages of the drugs persisted for months.
- Certain PBMs paid pharmacists LESS than pharmacists paid to obtain the medications. How can such a situation not be recognized as illegal when the PBMs, Lilly, and Novo Nordisk are receiving more than \$1,000 for a 30-

day supply of the drugs?

- Licensed pharmacies were authorized to compound the products to address shortages.
- Illegal, unlicensed "pseudo-pharmacies" and other online sources of the medications proliferated. The quality, contents, effectiveness, and safety of these products are unassessed and unknown, and place purchasers at risk. Counterfeit products are pervasive!
- The medications are "prescription" drugs but are widely available and used without a prescription.
- The FDA is almost paralyzed in attempting to monitor the quality and safety of the products that are not prepared by Lilly, Novo Nordisk, and licensed pharmacies that compound the products. It is overwhelmed by the demand and supplies from so many illegal and other questionable sources.
- Lilly and Novo Nordisk are not satisfied with the tens of billions of dollars they have already generated from these products. They want a larger portion of the revenues and have established their own "Direct" programs that bypass the local pharmacists and the counseling and services they can provide.
- When Lilly and Novo Nordisk were able to produce sufficient supplies of the medications to meet the demand, they insisted that the FDA and the pharmacies that compounded these products under the authorization of a "shortage" situation to discontinue doing so. Some pharmacists stopped and others did not. Because they were willing to address a "shortage" situation when it was advantageous for all parties, they should be permitted to continue to do so and provided immunity against challenges.
- The drugs are unprecedented in their effectiveness in helping patients reduce excess weight. This fact, coupled with greed, profit, and demand has obscured attention to product quality, safety issues, and risks. The "system" is out of control and widely violated and abused!
- Who should pay for the drugs? In recognition of the cost and anticipated demand for the drugs, some employer, union, and other prescription benefit plans declined to cover the drugs. Some plans covered the drugs with traditional coverage or in a "hybrid" shared coverage program. Some of these programs continue whereas others have been too costly and discontinued. Because so many of the individuals who are candidates for being prescribed a GLP-1 have Medicare Part D coverage, there

has been an expectation/demand by many that Medicare cover the costs. However, it was quickly recognized that the anticipated use and costs would bankrupt the program, and other alternatives are being considered.

### Continued approvals, off-label use, and chaos

As the weight loss action of the GLP-1s was capturing the greatest interest and had the potential for greatly expanded use and revenue, Lilly and Novo Nordisk devoted most of its research and development efforts to this area. Semaglutide was the first GLP-1 to be approved for the additional indication of reducing excess body weight, and Novo Nordisk developed new formulations that it distributed under the new trade name Wegovy to distinguish them from Ozempic formulations that were primarily indicated for the treatment of patients with diabetes.

Soon thereafter, tirzepatide was approved for the additional indication of reducing excess body weight, and Lilly developed new formulations that it distributed under the new trade name Zepbound to distinguish them from Mounjaro products. The Zepbound formulations and the initial Wegovy formulations are administered subcutaneously once a week. The two products have not been directly compared in clinical trials, and the fierce competition between the two corporate giants is intensive.

Notwithstanding the unprecedented demand and success for the subcutaneously administered formulations of the GLP-1s, many patients who are candidates for use of the GLP-1 drugs are needle-phobic. Novo Nordisk had developed an orally-administered formulation of semaglutide (with the trade name Rybelsus) for the treatment of patients with diabetes. When the FDA approved the tablet formulation to reduce excess body weight, Novo Nordisk brought the product to the market under the trade name Wegovy tablets, and discontinued the Rybelsus name.

On April 1, 2026, the FDA approved orforglipron (Foundayo – Lilly) tablets, a new GLP-1, for oral administration to reduce excess body weight. Both Foundayo and Wegovy tablets are administered once a day for this indication, but the two products have not been directly compared in clinical trials. The two oral products have different instructions for administration to assure optimal use.

Research studies conducted by Lilly and Novo Nordisk have provided documentation of effectiveness sufficient for FDA approval for additional indications. Zepbound has been approved for the treatment of obstructive sleep apnea in adults with obesity. Wegovy has been approved for the treatment of noncirrhotic metabolic dysfunction associated steatohepatitis (MASH). In addition to the tens of millions of individu-

als who are already treated or who are candidates for treatment with the GLP-1s for diabetes, overweight/obesity, and to reduce the risk of major cardiovascular events, the new indications increase by millions more the patient population of individuals who might benefit from their use.

And the successful research and development of additional GLP-1s and combination products continue unabated. The use of the medications by millions of individuals for whom they have been prescribed plus clinical studies have revealed potential additional uses, and some very preliminary observations have prompted some to suggest that they may even have benefit in conditions like cancers and Alzheimer's dementia. Retatrutide is a promising investigational GLP-1, that has two additional mechanisms of action. It is not yet approved by the FDA but is widely available from illegal sources. As the uses and products increase, so does the cost of using the GLP-1s.

The financial challenges for prescription benefit programs that include the GLP-1s for weight loss are already overwhelming. Millions of people want them but few are able to pay for them without financial assistance, and prescription drug plans either don't cover them, or cover them to the minimum extent possible. If there has been any common focus in response to the challenges, it has been, "Medicare should cover them" for the tens of millions of individuals in that program. However, the Medicare outpatient prescription drug benefit program (Part D) has prohibited coverage of drugs for weight loss. The unprecedented effectiveness of the GLP-1s for reducing excess body weight, and the demand and pressure from patients, sponsors, payors, administrators, and everyone else who is responsible for some of the cost of the coverage for the drugs, has resulted in legislators and health agency officials reconsidering the Medicare policy.

The Medicare Part D program already covers the GLP-1s when they are prescribed for the treatment of diabetes, and certain other situations. However, the recognition of their effectiveness in reducing weight has resulted in an exponential increase in the number of individuals who can benefit from their use. However, covering them for weight loss in patients who do not have a diagnosis of diabetes or another labeled indication would violate the Part D policy. The demands and pressures continued.

The Centers for Medicare and Medicaid Services (CMS) planned a demonstration project designated as BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive Health) in which a GLP-1 would be integrated for patients meeting certain criteria. However, in April it was announced that the implementation of the BALANCE program was being postponed. Instead, the GLP-1 Bridge

program was announced, to start on July 1, 2026 and to continue through December 31, 2027. The CMS press release includes the following statements:

“Eligible Medicare beneficiaries may now get certain GLP-1 medications for \$50 per month through the Medicare GLP-1 Bridge, a new CMS initiative to expand access to innovative treatments and test the impacts of increased access to GLP-1 drugs for weight management on the Medicare program.”

“Through the Medicare GLP-1 Bridge, eligible individuals enrolled in the Medicare Part D prescription drug coverage can obtain certain GLP-1 medications to lose weight or maintain weight reduction at a predictable and affordable cost of \$50 per month.”

“Not all Medicare beneficiaries will qualify for the Medicare GLP-1 Bridge, including individuals who already receive GLP-1 medications through their existing Medicare prescription drug coverage or are eligible for GLP-1 coverage through the Medicare Part D benefit.”

Although participants must be enrolled in the Medicare Part D prescription drug coverage, the Bridge program is operated completely apart from Medicare Part D. This increases the difficulty in understanding, determining patient eligibility, and implementing the program. There will probably be a slow uptake in participation as these questions are addressed. It is likely that unscrupulous individuals who attempt to exploit/circumvent or cheat the program have already determined ways to do that.

The Bridge program is complex, cumbersome, and confusing. Time will tell whether the Medicare Bridge program is successful, is a Bridge vulnerable to collapse, or is a Bridge to calamity.

## THE U.S. CAN'T AFFORD THE GLP-1s WITH CURRENT POLICIES AND PROGRAMS!

Lilly and Novo Nordisk deserve to be considered “heroes” for their innovative research and development of medica-

tions that are so highly effective for multiple conditions. Instead, because of the greed and obsession with profit of these companies, many view them as “villains!”

### Are there alternatives?

The availability of the GLP-1s has caused the prescription drug distribution and use system to spiral out of control. It will become even worse unless other measures are taken. My recommendations include one or more of the following:

**Price controls:** The list prices of the GLP-1s are more than \$1,000 for a one-month supply. I recommend that the federal government take action to limit the list prices to \$100 for a 30-day supply.

**Benefit programs:** Federal and commercial prescription benefit programs should not cover the GLP-1s when prescribed to reduce excess body weight in patients who do not have a diagnosis of diabetes or another weight-related comorbid condition.

**Exercise and diet:** The labeling for the GLP-1s specify that they are to be used in combination with a reduced calorie diet and increased physical activity. Federal and commercial prescription benefit programs should only cover GLP-1s to reduce excess body weight in patients who observe dietary restrictions and exercise recommendations, and whose participation in such programs can be verified.

**Nonprescription status:** Many individuals now obtain GLP-1s without a prescription (or appropriate clinical evaluation for benefit or risk), mostly from illegal online sources. For practical purposes, millions are using these agents now without meeting with a physician or other prescriber, or a pharmacist. The GLP-1 agonists should be switched from prescription-only to nonprescription availability from a pharmacist. The products will then not be covered by prescription drug programs and the prices will have to be sharply reduced to be competitive in the nonprescription marketplace.

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