

[Open Peer Review on Qeios](#)

# Examining Off-Label Prescribing of Ozempic for Weight-Loss

Magda Wojtara<sup>1</sup>, Yusra Syeda<sup>2</sup>, Nikodem Mozgala<sup>3</sup>, Ashmita Mazumder<sup>4</sup>

<sup>1</sup> University of Michigan - Ann Arbor

<sup>2</sup> Toronto Metropolitan University

<sup>3</sup> Jan Kochanowski University

<sup>4</sup> University of Toronto

**Funding:** No specific funding was received for this work.

**Potential competing interests:** No potential competing interests to declare.

## Abstract

Ozempic (semaglutide) is a US Food and Drug Administration (FDA) approved medication for the treatment of type 2 diabetes and more recently has been utilized in the management of chronic weight management in some patients. It belongs to a broader class of medications called glucagon-like peptide-1 (GLP-1) receptor agonists which help to lower the blood sugar levels of individuals with type 2 diabetes. There has been growing recent interest, especially on social media platforms such as Tik Tok, about the use of Ozempic for weight loss. While Ozempic has shown promising results in clinical trials for weight loss, there are several potential risks and concerns associated with its use. There is a lack of adequate long-term safety data on its use specifically for weight loss. Growing concerns around Ozempic include its potential misuse without proper medical supervision or its prescription off-label for weight loss leading to prescription shortages. Both of these are pressing concerns surrounding the use of this medication without medical need and ultimately resulting in risky and unnecessary medical interventions. Further study is needed in order to assess and communicate the long-term effects of Ozempic for weight loss, and health policy changes to ensure safe access.

**Magda Wojtara<sup>1,\*</sup>, Yusra Syeda<sup>2</sup>, Nikodem Mozgala<sup>3</sup>, Ashmita Mazumder<sup>4</sup>**

<sup>1</sup> *BS. Department of Human Genetics, University of Michigan Medical School; ORCID: 0000-0001-6903-0206; Email: [wojtaram@umich.edu](mailto:wojtaram@umich.edu); Ann Arbor, United States*

<sup>2</sup> *Daphne Cockwell School of Nursing, Toronto Metropolitan University; Toronto, Canada*

<sup>3</sup> *Collegium Medicum, Jan Kochanowski University; Kielce, Poland*

<sup>4</sup> *Department of Psychology, University of Toronto; Toronto, Canada*

**\*Corresponding author**

**Keywords:** ozempic, off-label medication, health policy, medical education, weight loss.

## Introduction

Ozempic, also known as semaglutide, was FDA approved in 2017 for the treatment of type 2 diabetes in adults. However, it has recently risen in prevalence as individuals have shown that Ozempic can also lead to significant weight loss in patients with and without diabetes. In a clinical study, subjects taking 1mg/week of Ozempic lost nearly 10 pounds over 30 weeks, nearly 5% of their body weight, and a waist shrinkage of 1.6 inches (Sorli et al., 2017). The use of Ozempic, off-label for weight management, was further popularized via social media (Shmerling, 2023). It is believed that Ozempic induces weight loss mechanistically through delayed gastric emptying, mimicking glucagon-like-peptide-1 (GLP-1), reducing liver fat, and improving insulin sensitivity. In June 2021, the FDA approved Wegovy, a higher-dose formulation of semaglutide compared to Ozempic, for weight management. However, Wegovy has recently undergone a shortage which has led Ozempic to be utilized off-label by individuals seeking to lose weight (Shmerling, 2023). Physicians may prescribe a drug off-label in order to take advantage of new treatment approaches before FDA approval, but this is without the benefit of an FDA-reviewed analysis of safety and effectiveness data (Congressional Research Service, 2023). However, the off-label prescribing of Ozempic may interfere with the availability of Ozempic for individuals with diabetes. As of this article, the hashtag #ozempic on Tik Tok has 931.8 million views and it is rapidly becoming associated as a “vanity” medication rather than a critical treatment for individuals with diabetes. Many are also troubled by social media platforms heralding Ozempic as a quick, cosmetic weight loss drug when it is, in fact, for long-term use as discontinuation can result in weight gain. A recent study found one year after the withdrawal of once-weekly Wegovy (2.4mg) and lifestyle intervention that participants regained two-thirds of their prior weight loss, with similar changes in cardiometabolic variables (Wilding et al., 2022).

## Off-Label Prescribing and Reduced Availability

Off-label drug use is defined as drug use for an unapproved indication, population, or dosage (Hendricks, 2017). The use of Ozempic as a weight-loss drug has risen due to online popularity. As obesity is a major factor in contributing to type 2 diabetes, Ozempic has major implications for managing both diseases. In obese individuals, insulin resistance is increased due to hormones, cytokines fatty acids, and other markers (Al-Goblan et al., 2014). Weight reduction is encouraged to reduce these markers to improve insulin sensitivity (Al-Goblan et al., 2014). Although weight loss can aid in obesity and type 2 diabetes, the risks of the potential complications of off-label use of Ozempic can be a concern. Patients who received semaglutide for weight loss had significant loss in body weight compared to those who received a placebo (Wilding et al., 2021). Initially, researchers have concluded that the long-term effect of GLP-1s have not been studied and remains unknown (Baggio and Drucker, 2007). However, after several years of clinical trials, semaglutide has been studied extensively.

With off-label prescribing, there is a potential for harm and adverse effects and patients can be exposed to unknown risks. Informed consent is also compromised, as patients may not have all the information needed to make well-informed medical decisions for treatment. While off-label prescribing can provide patients with alternative options that may be better

suited for them, there are some drawbacks for individuals who rely on Ozempic for its prescribed, FDA-approved utilization. As demand inevitably increases with off-label prescribing, a shortage of Ozempic is likely, and those with type 2 diabetes may struggle to access the medication. Thus it is up to healthcare providers to understand and evaluate each patient for an appropriate prescription ([Hendricks, 2017](#)).

## Alternative Medications To Ozempic

Liraglutide (Saxenda), Phentermine/Topiramate (Qsymia), and Orlistat (Xenical) are alternative medications prescribed for weight loss. Liraglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist that promotes satiety and reduces appetite. It is available in doses of 0.6mg, 1.2 mg, and 1.8mg per day, injected subcutaneously. Weight loss is dose-dependent; however, a mean reduction of -2.3kg has been recorded ([Dharmalingam et al., 2011](#)). Phentermine/Topiramate is a combination medication that suppresses appetite and increases feelings of fullness. Phentermine is a sympathomimetic amine that acts centrally as an appetite suppressant, while topiramate is an anticonvulsant drug that can also reduce appetite. The typical starting dose is phentermine 3.75 mg/topiramate 23 mg, gradually increasing over a few weeks to the recommended dose of phentermine 7.5 mg/topiramate 46 mg ([Cosentino et al., 2013](#)). Clinical trials have shown that phentermine and topiramate treatment can result in significant weight loss, with an average of around 5–15% over a year ([Cosentino et al., 2013](#)). Orlistat is a lipase inhibitor that works by preventing the absorption of dietary fats. It is available in doses of 10mg, 60mg, 120 mg, and 240 mg three times daily. Orlistat has been found to lead to modest weight loss, with studies indicating an average reduction of -3.19 kg after 1 and 2 years ([O'Meara et al., 2004](#)).

In comparison to semaglutide (Ozempic), which is also a GLP-1 receptor agonist, liraglutide has a similar mechanism of action. Both medications increase satiety and reduce appetite. However, semaglutide has been found to be more efficacious than liraglutide in weight loss. Clinical trials have shown that semaglutide can lead to an average weight loss of around -4.53kg after a 30-week period in comparison to an average of -2.3kg after 52 weeks which is higher than the weight loss observed with liraglutide. Liraglutide and semaglutide are known to cause gastrointestinal adverse effects such as nausea, vomiting, and diarrhea ([Dharmalingam et al., 2011](#)). Phentermine/topiramate may induce dry mouth, constipation, paresthesias of the extremities, and insomnia as side effects. Orlistat can lead to gastrointestinal side effects such as oily spotting, flatulence, and urgency to urinate. It is important to note that, due to their effects on decreasing blood sugar, liraglutide and semaglutide are approved for the treatment of type 2 diabetes. Orlistat and phentermine/topiramate, on the other hand, are not recommended for the management of diabetes. All of these medications can contribute to weight loss, but their efficacy, dosages, expected results, and adverse effects may vary.

## Social Media's Impact On Off-Label Prescribing

Social media platforms have opened channels for communication and dissemination of information online ([Vrontis et al., 2021](#)). A fairly recent avenue of marketing, known as influencer marketing, utilizes an individual's presence on social media for advertisement and endorsement of their product ([Jin et al., 2019](#)). Included in this category of influencers are

“patient influencers” who work with pharmaceutical companies to leverage the patient experience and expertise for the design, development, and promotion of their products and services ([WEGO Health, 2023](#)). Patient influencers aim to increase awareness and promote education on that particular disorder/disease by sharing experiences of their own ([Willis and Delbeare, 2022](#)). Pharmaceutical companies often garner little trust, however, by involving patient influencers they are able to separate the product from the brand to allow for better results ([Singh et al., 2023](#)). In fact, past research has reported that 44% of patients who requested medication advertised to them were then prescribed to them by their physician ([Willis and Delbeare, 2022](#)). Patient influencers often share their experiences on social media allowing for public conversation and debate on the topic. However, this practice often increases the chances of spreading misinformation and malpractice. A multitude of factors such as health literacy and scientific communication strategies may determine the understanding of the medication and its use. For example, in the context of Ozempic, individuals taking this medication off-label for weight loss experienced serious side effects such as diarrhea, nausea, and extreme facial thinning ([Singh et al., 2023](#)). Its popularity among patients especially on social media platforms such as TikTok, Twitter, and Instagram garnered attention and others were quick to notice the effects of the drug especially on appetite and weight loss ([Singh et al., 2023](#)). This shift in focus was undoubtedly one of the driving factors for the use of this drug for weight loss instead of diabetes and the shortage that followed.

Additionally, the exposure of Ozempic as a weight loss drug was exacerbated when popular celebrities were suspected to be using it. For example, the use of Ozempic by popular reality-tv celebrities further established the off-label use of this medication. Social media exposure of such kind has been linked to psychological disorders such as body dysmorphia, anorexia nervosa, and bulimia ([Becker, 2004](#)). Hence, it calls into question the effectiveness of social media marketing. It is important to consider the important role that social media/patient influencers played in presenting a drug, originally intended and marketed for patients with type-2 diabetes, as a miracle off-label drug for weight loss. While recent research has started to address these issues, we are nowhere closer to resolution. Pharmaceutical companies must address and control the impact their medication has on the general public by ensuring their patient influencers are given the necessary education and resources to successfully communicate the scope of the drug. In addition, further care must be taken to oversee the content created and shared by the influencers. Misinformation must be tackled with care and patient testimonials when applicable.

## Policy Implications

As a result of soaring demand, several insurance companies have imposed restrictions on access for both Ozempic and Wegovy. Many insurers are denying prior authorization requests for patients unless they have completed diet and exercise programs or tried other lower-cost drugs before semaglutide. Many healthcare professionals also encourage diet and exercise improvements in order to further health benefits on or off-Ozempic. Despite this, pharmaceutical companies know that many patients are still willing to pay approximately \$13,000 USD/yr out-of-pocket since it would not be covered under several insurance plans ([Modern Healthcare, 2023](#)). Prescribing of GLP-1s are up 152% from just a year ago ([Modern Healthcare, 2023](#)). Many uninsured or lower-income women, Black adults, and Hispanic adults have high rates

of obesity and would stand to benefit the most from significant weight loss, but are unable to access these costly medications ([NBC News, 2023](#)). The high out-of-pocket cost is unsustainable long-term for many. Some patients are turning to compounding pharmacies that can make generic semaglutide for \$300/month ([ABC News, 2023](#)). Compounding pharmacies are not without their own risks. According to the FDA, these medications are eligible for compounding given recent shortages, but the compounded versions “pose a higher risk” due to a lack of pre-market review ([ABC News, 2023](#)).

In the United States, Eli Lilly manufactures Mounjaro which performs a similar function to Ozempic and recently indicated plans for FDA approval for weight loss by the end of this year ([Good Morning America, 2023](#)). Outside of the US, Wegovy was recently approved in the United Kingdom for weight-loss ([Cosmopolitan UK, 2023](#)). However, online pharmacies in the United Kingdom have faced criticism for filling prescriptions for Ozempic for a reporter with a BMI of 20, while the drug should be discontinued once a patient’s BMI is below 27 ([The Guardian, 2023](#)). The availability of these drugs, without stringent health checks, is another cause for high concern.

## Concluding Thoughts

Semaglutide has been promising for treating type 2 diabetes. There are, like all drugs, potential concerns for users. For instance, during a clinical trial, the progression and worsening of diabetic retinopathy emerged ([Berkovic and Strollo, 2023](#)). But, when it is prescribed under advised conditions, semaglutide appears to be beneficial for its intended use. Regardless, effective weight-management programs should be individualized and personalized. Patients may have other coexisting conditions, different drug tolerance, and differing economic conditions. Further studies should be conducted to draw more direct comparisons between different types of drugs prescribed for this purpose, and the efficacy of various lifestyle interventions in isolation or in tandem with these drugs.

## Bibliography

- ABC News. “Woman Shares How She Afforded a Drug for Weight Loss after Being Denied by Insurance.” ABC News. Accessed May 21, 2023. <https://goodmorningamerica.com/wellness/story/high-cost-drugs-weight-loss-ozempic-mounjaro-users-99424157>.
- ———. “Woman Shares How She Afforded a Drug for Weight Loss after Being Denied by Insurance.” ABC News. Accessed May 21, 2023. <https://goodmorningamerica.com/wellness/story/high-cost-drugs-weight-loss-ozempic-mounjaro-users-99424157>.
- Al-Goblan, Abdullah S, Mohammed A Al-Alfi, and Muhammad Z Khan. “Mechanism Linking Diabetes Mellitus and Obesity.” *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy* 7 (December 4, 2014): 587–91. <https://doi.org/10.2147/DMSO.S67400>.
- Baggio, Laurie L., and Daniel J. Drucker. “Biology of Incretins: GLP-1 and GIP.” *Gastroenterology* 132, no. 6 (May 2007): 2131–57. <https://doi.org/10.1053/j.gastro.2007.03.054>.

- Becker, Anne E. "Television, Disordered Eating, and Young Women in Fiji: Negotiating Body Image and Identity during Rapid Social Change." *Culture, Medicine and Psychiatry* 28, no. 4 (December 2004): 533–59. <https://doi.org/10.1007/s11013-004-1067-5>.
- Bodie, Agata. "Off-Label Use of Prescription Drugs." Congressional Research Service, February 23, 2021. <https://crsreports.congress.gov/product/details?prodcode=R45792>.
- Cigrovski Berkovic, Maja, and Felice Strollo. "Semaglutide-Eye-Catching Results." *World Journal of Diabetes* 14, no. 4 (April 15, 2023): 424–34. <https://doi.org/10.4239/wjd.v14.i4.424>.
- Cosentino, Gina, Ariane O Conrad, and Gabriel I Uwaifo. "Phentermine and Topiramate for the Management of Obesity: A Review." *Drug Design, Development and Therapy* 7 (April 5, 2011): 267–78. <https://doi.org/10.2147/DDDT.S31443>.
- ———. "Phentermine and Topiramate for the Management of Obesity: A Review." *Drug Design, Development and Therapy* 7 (April 5, 2011): 267–78. <https://doi.org/10.2147/DDDT.S31443>.
- Cosmopolitan. "What You Need to Know about the Controversial 'skinny Jab' Approved for UK Use," March 8, 2023. <https://www.cosmopolitan.com/uk/body/health/a42877585/skinny-jab-uk-pharmacies/>.
- Davis, Nicola, and Nicola Davis Science Correspondent. "Online UK Pharmacies Prescribing Weight Loss Jabs to People with Healthy BMI." *The Guardian*, May 10, 2023, sec. Society. <https://www.theguardian.com/society/2023/may/10/online-uk-pharmacies-prescribing-weight-loss-jabs-to-people-with-healthy-bmi-investigation>.
- ———. "Online UK Pharmacies Prescribing Weight Loss Jabs to People with Healthy BMI." *The Guardian*, May 10, 2023, sec. Society. <https://www.theguardian.com/society/2023/may/10/online-uk-pharmacies-prescribing-weight-loss-jabs-to-people-with-healthy-bmi-investigation>.
- Dharmalingam, Mala, Usha Sriram, and Manash P. Baruah. "Liraglutide: A Review of Its Therapeutic Use as a Once Daily GLP-1 Analog for the Management of Type 2 Diabetes Mellitus." *Indian Journal of Endocrinology and Metabolism* 15, no. 1 (2011): 9–17. <https://doi.org/10.4103/2230-8210.77571>.
- Good Morning America. "Popular Diabetes Drug Mounjaro Could Be FDA-Approved for Weight Loss This Year, Company Says." Good Morning America. Accessed May 21, 2023. <https://www.goodmorningamerica.com/wellness/story/popular-diabetes-drug-mounjaro-fda-approved-weight-loss-98882665>.
- ———. "Popular Diabetes Drug Mounjaro Could Be FDA-Approved for Weight Loss This Year, Company Says." Good Morning America. Accessed May 21, 2023. <https://www.goodmorningamerica.com/wellness/story/popular-diabetes-drug-mounjaro-fda-approved-weight-loss-98882665>.
- Hendricks, Ed J. "Off-Label Drugs for Weight Management." *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy* 10 (June 10, 2017): 223–34. <https://doi.org/10.2147/DMSO.S95299>.
- Jin, S. Venus, Aziz Muqaddam, and Ehri Ryu. "Instafamous and Social Media Influencer Marketing." *Marketing Intelligence & Planning* 37, no. 5 (July 19, 2019): 567–79. <https://doi.org/10.1108/MIP-09-2018-0375>.
- MD, Robert H. Shmerling. "What Happens When a Drug Goes Viral?" Harvard Health, February 21, 2023. <https://www.health.harvard.edu/blog/what-happens-when-a-drug-goes-viral-202302212892>.

- Modern Healthcare. “Insurers, PBMs Restrict Access to Weight Loss Drugs as Demand Soars,” May 11, 2023. <https://www.modernhealthcare.com/insurance/pbms-insurers-ozempic-wegovy-weight-loss-drug-access-cigna-centene>.
- NBC News. “As Weight Loss Drugs Soar in Popularity, Many Who Could Benefit Can’t Get Them,” February 2, 2023. <https://www.nbcnews.com/health/health-news/ozempic-wegovy-weight-loss-drugs-demand-soars-rcna68425>.
- O’Meara, S., R. Riemsma, L. Shirran, L. Mather, and G. Ter Riet. “A Systematic Review of the Clinical Effectiveness of Orlistat Used for the Management of Obesity.” *Obesity Reviews* 5, no. 1 (February 2004): 51–68. <https://doi.org/10.1111/j.1467-789X.2004.00125.x>.
- ———. “A Systematic Review of the Clinical Effectiveness of Orlistat Used for the Management of Obesity.” *Obesity Reviews* 5, no. 1 (February 2004): 51–68. <https://doi.org/10.1111/j.1467-789X.2004.00125.x>.
- Singh, Yashaswini, Matthew D. Eisenberg, and Neeraj Sood. “Factors Associated With Public Trust in Pharmaceutical Manufacturers.” *JAMA Network Open* 6, no. 3 (March 14, 2023): e233002. <https://doi.org/10.1001/jamanetworkopen.2023.3002>.
- Sorli, Christopher, Shin-Ichi Harashima, George M. Tsoukas, Jeffrey Unger, Julie Derving Karsbøl, Thomas Hansen, and Stephen C. Bain. “Efficacy and Safety of Once-Weekly Semaglutide Monotherapy versus Placebo in Patients with Type 2 Diabetes (SUSTAIN 1): A Double-Blind, Randomised, Placebo-Controlled, Parallel-Group, Multinational, Multicentre Phase 3a Trial.” *The Lancet. Diabetes & Endocrinology* 5, no. 4 (April 2017): 251–60. [https://doi.org/10.1016/S2213-8587\(17\)30013-X](https://doi.org/10.1016/S2213-8587(17)30013-X).
- Vrontis, Demetris, Anna Makrides, Michael Christofi, and Alkis Thrassou. “Social Media Influencer Marketing: A Systematic Review, Integrative Framework and Future Research Agenda.” *International Journal of Consumer Studies* 45, no. 4 (July 2021): 617–44. <https://doi.org/10.1111/ijcs.12647>.
- WEGO Health. “About.” Accessed May 21, 2023. <https://www.wegohealth.com/company-info/about/>.
- Wilding, John P. H., Rachel L. Batterham, Melanie Davies, Luc F. Van Gaal, Kristian Kandler, Katerina Konakli, Ildiko Lingvay, et al. “Weight Regain and Cardiometabolic Effects after Withdrawal of Semaglutide: The STEP 1 Trial Extension.” *Diabetes, Obesity & Metabolism* 24, no. 8 (August 2022): 1553–64. <https://doi.org/10.1111/dom.14725>.
- Wilding, John P.H., Rachel L. Batterham, Salvatore Calanna, Melanie Davies, Luc F. Van Gaal, Ildiko Lingvay, Barbara M. McGowan, et al. “Once-Weekly Semaglutide in Adults with Overweight or Obesity.” *New England Journal of Medicine* 384, no. 11 (March 18, 2021): 989–1002. <https://doi.org/10.1056/NEJMoa2032183>.
- Willis, Erin, and Marjorie Delbaere. “Patient Influencers: The Next Frontier in Direct-to-Consumer Pharmaceutical Marketing.” *Journal of Medical Internet Research* 24, no. 3 (March 1, 2022): e29422. <https://doi.org/10.2196/29422>.
- ———. “Patient Influencers: The Next Frontier in Direct-to-Consumer Pharmaceutical Marketing.” *Journal of Medical Internet Research* 24, no. 3 (March 1, 2022): e29422. <https://doi.org/10.2196/29422>.