

The Ethical Concerns of Improper Semaglutide Administration After Acquisition From A Compounded Pharmacy

Syed Basit Haider, Renu Eugene Thomas, E'Joven Davon Reed, Aneesha Shaju, Bushra Bangash, Jakob Schnell, Edrianna Ablola.

Background

- Semaglutide is a once weekly diabetes therapy introduced as an alternative to daily liraglutide.
- Semaglutide was initially trialed in 2008. Then in 2012 by the pharmaceutical company Novo Nordisk. Clinical trials concluded in 2017 with a Phase 3 randomized, double-blind, trial assessing its efficacy vs placebo alongside lifestyle and diet changes.
- A 2022 review of anti-obesity treatments found that Semaglutide as well as tirzepatide (which has an overlapping mechanism of action) were more promising than previous anti-obesity drugs, although less effective than bariatric surgery.
- The FDA approved Semaglutide for T2DM in 2017. Ozempic was approved in 2017. Sept 2019 for Rybelsus and 2021 for Wegovy. Mounjaro (for type 2 diabetes) and Zepbound (for weight loss) — in May 2022 and November 2023, respectively.

Case Description

A 31-year-old F with PMH of obesity presented with intractable nausea and vomiting. Pt was initiated on Semaglutide injections for weight loss by her PCP, however, given prohibitive costs and supply chain issues pt had not initiated her medication until a month later after purchasing from a compounding pharmacy. Her PCP sent instructions via text message after explaining in person at her initial evaluation. Pt was meant to initiate at 5 units (0.25mg/0.05ml) SQ, however mistakenly injected 50 units (2.5mg/0.5ml) after misreading the text message.

Concerns of Compounded Semaglutide

Incorrect formulations containing too little, too much or no active ingredient at all.

Compounders may use salt forms: sodium and acetate. These are different active ingredients than those used the approved drug.

Peptide-related impurities may stimulate an immune reaction upon repeated injections- worst case: anaphylaxis

- Multiple state boards of pharmacy and patient/ practitioner advocacy groups have cautioned against compounded semaglutide prescription and use.
- The Mississippi State Board of Medical Licensure “strongly advise[d] medical licensees to refrain from prescribing, dispensing, or administering compounded semaglutide until further notice” because such drugs are “unproven and potentially unsafe.”
- Alongside compounded semaglutide, there is the addition of “illegally marketed semaglutide”, available via social media and the internet.

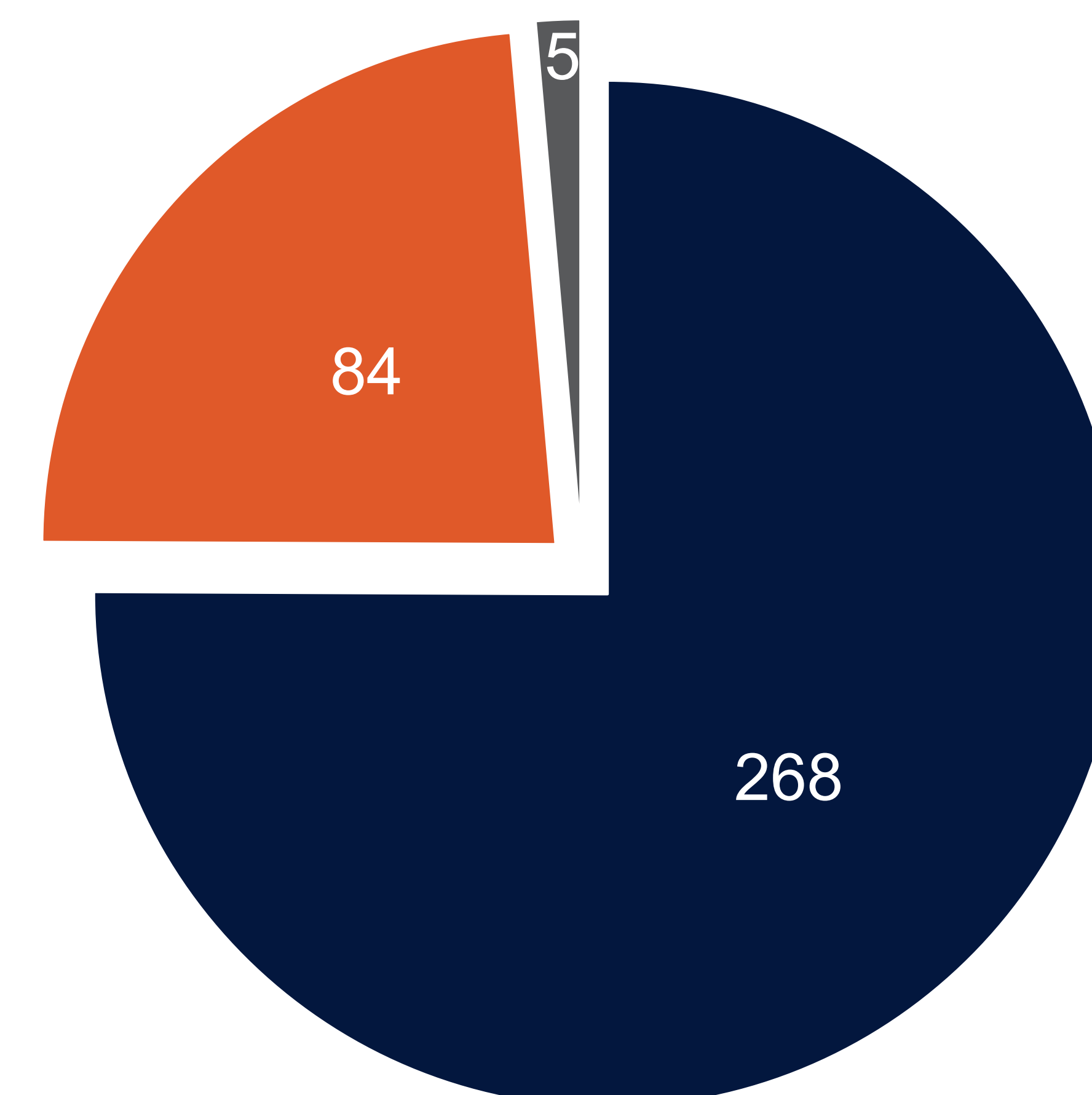
This research was supported (in whole or in part) by HCA Healthcare and/or an HCA Healthcare affiliated entity. The views expressed in this publication represent those of the author(s) and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities.

Data

Dose Administration Guide, Wegovy Subcutaneous

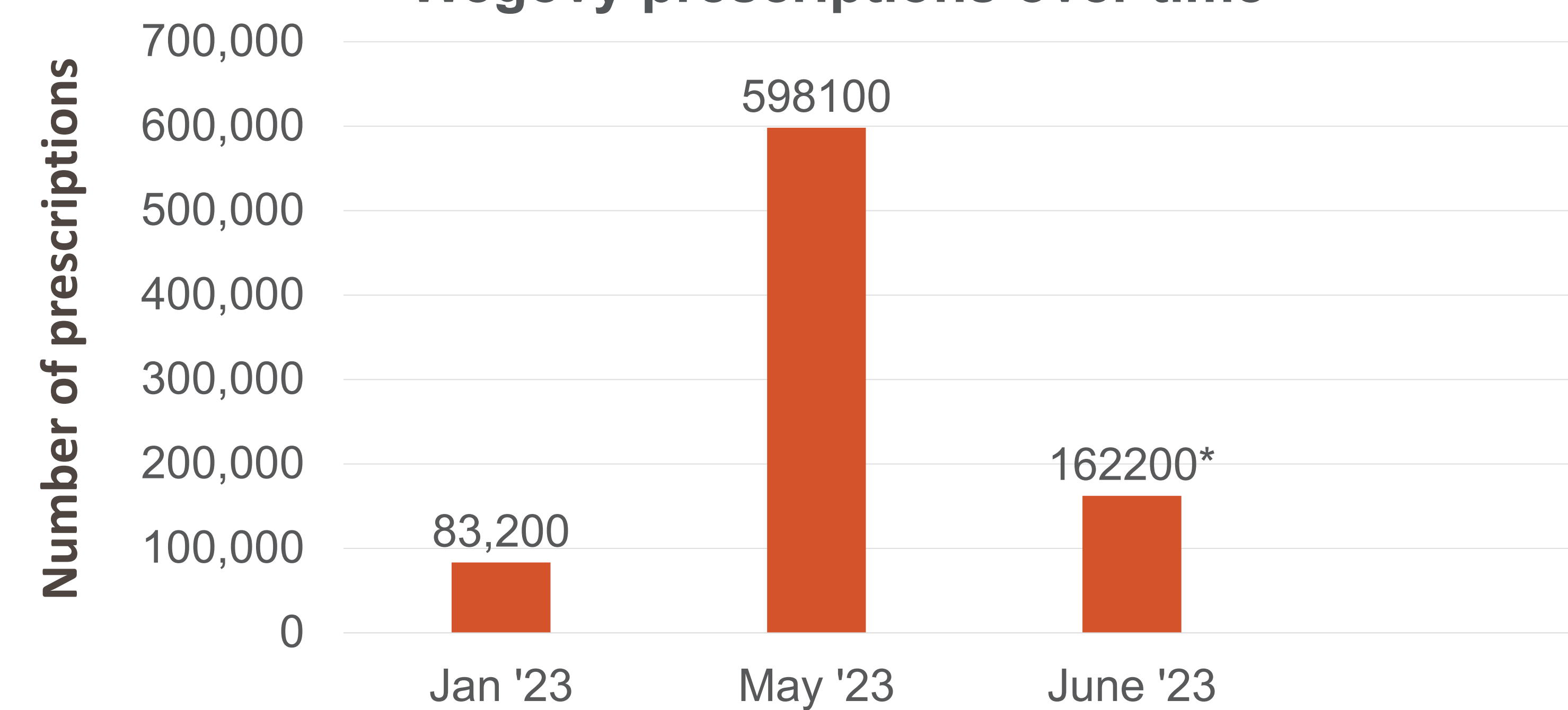
Time frame	Dose (subcutaneous)
Week 1 through week 4	0.25mg once weekly
Week 5 through week 8	0.5mg once weekly
Week 9 through week 12	1mg once weekly
Week 13 through week 16	1.7mg once weekly
Week 17 and after	2.4mg once weekly

Adverse Events of Compounded Semaglutide per FAERS



■ Serious AE ■ AE requiring Hospitalizations ■ Deaths

Wegovy prescriptions over time



*Drugmaker limited supplies to the United States

Discussion

- Semaglutide is Glucagon-Like Peptide-1 Receptor Agonist.
- Ozempic is indicated for improve blood sugar (glucose) in adults with **type 2 diabetes** and to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes with known heart disease.
- Wegovy is indicated alongside a reduced calorie meal plan and increased physical activity to assist **with weight loss** in adults with obesity, some children aged ≥12 years with obesity.
- Rybelsus is indicated for individuals with **T2DM** to improve blood sugars alongside diet and exercise.
- Mounjaro was approved for **type 2 diabetes** in May 2022.
- Zepbound was approved for **weight loss** in November 2023.

Conclusion

- The popularity of Semaglutide has exploded since its introduction through word of mouth and social media testimonials
- While the benefits of the various formulations of Semaglutide are undoubtedly visible, the evident concerns on the approval/use of compounded semaglutide is a question that concerns many patients and clinicians. Having too many unknowns and little data to endorse its efficacy, with loose regulation, the possibilities of harm are real and ever present.

References

- Novo Nordisk. Semaglutide Information. Published February 2024. Accessed Feb 17, 2024. <https://novomedlink.com/semaglutide.html>.
- Bridget B. What doctors should know about popular weight-loss drugs. January 25, 2024. Accessed Feb 24, 2024. <https://aamc.org/news>
- NovoMedLink. Compounding Letter. February 2024. Accessed Mar 01, 2024. <https://www.novomedlink.com/content/dam/novomedlink/semaglutide/Compounding-Letter.pdf>