

NOTE

COMPOUNDED DRUGS:
AN UPRISE OF TRADEMARK INFRINGEMENT LAWSUITS
CALLING FOR MORE FDA REGULATION

*Vanessa Sabrina Bittar**

I. INTRODUCTION 587

II. COMPOUNDED DRUGS, PHARMACIES, & INTELLECTUAL PROPERTY..... 591

A. COMPOUNDED DRUGS: A TEMPORARY SOLUTION TO DRUG SHORTAGES 591

 1. *Drug Shortages* 592

 2. *The Role of Compounded Drugs in Patient Care* 593

 3. *FDA Drug Approval Process*..... 595

B. PATENT LAW & ITS USE IN THE PHARMACEUTICAL INDUSTRY 596

C. TRADEMARK ACT: OVERVIEW OF THE LANHAM ACT..... 597

D. FDA & LANHAM ACT INTERSECTING 598

E. CURRENT FDA REQUIREMENTS FOR THE ADVERTISEMENT OF DRUGS 599

F. CONGRESS'S ATTEMPT AT PROTECTING CONSUMERS FROM DECEITFUL DRUG ADVERTISING 601

III. INTELLECTUAL PROPERTY ISSUES WITHIN COMPOUNDED DRUGS 602

A. WHEN TRADEMARK INFRINGEMENT & FALSE ADVERTISING OCCUR 603

B. TRADEMARK INFRINGEMENT & FALSE ADVERTISING CASES AGAINST COMPOUNDED DRUGS..... 604

 1. *Descriptive Fair Use*. 609

 2. *Nomative Fair Use*. 611

* © Copyright 2025, Vanessa Bittar, J.D. Candidate, 2026, George Washington University Law School; B.A., Fashion Studies, 2023, Columbia College Chicago. I would like to express my deepest gratitude to my family and closest friends for their unwavering love, support, and encouragement throughout this process. Also a special thank you to Professor Robert Brauneis, who taught me all things trademark and whose guidance was instrumental in shaping this work. Their contributions, in different but equally meaningful ways, made this work possible.

IV. PROTECTING TRADEMARKS BY GIVING THE FDA MORE AUTHORITY TO EXPAND ON CURRENT REGULATIONS..... 614

A. FDA'S ATTEMPT AT REGULATING THE PROMOTION OF COMPOUNDED DRUGS: OVERTURNED..... 614

B. MISBRANDED DRUGS..... 615

V. CONCLUSION 617

LIST OF FIGURES

1. Figure 1. A Statement from Houston Weight Loss Center’s Website (1 of 2) 605

2. Figure 2. Houston Weight Loss Center Marketing Tirzepatide on their Instagram Page 606

3. Figure 3. A Statement from Houston Weight Loss Center’s Website (2 of 2) 607

4. Figure 4. Novo Nordisk’s Logo for “OZEMPIC” 613

5. Figure 5. Recommended Mark to use Under Nomative Fair Use. 613

I. INTRODUCTION

Ozempic is a GLP-1 injection, mainly used to treat diabetes, containing the active ingredient semaglutide, which increases insulin levels and decreases blood sugar in a person's body.¹ Social media has brought attention to the benefit of one of the side effects of semaglutide: weight loss.² An increasing number of celebrities and social media influencers showing off their weight loss as a result of Ozempic has led many people to request a prescription from their doctors, even though they are not diabetic, causing the first Ozempic shortage in early 2022.³ Wegovy, also a semaglutide injection, fell to a shortage at the same time as Ozempic.⁴ Mounjaro, another diabetes medication that has an active ingredient of tirzepatide, had its first shortage in late 2022.⁵ According to the U.S. Food and Drug Administration (FDA), all three medications were in shortage for more than 2 years and are available as of 2024.⁶ Semaglutide and tirzepatide are both considered GLP-1 receptor agonists, meaning they both mimic the GLP-1 hormone in your body that makes you feel less hungry.⁷

¹ *Semaglutide Injection*, CLEVELAND CLINIC, <https://my.clevelandclinic.org/health/drugs/19011-semaglutide-injection> [perma.cc/4Q5Q-X8HY].

² Yasmine Tayag, *The Ozempic Shortage Is Over*, THE ATLANTIC (Aug. 16, 2024), <https://www.theatlantic.com/health/archive/2024/08/future-ozempic-will-be-riddled-dupes/679484/> [perma.cc/8VTS-QV36].

³ Robert H. Shmerling, *What Happens When a Drug Goes Viral?*, HARVARD HEALTH PUBLISHING (Feb. 21, 2023), <https://www.health.harvard.edu/blog/what-happens-when-a-drug-goes-viral-202302212892> [https://perma.cc/C4PY-A4TR]; FOOD & DRUG ADMIN., DECLARATORY ORDER: RESOLUTION OF SHORTAGES OF SEMAGLUTIDE INJECTION PRODUCTS (OZEMPIC AND WEGOVY) 1 (2025).

⁴ Annika Kim Constantino, *Novo Nordisk's Ozempic and Wegovy Now Available in the U.S. After Shortages, FDA Says*, CNBC (Oct. 30, 2024), <https://www.cnbc.com/2024/10/30/novo-nordisks-ozempic-wegovy-now-available-after-shortages.html> [perma.cc/Z922-4MDQ].

⁵ Dani Blum, *Mounjaro and Zepbound Are No Longer in Shortage, F.D.A. Says*, N.Y. TIMES (Oct. 3, 2024), <https://www.nytimes.com/2024/10/03/well/mounjaro-zepbound-shortage-compounded-tirzepatide.html> [perma.cc/NQM7-QBRU].

⁶ *Id.*

⁷ Catherine Crider, *How Do Tirzepatide and Semaglutide Compare for Weight Loss?*, HEALTHLINE (Sep. 10, 2024), <https://www.healthline.com/health/tirzepatide-vs-semaglutide#tirzepatide-vs-semaglutide> [perma.cc/FH4F-MZLQ].

While the injections were in short supply, diabetes patients in need of medicine still had an option.⁸ When an FDA-approved drug is not available in the market due to high demand, the FDA places the drug on its shortage list, and pharmacies that specialize in compounding are authorized to create an identical copy of the specific drug in need.⁹ Although patients are offered the injections with the same active ingredient, compounded drugs are not FDA-approved, meaning the medicine has not been tested for its safety, quality, and effectiveness for its intended use.¹⁰ The FDA is a United States government agency that ensures food and health-related products meet certain quality and safety standards before they are placed in the market.¹¹ Compounding pharmacies are overseen by State Boards of Pharmacies; the FDA helps regulate whether pharmacies are making unauthorized copies of FDA-approved drugs that are currently available in the market.¹²

⁸ Beth Sissons, *Compounded Semaglutide the Same as Ozempic?*, HEALTHLINE (Apr. 9, 2025), <https://www.healthline.com/health/drugs/compounded-semaglutide-vs-ozempic> [https://perma.cc/FG8Q-NDXV].

⁹ *Frequently Asked Questions about Drug Shortages*, FOOD & DRUG ADMIN. (Dec. 18, 2014), <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages> [https://perma.cc/8QK8-CBAP]; *Compounding When Drugs Are on FDA's Drug Shortage List*, FOOD & DRUG ADMIN. (Aug. 8, 2025), <https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list>, [https://perma.cc/W49N-P2XS].

¹⁰ *Compounding and the FDA: Questions and Answers*, FOOD & DRUG ADMIN. (Nov. 15, 2024), <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers> [perma.cc/J2KY-US94] [hereinafter *Compounding and the FDA*].

¹¹ Mariel Ferragamo & Claire Klobucista, *What is the FDA's Role in Public Health?*, COUNCIL ON FOREIGN RELATIONS (Jan. 27, 2025), <https://www.cfr.org/background/what-fdas-role-public-health> [perma.cc/F7AP-YPRH].

¹² Allie Weintraub, *FDA Says This Weight Loss Drug Shortage is Over, But Patients Worry About Cost and Availability*, CBS NEWS (Oct. 23, 2024), <https://www.cbsnews.com/news/tirzepatide-shortage-zepbound-mounjaro-eli-lilly-patient-concerns/> [perma.cc/EUU4-CEPW]; *Compounding and FDA Questions and Answers*, FOOD & DRUG ADMIN. (Sep. 16, 2025), <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers> [https://perma.cc/2M43-7RS4].

The practice of compounding drugs has long been an essential part of pharmaceutical practice.¹³ Compounded drugs are important in providing treatment to patients who cannot take an FDA-approved drug, such as a patient who cannot swallow a tablet and needs the medication in liquid form.¹⁴ They are also an important substitute for pharmaceutical drugs that are currently experiencing a shortage due to consumer high demand, like in the case of semaglutide and tirzepatide injections.¹⁵

There is a legal grey zone when it comes to the practice of compounding: compounding pharmacies may be exempted from patent infringement claims.¹⁶ Claims prevail under patent infringement only when the compounded drug is an identical copy of a commercially available drug or when the drug is not tailored to a patient's specific needs.¹⁷ No court has decided whether compounded drugs during a shortage constitute patent infringement.¹⁸ However, this ensures that patients are given continuing access to medications despite the manufacturer's inability to keep up with consumer demand.¹⁹ For the purpose of this Note, this will be assumed to be ethical. However, manufacturing companies have still been suing compounded pharmacies for the creation of their drugs that are not FDA-approved, due to putting patients who would use the name brand at risk.²⁰

Nevertheless, many compounding pharmacies are infringing on trademarks by creating deceptive advertisements using the actual manufacturer's

¹³ Maria Carvalho & Isabel F. Almeida, *The Role of Pharmaceutical Compounding in Promoting Medication Adherence*, 15 PHARM. 1091, 1091 (2022).

¹⁴ Blum, *supra* note 5.

¹⁵ Carvalho & Almeida, *supra* note 13, at 1091.

¹⁶ *Intellectual Property Challenges for 503A Pharmacy Compounding*, FRIER LEVITT (Apr. 19, 2024), <https://www.frierlevitt.com/articles/intellectual-property-challenges-for-503a-pharmacy-compounding/> [perma.cc/WEY9-3DZJ].

¹⁷ Martha M. Rumore, *Legal Battles Intensify: Pharmaceutical Manufacturers' Lawsuits Targeting Compounding Pharmacies*, PHARMACY TIMES (July 12, 2023), <https://www.pharmacytimes.com/view/legal-battles-intensify-pharmaceutical-manufacturers-lawsuits-targeting-compounding-pharmacies> [perma.cc/DKK6-8R8P].

¹⁸ Schweta Kumar, *Compounding Inequities Through IP and Unfair Competition*, 102 WASH. U. L. REV. 371, 412 (2024).

¹⁹ Rumore, *supra* note 17.

²⁰ *Id.* at 1.

name, using the brand's trade dress, and making misleading comparisons.²¹ This is leading consumers to mistakenly believe the compounded drugs are coming from the actual manufacturers or are otherwise sponsored by the manufacturers of the FDA-approved pharmaceuticals.²²

Pharmaceutical drugs that are compounded during drug shortages are leading to a rise in trademark infringement due to their misleading advertisements.²³ A possible solution would be the FDA requiring compounded drug advertisements to have a standard disclaimer that would be displayed throughout any advertisement that has a visual component, an audio disclaimer for audio advertisements, and limits on the use of brand names. The disclaimers will state that the product is not FDA-approved and is a compounded version of the brand name. Not only will this prevent trademark infringement for manufacturers of FDA-approved drugs, but it will also ensure safety for consumers who are not aware that compounded drugs do not come from the same manufacturer as the brand-name and are not tested for their quality, effectiveness, and safety.

There has been discussion on the need for the FDA to expand on current regulations and require mandatory trademark review for all drug trademarks through its Labeling and Nomenclature Committee because the FDA and the Patent and Trademark Office's (PTO) current evaluation process "fails to acknowledge sufficiently the specific mandates of the PTO and FDA."²⁴ However, this Note will argue for Congress to expand on current regulations, such as the Drug Quality and Security Act, to give the FDA more authority to add restrictions to the advertising and marketing of compounded drugs. Part II of this Note gives an overview of drug shortages, what compounded drugs are, what it means for a drug to be "essentially a copy" of an FDA-approved drug, why compounding pharmacies are allowed to create identical drugs during a drug shortage, and, most importantly, the process of a drug getting FDA-approved.²⁵ Part III of this

²¹ *Id.* at 3.

²² *Id.*

²³ *See infra* Part IV.

²⁴ Danielle A. Gentin, *You Say Zantac, I Say Xanax: A Critique of Drug Trademark Approval and Proposals for Reform*, 55 *FOOD & DRUG L. J.* 255, 267 (2000).

²⁵ Discussing the FDA-approval process is important because drug companies like Eli Lilly and Novo Nordisk are claiming that their drugs have gone through rigorous testing, and they put down a lot of money in order to get their drugs approved. The main false advertising claims these companies have made is that the compounded drugs they are advertising are FDA-

Note discusses trademark infringement and false advertising issues that arise from advertising and selling compounded drugs, and why descriptive and nominative fair use does not apply in the cases filed by Eli Lilly and Novo Nordisk against companies selling compounded drugs. Lastly, Part IV gives an analysis of how there are not enough restrictions in current drug advertising regulations and proposes that the ongoing issue of trademark infringement and false advertising may be resolved if Congress gives the FDA more authority to limit the advertising of compounded drugs.

II. COMPOUNDED DRUGS, PHARMACIES, & INTELLECTUAL PROPERTY

Part II gives an overview of compounded pharmacies and drugs, and the role trademark and patent law play in this industry. First, Section A discusses what the FDA considers a drug shortage, what compounding pharmacies are, how compounding pharmacies play a role in these shortages, and the FDA approval process. Second, Section B discusses patent law and its relevance in the compounded drug market. Third, Section C provides an overview of the Lanham Act and the relevant factors that affect manufacturers. Fourth, Section D, the intersection of the Lanham Act and the FDA. Fifth, Section E discusses current FDA requirements for the advertisement of drugs and bills that Congress has passed for consumer safety on drug advertisement and compounded drugs. Lastly, Section F discusses action Congress has already taken to protect consumers from deceitful drug advertising.

A. COMPOUNDED DRUGS: A TEMPORARY SOLUTION TO DRUG SHORTAGES

A compounded drug is essentially an identical copy of a drug that has already been released to the public.²⁶ There are three requirements for a compounded drug to be “essentially a copy” of a commercially available drug: the compounded drug must (i) have the same active ingredient, (ii) be within 10% of the dosage strength, and (iii) have the same route of administration as the FDA-

approved, when they are not. Complaint at 2, *Eli Lilly & Co. v. Bergeron*, No. 4:24-cv-2313 (S.D. Tex. June 20, 2024), Dkt. No. 1.

²⁶ Alan G. Minsk & Alexander B. Foster, *FDA Releases Draft Guidance on Compounded Drugs, Helps to Answer “When Are They Copies?”*, ARNALL GOLDEN GREGORY LLP (July 19, 2016), <https://media.agg.com/wp-content/uploads/2019/07/17213308/Minsk-Foster-FDA-Releases-Draft-Guidances-on-Compounded-Drugs-Helps-to-Answer-When-are-t.pdf> [perma.cc/55AW-T3M8].

approved drug.²⁷ The FDA only has two exceptions for allowing the production of a compounded drug: the drug is currently on the market and needs to be adjusted for an individual patient's need, or to replace a drug experiencing a shortage in the market.²⁸ This Note discusses the latter.

1. *Drug Shortages*

At the beginning of 2024, the number of drugs on the shortage list reached an all-time high of 323 in the United States, but decreased to 277 as of September 2024.²⁹ Despite the decrease, about 50% of the pharmaceutical drugs remained on the shortage list for more than 2 years.³⁰ The most common types of drugs that are currently on the shortage list include ADHD medication, pain treatments, chemotherapy drugs, insulin, and diabetes medication (now commonly used as a weight loss medication).³¹

The FDA considers a drug to be in shortage when “the total supply of all versions of a commercially available product cannot meet the current demand, and a registered alternative manufacturer will not meet the current and/or projected demands for the potentially medically necessary use(s) at the patient level.”³² Once the drug manufacturers can produce enough of the drugs to meet the demand, the drug will then be taken off the shortage list, and the compounded drugs can no longer be sold.³³ Under the FDCA, compounded drugs cannot be sold if they are a replica of a commercially available drug,³⁴ but there is an exception when it comes to shortages.³⁵ When there is no shortage, the only

²⁷ *Id.*

²⁸ *Compounding and the FDA, supra* note 10.

²⁹ Brooke McCormick, *5 Essential Drugs Currently Facing Shortages*, AM. J. MANAGED CARE (Nov. 1, 2024), <https://www.ajmc.com/view/5-essential-drugs-currently-facing-shortages> [perma.cc/MJ4A-LUV9].

³⁰ *Id.*

³¹ *Id.*

³² Amelia Poulin, *Improving Access to Critical Medications: A Policy Toolkit for Health Agency Program Leadership*, ASSOC. OF STATE & TERRITORIAL HEALTH OFFS. (Sep. 30, 2024), <https://www.astho.org/topic/toolkit/improving-access-to-critical-medications/> [https://perma.cc/QT4M4-YBMF].

³³ *See id.*

³⁴ 21 U.S.C. § 353a (2013).

³⁵ *Compounding When Drugs are on FDA's Drug Shortages List*, FOOD & DRUG ADMIN. (Aug. 08, 2025), <https://www.fda.gov/drugs/human-drug->

exception for a drug to be compounded is to meet a unique requirement for a patient.³⁶

2. *The Role of Compounded Drugs in Patient Care*

Compounded drugs play a big role in the pharmaceutical industry by providing patients with another option for drugs not available in the market due to high demand. When an FDA-approved drug is in short supply, a compounded version of the drug becomes an option for consumers who are in need of the medicine.³⁷ A compounded drug is generally altered by a pharmacist to tailor a medication to a patient's requirements when the standard medication does not meet the patient's specific needs.³⁸ Compounded drugs are not FDA approved, so they "do not undergo FDA review for safety, effectiveness, or quality before they are marketed."³⁹ Compounded drugs make up between 1% and 3% of pharmaceutical prescriptions in the United States.⁴⁰

Seventy-five hundred out of fifty-six thousand pharmacies in the United States specialize in compounding medicine.⁴¹ These pharmacies and their pharmacists are looked over by both federal and state authorities: the FDA and the State Board of Pharmacy.⁴² Compounded pharmacies are regulated by State Boards of Pharmacy, but there has been a push for greater scrutiny, so compounding pharmacies have been divided into either § 503A or 503B under the

compounding/compounding-when-drugs-are-fdas-drug-shortages-list [perma.cc/YS7B-FQWN] [hereinafter *Compounding from Shortage List*].

³⁶ See FRIER LEVITT, *supra* note 16.

³⁷ *Compounding from Shortage List*, *supra* note 35.

³⁸ *What Are Compounded Medications?*, NAT'L COUNCIL ON AGING (Sep. 6, 2024), <https://www.ncoa.org/article/what-are-compounded-medications/> [perma.cc/CT7E-49FA].

³⁹ *Compounding from Shortage List*, *supra* note 35.

⁴⁰ *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, NAT'L ACADS. OF SCI., ENG'G & MED. (July 1, 2020), <https://www.ncbi.nlm.nih.gov/books/NBK562881/> [https://perma.cc/7LCD-QWCT].

⁴¹ *Id.*

⁴² *See id.*

FDCA.⁴³ Section 503A pharmacies compound to patients' specific needs⁴⁴ and are limited to dispensing for home use only, so the pharmacy can only do small batches of compounded drugs at a time.⁴⁵ On the other hand, § 503B pharmacies are those with outsourcing facilities that sell large batches of compounded drugs to healthcare facilities for office use only.⁴⁶ These pharmacies are permitted to provide consistent access to medication, like semaglutide, by producing large batches without individual prescriptions.⁴⁷ Section 503B pharmacies are used during drug shortages for widespread distributions.⁴⁸ Section 503B allows for compounded drugs to be marketed without the FDA's approval only if the pharmacies have met certain conditions, such as labeling requirements.⁴⁹ Section 503A and 503B pharmacies are both prohibited from compounding replicas of drugs that are commercially available on the market, unless it is on the shortage list.⁵⁰ Otherwise, it is subject to patent infringement.⁵¹

⁴³ *503A vs. 503B: A Quick-Guide to Compounding Pharmacy Designations & Regulations*, THE FDA GROUP (Nov. 16, 2021), <https://www.thefdagroup.com/blog/503a-vs-503b-compounding-pharmacies> [perma.cc/7SY3-RATC].

⁴⁴ Blum, *supra* note 5. As stated before, a patient's specific need may include turning a pill form of medicine into liquid or adding flavor to a bitter tasting medication to make it easier for the patient to take.

⁴⁵ *503A vs. 503B: A Quick-Guide to Compounding Pharmacy Designations & Regulations*, *supra* note 43.

⁴⁶ *See The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, *supra* note 40.

⁴⁷ *See id.*

⁴⁸ *See id.*

⁴⁹ Tim Dunker, *Can't Dismiss Lanham Act Claim Based on FDCA Preemption*, McDERMOTT WILL & SCHULTE: IP UPDATE (Aug. 25, 2022), <https://www.ipupdate.com/2022/08/cant-dismiss-lanham-act-claim-based-on-fdca-preemption/> [perma.cc/A5MC-4DL2]; 21 U.S.C. § 353b.

⁵⁰ *Intellectual Property Challenges for 503A Pharmacy Compounding*, *supra* note 16.

⁵¹ *Id.*

3. FDA Drug Approval Process

It is very challenging and costly for a drug to be FDA-approved.⁵² First, the company seeking approval must conduct laboratory tests to determine the safety and effectiveness of its drug.⁵³ The companies then have to go through three phases of clinical trials before they submit their clinical test results to the FDA for approval.⁵⁴ The three-phase trials can cost hundreds of millions of dollars.⁵⁵ Through the three phases, data is collected on the safety and dosage of the drug, the efficiency and side effects, and any adverse reactions from the drug.⁵⁶ This involves finding thousands of participants of various ages, genders, ethnicities, and comorbid conditions.⁵⁷ The test results are then submitted to the FDA and are reviewed by the Center for Drug Evaluation and Research “physicians, statisticians, chemists, pharmacologists, and other scientists.”⁵⁸ It can take six to ten months for the FDA to review the information and decide whether to approve it or not.⁵⁹ If the benefits of the drug outweigh the risks, the FDA is most likely to

⁵² It is important to know the process of the FDA-approval process to understand why it is deceitful for company selling drugs to advertise themselves as “FDA approved” when they have not gone through the approval process.

⁵³ See *Frequently Asked Questions about the FDA Drug Approval Process*, FOOD & DRUG ADMIN. (Feb. 2, 2017), <https://www.fda.gov/drugs/special-features/frequently-asked-questions-about-fda-drug-approval-process> [perma.cc/S86U-YDAY].

⁵⁴ *Understanding the Phases of FDA Approval for Drug Development*, SYNER-G BIOPHARMA GROUP (June 24, 2024), <https://synergbioharma.com/phases-fda-approval-drug-development/> [perma.cc/E6X7-968W].

⁵⁵ *Cost of Clinical Trials For New Drug FDA Approval Are Fraction of Total Tab*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Sep. 24, 2018), <https://publichealth.jhu.edu/2018/cost-of-clinical-trials-for-new-drug-FDA-approval-are-fraction-of-total-tab> [perma.cc/Q3BW-NR24] [hereinafter *Cost of Clinical Trials*].

⁵⁶ Dunker, *supra* note 49; *Cost of Clinical Drug Trials*, *supra* note 55.

⁵⁷ *Id.*

⁵⁸ *How Drugs Are Developed and Approved*, FOOD & DRUG ADMIN. (Oct. 24, 2022), <https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved> [https://perma.cc/Z7C7-JFVS].

⁵⁹ Juhi Kunde, *How Do Drugs Get Approved (and Fast-Tracked) by the FDA?*, LUNGEVITY (Aug. 27, 2024), <https://www.lungevity.org/blogs/how-do-drugs-get-approved-and-fast-tracked-by-fda> [perma.cc/7FR9-V49B].

approve.⁶⁰ Once the drug is approved, it will continue to be tested on large populations in the public, which plays a crucial role in monitoring long-term effects.⁶¹ This is when patients report any adverse side effects they may have when taking the drug.⁶² It can cost companies millions of dollars to get the data needed for the clinical trials.⁶³ Simply put, the process of getting a drug FDA-approved is time-consuming and costly.

B. PATENT LAW & ITS USE IN THE PHARMACEUTICAL INDUSTRY

The Patent Act is a federal statute protecting “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁶⁴ Pharmaceutical drugs have three requirements for the invention of the drug to be patentable: the drug must not be already known to the public, it must not be an obvious development for a skilled professional in the field, and it must be useful in a way that it fulfills its intended purpose.⁶⁵

It is unlikely a patent holder will prevail with a patent infringement claim if a drug is on the FDA shortage list or if the drug is compounded for individual needs.⁶⁶ The Alliance for Pharmacy Compounding has claimed that this may be because the “FDA guidance on compounding makes no distinction for a patented drug.”⁶⁷ It may be because patients who are in need of a medication have the right to have access to it; otherwise, their lives may be at risk. However, by allowing

⁶⁰ *Is It Really ‘FDA Approved’?*, FOOD & DRUG ADMIN. (May 10, 2022), <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> [https://perma.cc/J37P-S72F].

⁶¹ *Compounding Inspections*, *supra* note 52; *Cost of Clinical Drug Trials*, *supra* note 55.

⁶² *Id.*

⁶³ Abigail Beaney, *FDA Drug Application Costs Set To Rise To \$4.3m from October*, CLINICAL TRIALS ARENA (July 31, 2024), <https://www.clinicaltrialsarena.com/news/fda-cost-revealed-2025-application-drug> [perma.cc/8PJB-ULF3].

⁶⁴ 35 U.S.C. § 101.

⁶⁵ Tony Pistilli, *Pharmaceutical Patent Regulation in the United States*, THE ACTUARY (Feb. 2021), <https://www.theactuarmagazine.org/pharmaceutical-patent-regulation-in-the-united-states/> [perma.cc/EKP8-33NX].

⁶⁶ *See* Rumore, *supra* note 17.

⁶⁷ Kumar, *supra* note 18, at 381.

compounding pharmacies to create copycat of drugs in times of need, it opens the doors to trademark infringement claims.

C. TRADEMARK ACT: OVERVIEW OF THE LANHAM ACT

The Lanham Act, also known as the Trademark Act of 1946 (the “Lanham Act”), is the federal statute governing trademark law that provides causes of action for false advertising, unfair competition, and consumer confusion.⁶⁸ The Act states that when registering a trademark, there are three requirements in order to be eligible for protection:⁶⁹ the mark must be used in commerce, meaning the right in a mark cannot be reserved if it is not connected with goods or services in the ordinary course of trade,⁷⁰ it must be distinctive, meaning the word or symbol must serve a source identifying function as a mark,⁷¹ and the mark must be non-functional, meaning it is not essential to the product’s use and is used only to identify the product.⁷²

Unfair competition and false advertising are also protected by the Lanham Act.⁷³ False advertising falls under unfair competition, which protects consumers from being deceived by the source of the goods they are purchasing.⁷⁴ It also protects companies from their trademarks being used without permission and in a deceitful way.⁷⁵ There are five elements of false advertising: “(1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the

⁶⁸ See 15 U.S.C. § 1127.

⁶⁹ See 15 U.S.C §§ 1051–52.

⁷⁰ See Igor Demcak, *What Does ‘Use in Commerce’ Mean?*, TRAMA TM, <https://www.tramatm.com/en/trademark-questions-and-answers/specifics-of-us-trademarks/what-does-use-in-commerce-mean> [https://perma.cc/6U5A-EQKS].

⁷¹ See *What Makes a Trademark “Distinctive” and Why Does That Matter?*, OPPENHUIZEN LAW PLC, <https://www.oppenhuizen.com/what-makes-distinctive/> [perma.cc/HKW2-4H6C].

⁷² See 15 U.S.C §§ 1051–52.

⁷³ 15 U.S.C § 1127.

⁷⁴ See *Do I Have a Lanham Act Claim Against My Competitor for False Advertising?*, BONA LAW (Aug. 25, 2019), <https://www.bonalaw.com/insights/legal-resources/do-i-have-a-lanham-act-claim-against-my-competitor-for-false-advertising> [perma.cc/N4TD-Q3GJ].

⁷⁵ *Id.*

deception had a material effect on purchasing decisions; (4) the misrepresented product or service affects interstate commerce; and (5) the movant has been—or is likely to be—injured as a result of the false advertising.”⁷⁶

Unlike the Patent Act, compounded drugs are not exempted from the Lanham Act, so pharmaceutical companies can still be held liable for trademark infringement, regardless of whether the drug was compounded for a shortage or an individual need.⁷⁷ Many pharmaceutical companies have been found liable for trademark infringement and false advertising under the Lanham Act, and there are currently many ongoing cases that will be discussed in the following Section.⁷⁸

D. FDA & LANHAM ACT INTERSECTING

The Federal Food, Drug, and Cosmetic Act (FDCA) is regulated by the FDA to “oversee and regulate the production, sale, and distribution of food, drugs, medical devices, and cosmetics,” which includes the regulation of prescription drug advertisements.⁷⁹ If a Lanham Act claim challenges an FDCA policy choice, it may be barred because the court would need to interpret or enforce an FDCA regulation.⁸⁰ This is typically when a claim of false advertising involves an FDA-regulated product,⁸¹ but in more recent cases, there have been claims intersecting

⁷⁶ *Fort Lauderdale Business Litigation: Claims of False Advertising Under the Lanham Act*, MAVERICK L. FIRM (June 14, 2023), <https://www.mavricklaw.com/blog/fort-lauderdale-business-litigation-claims-of-false-advertising-under-the-lanham-act/> [https://perma.cc/H3NN-CH2R].

⁷⁷ See Rumore, *supra* note 17.

⁷⁸ *Id.*

⁷⁹ Clinton Lam & Preeti Patel, *Food, Drug, and Cosmetic Act*, NAT’L LIBR. MED. (July 31, 2023), <https://www.ncbi.nlm.nih.gov/books/NBK585046/> [perma.cc/FG8V-MYUJ].

⁸⁰ Michelle Yeary, *The Intersection Between the Lanham Act and the FDCA*, DRUG & DEVICE LAW BLOG (Mar. 29, 2022), <https://www.druganddevicelawblog.com/2022/03/the-intersection-between-the-lanham-act-and-the-fdca.html> [perma.cc/PK58-9RTK].

⁸¹ Paul Rubin, *Preclusion, Primary Jurisdiction, and Private Enforcement: The Intersection of the Lanham Act and the Federal Food, Drug, and Cosmetic Act*, BLOOMBERG L. (May 2, 2014), <https://news.bloomberglaw.com/pharma-and-life-sciences/preclusion-primary-jurisdiction-and-private-enforcement-the-intersection-of-the-lanham-act-and-the-federal-food-drug-and-cosmetic-act> [perma.cc/DFX8-VRVM].

trademark infringement and FDA-approved products.⁸² The Lanham Act and the FDCA serve different purposes; where “the Lanham Act is primarily concerned with the truth or falsity of advertising claims to protect commercial interests, the FDCA is primarily concerned with protecting the public interest in the safety and efficacy of FDA-regulated products.”⁸³ This was addressed in a 2014 Supreme Court case, where the court held that the Lanham Act is not preempted by FDA Regulation.⁸⁴ In *POM Wonderful LLC v. Coca-Cola Co.*, the court found that the Lanham Act and the FDCA do not forbid or limit Lanham Act claims challenging labels that are regulated by the FDCA.⁸⁵ Although the Lanham Act and FDA policies tend to conflict with each other, the court noted that they complement each other because they both touch on food and beverage labeling.⁸⁶ Thus, a claim that intersects the Lanham Act and an FDA policy is not forbidden from being brought into court, as long as the plaintiff is not suing under the Lanham Act to enforce the FDCA or its regulations.⁸⁷

E. CURRENT FDA REQUIREMENTS FOR THE ADVERTISEMENT OF DRUGS

The FDA regulates prescription drug advertising, while the Federal Trade Commission (FTC) regulates over-the-counter drug advertising.⁸⁸ Since the practice of compounding drugs is generally for medication that is given by prescription, FTC advertising regulations will not apply here.⁸⁹

⁸² See Complaint at 3, *Eli Lilly & Co. v. Bergeron*, No. 4:24-cv-2313 (S.D. Tex. June 20, 2024), Dkt. No. 1.

⁸³ Rubin, *supra* note 81.

⁸⁴ *POM Wonderful LLC v. Coca-Cola Co.*, 537 U.S. 102, 113 (2014).

⁸⁵ *Id.*

⁸⁶ *Id.* at 115.

⁸⁷ *Id.* at 119.

⁸⁸ *Prescription Drug Advertising Questions and Answers*, FOOD & DRUG ADMIN. (June 19, 2015), <https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers> [perma.cc/K8GE-SEWE] [hereinafter *Prescription Drug Advertising*].

⁸⁹ See *Do You Need a Prescription for a Compounding Pharmacy?*, THE HEALTHY CHOICE (Jan. 21, 2025), <https://www.thehealthychoice.net/do-you-need-a-prescription-for-a-compounding-pharmacy/> [https://perma.cc/SFV8-Y29A].

The FDA currently has a guideline for the advertisement of FDA-approved drugs.⁹⁰ The guideline states that the advertisement for the product must include “the name of the drug (brand and generic),” “at least one FDA-approved use for the drug,” and “the most significant risks of the drug.”⁹¹ For print advertisements, there must be a brief summary about the drug, including all of the risks associated with taking the drug.⁹² For broadcast advertisements, the drug’s most important risks must be audibly presented, stating all of the risks associated with taking the drug or sources where the viewers may find the prescribing information for the drug.⁹³ This must be at a pace that is easy for a typical listener to understand.⁹⁴ If the advertisement is occurring on television, a disclaimer of the risks associated with taking the drugs must be displayed with enough time for easy reading, and it must also be presented audibly.⁹⁵ Also, the style and color of the font must be legible to an ordinary viewer.⁹⁶

The advertisements for compounded drugs cannot be deceiving; drug manufacturers must present all of the drug’s risks and benefits and may not promote the drug to be more effective than it really is.⁹⁷ The FDA must take action if it finds a drug advertisement to be false or misleading by falsely presenting it as FDA-approved.⁹⁸

⁹⁰ *Basics of Drug Ads*, FOOD & DRUG ADMIN. (June 19, 2015), <https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads> [<https://perma.cc/HL8P-S9JE>].

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ See *FDA Issues Final Guidance on Direct-to-Consumer Prescription Drug Advertisements*, CROWELL & MORING (Jan. 11, 2024), <https://www.crowell.com/en/insights/client-alerts/fda-issues-final-guidance-on-direct-to-consumer-prescription-drug-advertisements> [<https://perma.cc/PPP2-NNYE>].

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *From The Manufacturers’ Mouth to Your Ears: Direct to Consumer Advertising*, FOOD & DRUG ADMIN. (Dec. 23, 2015), <https://www.fda.gov/drugs/special-features/manufacturers-mouth-your-ears-direct-consumer-advertising> [<https://perma.cc/6SW3-YVM5>].

⁹⁸ *Id.*

F. CONGRESS'S ATTEMPT AT PROTECTING CONSUMERS FROM
DECEITFUL DRUG ADVERTISING

Congress has made an effort to protect consumers from harmful drugs by passing a bill to give the FDA more authority for drug safety regulations. In 2013, Congress passed the Drug Quality and Security Act (DQSA), which has two parts: the Compounding Quality Act (CQA) and the Drug Supply Chain Security Act (DSCSA).⁹⁹ The CQA is to help improve the safety of compounded drugs for patients and regulate compounding pharmacies.¹⁰⁰ The purpose of the DQSA is to give the FDA more authority to regulate and monitor the safety of drugs.¹⁰¹ It requires the FDA to electronically identify and trace prescription drugs as they move through the supply chain to prevent harmful drugs from entering the drug supply chain.¹⁰²

Congress continues to take action to protect consumers from deceitful drug advertising. In 2024, the Protecting Patients from Deceptive Drug Ads Online Act was introduced in the United States Senate and is currently pending.¹⁰³ The Act's purpose is to protect consumers by targeting deceptive or misleading information about pharmaceutical drugs posted by social media influencers, healthcare providers, and telehealth companies.¹⁰⁴ This Act is intended to expand upon the FDA advertising guidelines for print and broadcast product claims advertisements by requiring the same guidelines for social media.¹⁰⁵ This means that any influencer, healthcare provider, or telehealth company must list an accurate summary of the drug and all risks and side effects that the medication

⁹⁹ *Examining Implementation of the Compounding Quality Act: Hearing Before the Subcomm. on Health*, House Comm. on Energy and Commerce (2018) (testimony of Scott Gottlieb, M.D., Commissioner of Food and Drugs).

¹⁰⁰ *DQSA – Drug Quality and Security Act (HR 3204)*, PCCA, <https://www.pccarx.com/AboutUs/glossary/DQSADrugQualityandSecurityAc> [<https://perma.cc/96J8-3FLR>].

¹⁰¹ *See id.*

¹⁰² *Drug Supply Chain Security Act (DSCSA)*, FOOD & DRUG ADMIN. (Jan 15, 2025), <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa> [<https://perma.cc/4HWD-A72L>].

¹⁰³ *See Stopping Misleading RX Drug Ads on Social Media*, GENERATION PATIENT, <https://generationpatient.org/stop-misleading-rx-ads> [perma.cc/9NVH-AL45].

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

may cause when they advertise the drug.¹⁰⁶ The Act also directs the FDA to monitor social media posts and take action if it sees misleading information.¹⁰⁷ This is so important today because many people look up to influencers on social media and trust the information they are sharing about the products they are using.¹⁰⁸ Also, many compounded drugs are being advertised on social media today.¹⁰⁹

Overall, Congress has been making an effort to regulate deceptive advertising for commercial drugs. The FDA also has strict regulations when it comes to the advertising and promotion of FDA-approved drugs. Why hasn't Congress enacted a rule to protect consumers from deceitful advertisements of compounded drugs? Why hasn't the FDA expanded its restrictions on the advertising of compounded drugs? The following Part shows the effects of Congress and the FDA not being stricter on advertising efforts.

III. INTELLECTUAL PROPERTY ISSUES WITHIN COMPOUNDED DRUGS

Part III first discusses what elements must be met for a trademark infringement and false advertising claim. Then it discusses trademark issues the manufacturers of Ozempic and Mounjaro have encountered with compounding pharmacies: In 2024, Novo Nordisk, the manufacturer of Ozempic, filed nine suits against medical spas, weight loss clinics, and other companies for unlawful marketing.¹¹⁰ Eli Lilly, the manufacturer of Mounjaro, also filed suit in 2024 against Houston Weight Loss Center for trademark infringement and false advertising.¹¹¹ This Part ends by discussing descriptive and nominative fair use and why fair use does not apply to the current cases against compounded drugs.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Do Consumers Have Trust in Influencers? Here's What Statistics Show*, SLICKTEXT (Mar. 11, 2025), <https://www.slicktext.com/blog/2021/06/social-media-influencer-statistics-survey/> [<https://perma.cc/D7QG-JPJB>].

¹⁰⁹ *See* Complaint at 8, *Eli Lilly & Co. v. Bergeron*, No. 4:24-cv-2313 (S.D. Tex. June 20, 2024), Dkt. No. 1.

¹¹⁰ *Novo Nordisk Escalates Legal Actions to Safeguard Patients from Potentially Harmful Compounded "Semaglutide" Drugs*, NOVO NORDISK (May 30, 2024), <https://www.novonordisk-us.com/media/news-archive/news-details.html?id=168519> [perma.cc/2BV6-ZDCR].

¹¹¹ Complaint at 1, *Bergeron*, No. 4:24-cv-2313.

A. WHEN TRADEMARK INFRINGEMENT & FALSE ADVERTISING OCCUR

Trademark infringement occurs “when someone uses a trademark in connection with the sale or advertising of goods or services that is likely to cause consumer confusion or mistake about the source of the goods or services.”¹¹² All Circuits have similar elements in determining if there is a trademark infringement.¹¹³ Three elements that all Circuits look at and are most relevant in this case are (i) the Defendant used the mark in commerce without the plaintiff’s authorization, (ii) the Defendant used the mark “in connection with the sale, offering for sale, distribution, or advertising of goods or services” and (iii) actual evidence that the Defendant’s use of the mark is likely to confuse consumers.¹¹⁴ When it comes to relatedness of goods or services, if two companies are selling the same type of products, then it is more likely that a consumer will confuse the source of the goods or services.¹¹⁵ This is relevant to compounded medicine because companies are using the known names of FDA-approved diabetes drugs, such as Ozempic, in their advertisements, which leads ordinary consumers to believe that they are purchasing the well-known name for a semaglutide medication.¹¹⁶ There is evidence that a consumer is likely to be confused when it is likely for an ordinary consumer to be misled by the source of the goods or services of the product they are purchasing.¹¹⁷ Eli Lilly and Novo Nordisk are mostly concerned with their trademarks being used for products that are not FDA-approved, connecting their name brand with products that may be a potential risk for consumers to take.¹¹⁸

¹¹² Elijah Hartman, *The Basics on United States Trademark Infringement Law*, HARRIS SLIWOSKI (July 10, 2024), <https://harris-sliwoski.com/blog/the-basics-on-united-states-trademark-infringement-law/> [perma.cc/B99T-2NTJ].

¹¹³ Richard Stim & Amanda Hayes, *Likelihood of Confusion: How Do You Determine if a Trademark is Infringing?*, NOLO (June 6, 2025), <https://www.nolo.com/legal-encyclopedia/likelihood-confusion-how-do-you-determine-trademark-infringing.html> [perma.cc/PSJ8-6MM7].

¹¹⁴ *Id.*

¹¹⁵ *Seven Factors For Identifying Trademark Likelihood of Confusion*, CORSEARCH, <https://corsearch.com/content-library/blog/seven-factors-for-identifying-trademark-likelihood-of-confusion/> [perma.cc/UUE9-89R8].

¹¹⁶ Complaint at 15, *Bergeron*, No. 4:24-cv-2313.

¹¹⁷ *See id.* at 22.

¹¹⁸ *See An Open Letter From Eli Lilly and Company Regarding Certain Practices Related to Mounjaro® and Zepbound®*, LILLY INVESTORS (June 20, 2024), <https://investor.lilly.com/node/50961/pdf> [perma.cc/NRV8-KZ7J]; *see also*

The Lanham Act prohibits two types of false advertising: first, advertisements that provide false information, and second, advertisements that, even though they are not fully false, are likely to mislead consumers.¹¹⁹ This is to protect businesses from unfair competitive practices that may harm their sales and consumers from deception.¹²⁰ The example given in the paragraph above also falls under false advertising because the misrepresentation of the compounded drugs being FDA-approved was likely to influence a consumer's purchasing decision.

B. TRADEMARK INFRINGEMENT & FALSE ADVERTISING CASES AGAINST COMPOUNDED DRUGS

Eli Lilly brought a suit against a clinic named Houston Weight Loss Center for trademark infringement on their marks MOUNJARO® and ZEPBOUND®, false designation of origin, false advertising, and unfair competition.¹²¹ Lilly registered "ZEPBOUND" as a trademark in April 2022¹²² and registered "MOUNJARO" in November 2019.¹²³ Lilly claims that Houston Weight Loss Center is using Lilly's trademarks in their marketing efforts to deceive consumers into believing their compounded tirzepatide is the genuine FDA-approved

Novo Nordisk, *Novo Nordisk Takes Actions to Help Protect US Patients from Unlawful Sales of Non-FDA Approved Medicines Claiming to Contain Semaglutide*, PR NEWSWIRE (June 20, 2023), <https://www.prnewswire.com/news-releases/novo-nordisk-takes-actions-to-help-protect-us-patients-from-unlawful-sales-of-non-fda-approved-medicines-claiming-to-contain-semaglutide-301855294.html> [https://perma.cc/S93M-8E76] [hereinafter *Novo Nordisk Takes Action*].

¹¹⁹ *Reminder: The Lanham Act is a Powerful Weapon Against False Advertising*, POLLARD PLLC (Mar. 26, 2017), <https://pollardllc.com/lanham-act-powerful-false-advertising/> [https://perma.cc/WCY4-VX6H].

¹²⁰ *Lanham Act and False Advertising: How to Protect Your Business*, GORDON LAW, <https://gordonlaw.com/learn/lanham-act-false-advertising/> [perma.cc/EZG5-8SPH].

¹²¹ Complaint at 1, *Bergeron*, No. 4:24-cv-2313.

¹²² *Trademark Details for ZEPBOUND*, HUSKI.AI, <https://huski.ai/trademark-details-mark-zepbound-country-us-serial-number-US-TM-97362818> [perma.cc/N2RF-E4HG].

¹²³ *Trademark Details for MOUNJARO*, HUSKI.AI, <https://huski.ai/trademark-details-mark-mounjaro-country-us-serial-number-US-TM-88680946> [perma.cc/3ZFK-5Y95].

tirzepatide that Lilly manufactures.¹²⁴ Lilly claims that Houston Weight Loss Center did not undergo the years of rigorous approval processes that are required to get a drug FDA-approved.¹²⁵ Lilly is also the only manufacturer of the FDA-approved GLP-1 medication with the active ingredient tirzepatide.¹²⁶ There is a growing awareness of the risk of taking compounded tirzepatide, which may rupture the reputation that Lilly has built if their name is associated with the compounded drugs.¹²⁷ Images of the Houston Weight Loss Center's advertising efforts that are being used in this case are below.

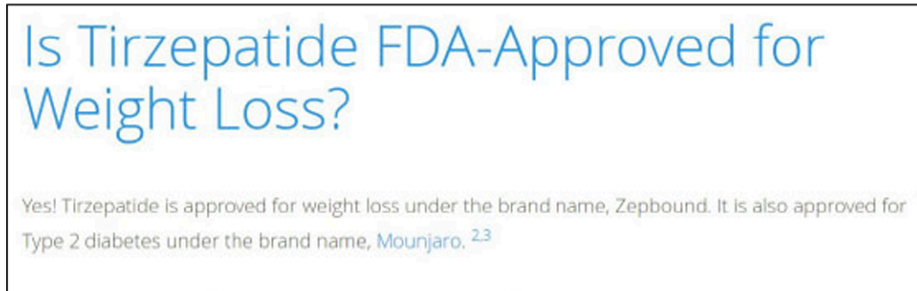


Figure 1. A Statement from Houston Weight Loss Center's Website (1 of 2) ¹²⁸

¹²⁴ Complaint at 3, *Bergeron*, No. 4:24-cv-2313.

¹²⁵ *Id.* at 4.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ This is an image from Houston Weight Loss Center's website, a statement stating that tirzepatide is FDA approved, which is only true for Zepbound and Mounjaro, not the compounded version they are offering. Complaint at 16, *Bergeron*, No. 4:24-cv-2313. They make no comment about how they sell the compounded version of the drug. *See generally id.* Lilly alleges this is likely to lead consumers to believe they are selling tirzepatide that is tested for its safety and effectiveness by starting off the answer to the question with "Yes!" *Id.* at 16. The clinic made no disclaimer stating their version of the drug is not FDA-approved. Lilly alleges this is false advertising. *Id.*

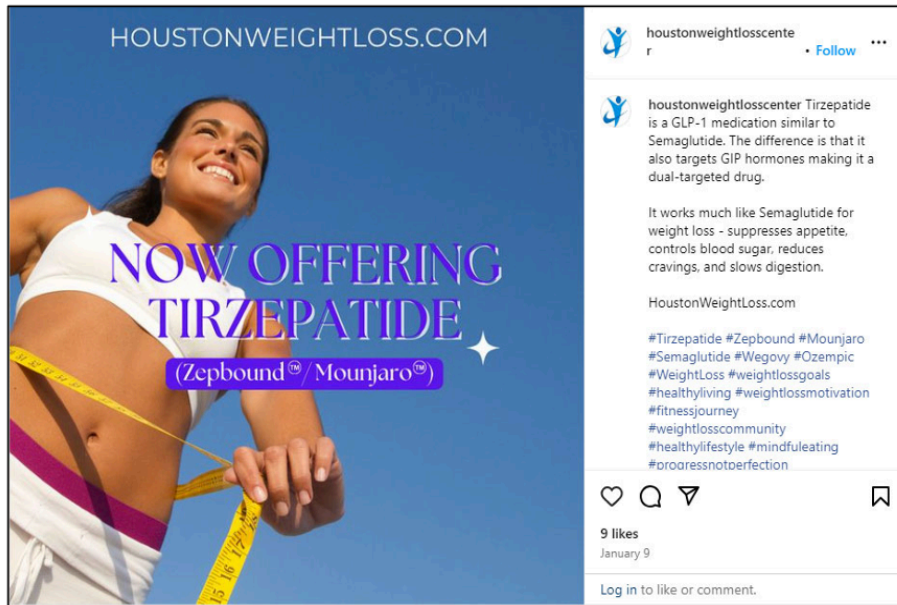


Figure 2. Houston Weight Loss Center Marketing Tirzepatide on their Instagram Page. ¹²⁹

¹²⁹ This is an image from Houston Weight Loss Center's Instagram page. Complaint at 17, *Bergeron*, No. 4:24-cv-2313. The company is using Lilly's trademarks "Zepbound" and "Mounjaro" to market their compounded version of tirzepatide. *Id.* Lilly alleges that this is deceitful because an ordinary consumer will recognize these well-known names and believe this is what the clinic is offering. *Id.* at 18. Lilly states it is likely the clinic is intending to benefit from using the "Zepbound" and "Mounjaro" mark because it is well-known with consumers who are looking to lose weight and known to be safe. *Id.* The clinic also uses the hashtags "#Zepbound" and "#Mounjaro" to attract consumers who are looking for clinics selling those semaglutide. *Id.* at 17. There is no disclaimer that they offer the compounded version of the drugs. Lilly alleges this falls under trademark infringement and false advertising. *Id.*

Clinical Trial Results – Tirzepatide for Weight Loss

In the Surmount 1 clinical trial, Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health. The trial was a randomized, double blind, placebo-controlled study lasting 72 weeks that included 2,539 participants. Participants were required to have a BMI of 30 or greater, or, BMI of 27 or greater with at least one weight-related health problem.

- Tirzepatide 5-mg doses – Average change in weight was -15%
- Tirzepatide 10-mg dose – Average change in weight was -19.5%
- Tirzepatide 15-mg dose – Average change in weight was -20.59%

Placebo – Average change in weight was -3%

Along with these significant weight loss results there were also improvements in all prespecified cardiometabolic measures for participants taking Tirzepatide.¹

Figure 3. A Statement from Houston Weight Loss Center's Website. (2 of 2)¹³⁰

Just last year, Eli Lilly settled with a South Carolina medical spa, Totality Medispa, where both parties agreed the medical spa would stop misleading consumers about the source of the tirzepatide offered at their clinic.¹³¹ Lilly asked

¹³⁰ This is an image from Houston Weight Loss Center's website, using data that was collection from a Lilly "Surmount 1 clinical trial" and claiming these are the results for the tirzepatide they are offering, when in fact the drug they are offering has not been used in any clinical trials nor has it been in tested in any capacity. Complaint at 19, *Bergeron*, No. 4:24-cv-2313. Lilly alleges an ordinary consumer seeing this data may either believe the clinic tested the compounded drug they are offering, and these are the results, or they would achieve the same results from the clinic's compounded drugs. *Id.* at 18–19. There is also no disclaimer that they are offering the compounded version of the drugs. *See generally id.* Lilly alleges this falls under false advertising since the clinic is advertising results from a trial for a drug they are not offering. *Id.* at 19.

¹³¹ OVERHAUSER L. OFF., *Eli Lilly Settles with Totality Medispa Over False Advertising*, IND. INTELL. PROP. L. NEWS (May 31, 2024),

Totality to stop using their marks, “MOUNJARO” and “ZEPBOUND,” when promoting their products, and to clearly state on their website that their drug is a compounded version of tirzepatide and it is not FDA-approved.¹³² Lilly called on state and federal regulators to help manufacturers with the ongoing issue with the sale of compounded drugs that are misleading consumers.¹³³ Eli Lilly continues to battle against companies selling compounded tirzepatide.¹³⁴ At the start of 2025, Lilly sued two medical spas for stating their compounded tirzepatide was “proven to be safe and effective for weight loss.”¹³⁵ Lilly has released a statement stating Mounjaro and Zepbound are the only FDA-approved tirzepatide medicines, and they will continue to take legal action against companies that falsely claim their products are Mounjaro, Zepbound, or FDA-approved tirzepatide.¹³⁶

In 2024, Novo Nordisk has also taken legal actions against several companies that were selling compounded semaglutide with high levels of impurities that may pose significant risks to patients.¹³⁷ From 2023 to 2024, Novo filed sixteen lawsuits against companies marketing compounded semaglutide medicine, with a trademark infringement claim in every lawsuit.¹³⁸ Novo Nordisk registered “OZEMPIC” as a trademark in July 2017¹³⁹ and registered “WEGOVY”

<https://www.iniplaw.org/eli-lilly-settles-with-totality-medispa-over-false-advertising/> [perma.cc/VHK4-6TY9].

¹³² *Id.*

¹³³ *Id.*

¹³⁴ Manas Mishra, *Lilly Sues Two Medical Spas Over Copycat Weight-Loss Drugs*, REUTERS (Jan. 13, 2025), <https://www.reuters.com/business/healthcare-pharmaceuticals/lilly-sues-two-medical-spas-over-copycat-weight-loss-drugs-2025-01-13/> [perma.cc/WTG2-ZHUF].

¹³⁵ *Id.*

¹³⁶ *An Open Letter From Eli Lilly and Company Regarding Certain Practices Related to Mounjaro® and Zepbound®*, LILLY INVESTORS (June 20, 2024), <https://investor.lilly.com/node/50961/pdf> [perma.cc/NRV8-KZ7J].

¹³⁷ Patrick Wingrove, *Wegovy Maker Novo Nordisk Sues Nine Spas, Clinics, and Pharmacies over Copycat Drugs*, REUTERS (May 30, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/wegovy-maker-novo-nordisk-sues-nine-spas-clinics-pharmacies-over-copycat-drugs-2024-05-30/> [perma.cc/WNW3-CMLC].

¹³⁸ *See id.*

¹³⁹ OZEMPIC – Trademark Details, JUSTIA TRADEMARKS, <https://trademarks.justia.com/791/59/ozempic-79159431.html> [perma.cc/6RTL-2S5M].

in December 2021.¹⁴⁰ Just like Lilly, Nordisk is claiming companies are using their marks “OZEMPIC” and “WEGOVY” to promote their compounded semaglutide drugs.¹⁴¹ Nordisk also wants to prevent consumers from being misled about the safety and quality of the compounded semaglutide because compounded pharmacies did not go through the same testing as the FDA-approved semaglutide.¹⁴² Nordisk released a company statement on their website about their effort to take action to prevent companies from selling compounded semaglutide that are misleading consumers into believing their products are FDA-approved.¹⁴³

There are two types of fair use that allow the use of another owner’s trademark: descriptive fair use and nominative fair use.¹⁴⁴ This Section discusses when the two types of fair use apply, specific examples, and why it likely does not apply in the current lawsuit with compounded drugs.

1. *Descriptive Fair Use*

Descriptive fair use is an affirmative defense provided by the Lanham Act.¹⁴⁵ It permits a trademark to be used to describe one’s goods or services and has three elements that must be met: the mark must not be used to indicate the source of the goods, the mark must be used to describe the goods, and the mark must be used in good faith.¹⁴⁶ An example of descriptive fair use is if a company trademarked “Building Bricks,” someone may still describe their product as “building bricks” in their advertisement of a building block toy, as long as they aren’t naming their brand of blocks “Building Bricks.”¹⁴⁷

Although it may sound logical for compounding pharmacies to use the trademark “OZEMPIC” or “MOUNJARO” to describe their products to

¹⁴⁰ WEGOVY – Trademark Details, JUSTIA TRADEMARKS, <https://trademarks.justia.com/793/03/wegovy-79303393.html> [perma.cc/N2MQ-JJNG].

¹⁴¹ *Novo Nordisk Takes Action*, *supra* note 118.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Amanda Hayes, *Fair Use Defense: When Can You Use Another Owner’s Trademark Without Permission?*, NOLO (Jan. 27, 2023), <https://www.nolo.com/legal-encyclopedia/when-you-need-permission-use-trademarks.html> [perma.cc/N73F-BDP4].

¹⁴⁵ 15 U.S.C. § 1115(b)(4).

¹⁴⁶ *Id.*

¹⁴⁷ Hayes, *supra* note 144.

consumers who are more familiar with those marks, this is not what descriptive fair use allows; they must use a descriptive term.¹⁴⁸ A trademark is considered a descriptive term when there is descriptive meaning in addition to its secondary meaning.¹⁴⁹ A descriptive term is commonly an adjective that describes a characteristic or attribute of a good or service.¹⁵⁰ Typically, pharmaceutical drug names are “fanciful,” meaning they are made-up marks with no pre-existing meaning.¹⁵¹ Descriptive fair use would never apply with the use of fanciful marks.¹⁵² Compounded pharmacies are better off using the generic names of the drugs, like semaglutide and tirzepatide, because generic terms are excluded from trademark protection, regardless of whether there is a secondary meaning.¹⁵³ A mark acquires a “secondary meaning” when consumers can distinguish the source-identifying meaning from the ordinary meaning of the word.¹⁵⁴

¹⁴⁸ *Id.*

¹⁴⁹ *Fair Use of Trademarks (Intended for a Non-Legal Audience)*, INT’L TRADEMARK ASS’N (Dec. 16, 2020), <https://www.inta.org/fact-sheets/fair-use-of-trademarks-intended-for-a-non-legal-audience/> [<https://perma.cc/4YZH-A6TQ>].

¹⁵⁰ *Descriptive Trademarks: Everything You Need to Know*, COHN LEGAL, PLLC, <https://www.cohnlg.com/descriptive-trademarks-everything-you-need-to-know/> [perma.cc/L87D-CQY3].

¹⁵¹ *See Strong Trademarks*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/trademarks/basics/strong-trademarks> [perma.cc/E3X9-L9KR]. Since most of the trademarks for the name of pharmaceuticals bear no additional meaning beyond the context of the trademark for the drug itself, it is a fanciful mark.

¹⁵² Ryan Williams, *Trademark Fair Use: The Business Guide*, MARQVISION (Dec. 1, 2023), <https://www.marqvision.com/blog/trademark-fair-use-the-business-guide> [perma.cc/Z3ZC-MNU5]; *Ever Wonder How Drugs Get Their Names?*, Pfixer, <https://www.pfizer.com/news/behind-the-science/ever-wonder-how-drugs-get-their-names> [<https://perma.cc/29VV-B3EN>].

¹⁵³ Benjamin C. Stasa, *Generic Terms and Trademark Protection: Understanding and Navigating the Landscape*, BROOKS (June 19, 2022), <https://www.brookskushman.com/insights/generic-terms-and-trademark-protection-understanding-and-navigating-the-landscape/> [<https://perma.cc/9LKA-CDBR>].

¹⁵⁴ *Id.*

2. *Nominative Fair Use*

Nominative fair use also allows the use of trademarked names and logos and is only recognized as an affirmative defense by the Third Circuit.¹⁵⁵ The Ninth Circuit uses nominative fair use as a test to analyze the likelihood of confusion with a trademark infringement claim.¹⁵⁶ Courts use a three-step test to determine if nominative fair use applies: “(1) whether the use of the plaintiff’s mark is necessary to describe the plaintiff’s product or service and the defendant’s product or service; (2) whether only so much of the plaintiff’s mark is used as is necessary to describe the plaintiff’s product or service; and (3) whether the defendant’s conduct or language reflects the true and accurate relationship between the plaintiff and the defendant’s products or services.”¹⁵⁷ The defendant cannot imply that there is a sponsorship or endorsement between their company and the plaintiffs.¹⁵⁸ An example of a nominative fair use is a coffee shop naming a branded coffee bean, such as “Lavazza,” to advertise the type of coffee beans they use with their services.

Even if trademark infringement claims against compounding pharmacies arise in the Third Circuit, which recognizes nominative fair use as an affirmative defense, the company selling compounded drugs may not prevail if its advertisements were meant to deceive consumers. For example, in the Eli Lilly case, Houston Weight Loss Center is using the names “ZEPBOUND” and “MOUNJARO” as a way to deceive consumers into believing they are offering the FDA-approved product in their clinic.¹⁵⁹ The clinic’s target audience is consumers who are trying to lose weight, and the clinic intends to draw in these consumers by using the well-known marks.¹⁶⁰ Nominative fair use would apply if they were

¹⁵⁵ J. David Mayberry, *Nominative Trademark Use: Affirmative or Negative Defense to Infringement?*, AM. BAR ASSOC. (Mar. 30, 2022), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2021-22/march-april/nominative-trademark-use-affirmative-negative-defense-infringement/ [perma.cc/TGJ3-Q4PM].

¹⁵⁶ Ira S. Sacks & Rachel B. Rudensky, *Nominative Fair Use: The Second Circuit Joins Neither The Third Nor Ninth Circuits In Its Approach*, AKERMAN (May 31, 2016), <https://www.akerman.com/en/perspectives/nominative-fair-use-the-second-circuit-joins-neither-the-third.html> [https://perma.cc/LVV5-JDY7].

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ Complaint at 21, *Bergeron*, No. 4:24-cv-2313.

¹⁶⁰ *Id.*

a clinic offering the actual FDA-approved semaglutide that was manufactured by Eli Lilly, and they used the marks “ZEPBOUND” and “MOUNJARO” to advertise the goods they are providing with their services, without implying a sponsorship or endorsement.¹⁶¹

If an advertisement of a compounded drug were to use an FDA-approved drug mark, such as “OZEMPIC,” to inform consumers that they are using the same active ingredient (e.g., semaglutide), it is recommended that the brand name be used in a way that avoids implication of endorsement or affiliation with the FDA-approved product.¹⁶² One way to help minimize confusion is by displaying the brand name in plain text only, ideally in black font and without the distinctive styling used by the original manufacturer (example shown below).¹⁶³ Additionally, the brand name should not appear in a font size larger than that used for the name of the active ingredient.¹⁶⁴ Comparisons between the compounded product and the FDA-approved drug should generally be avoided to reduce the risk of misleading claims.¹⁶⁵

¹⁶¹ Mayberry, *supra* note 155.

¹⁶² *See id.*

¹⁶³ *See id.*

¹⁶⁴ *See id.*

¹⁶⁵ *See id.*



Figure 4. Novo Nordisk's Logo for "OZEMPIC." ¹⁶⁶

OZEMPIC

Figure 5. Recommended Mark to use Under Normative Fair Use. ¹⁶⁷

¹⁶⁶ OZEMPIC, U.S. Trademark Application Serial No. 79,414,842 (filed Aug. 28, 2024). This is the graphic design for the trademark "OZEMPIC" that Novo Nordisk commonly uses in advertising. *Id.* It has a red and orange ombre effect and the lower case "i" that gets narrower as it goes down. *Id.* This design is also used in the color black.

¹⁶⁷ OZEMPIC, Registration No. 4,774,881. In an instance where a company wanted to use the mark "OZEMPIC" on their compounded drug to communicate with consumers that they are offering the compounded version, then it may look like this: all uppercase letters and only the black color font with a basic font style. They may not use the red and orange colors and may not use the lower case "i" used in the logo above this image. In a case where the background is a dark or black color, then the company may use this style in a white color font.

IV. PROTECTING TRADEMARKS BY GIVING THE FDA MORE AUTHORITY TO EXPAND ON CURRENT REGULATIONS

Part IV first discusses a 2014 Supreme Court case that overturned the FDA's attempt to ban the advertisement of compounded drugs altogether, and a statute addressing misbranded drugs. This Part then discusses possible solutions to help prevent trademark infringement in the marketing of compounded drugs. These solutions expand on previous bills that Congress has enacted and current regulations that FDA-approved drugs must follow.

A. FDA'S ATTEMPT AT REGULATING THE PROMOTION OF COMPOUNDED DRUGS: OVERTURNED

Banning the advertisement of compounded drugs altogether may seem like the best option for protecting the manufacturers of FDA-approved drugs and consumers; however, the Supreme Court has held this to be unconstitutional.¹⁶⁸ The FDA once prevented false advertising from compounded pharmacies by regulating the advertisement of the compounded drugs.¹⁶⁹ Section 503A prohibited the advertising of compounded drugs until 2002, when the Supreme Court held in *Thompson v. Western States Medical Center* that the advertising and solicitation provisions in § 503A were unreasonable and violated compounding pharmacies' First Amendment Right of Free Speech.¹⁷⁰ The court noted that not all regulation of commercial speech is unconstitutional.¹⁷¹ If the commercial speech concerns unlawful activity or is misleading, then the speech is not protected by the First Amendment.¹⁷² Thus, a compounding pharmacy advertising its products using the trademark of an FDA-approved drug is not protected speech if it is misleading. Without fully banning the advertisements of compounded drugs, it is possible to put a few reasonable restrictions that will allow compounding pharmacies to exercise their freedom of speech, while also protecting consumers from deceitful advertisements and manufacturers from trademark infringement.

¹⁶⁸ *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 377 (2002).

¹⁶⁹ Eli Tomar, *Compounding the Off-Label Promotion Debate: How FDA Could Regulate the Promotion of Unapproved Drugs*, FOOD & DRUG L. INST. (Oct. 2017), <https://www.fdpi.org/2017/10/compounding-off-label-promotion-debate-fda-regulate-promotion-unapproved-drugs/> [<https://perma.cc/6WLF-RP9R>].

¹⁷⁰ *Thompson*, 535 U.S. at 377.

¹⁷¹ *Id.* at 367.

¹⁷² *Id.*

B. MISBRANDED DRUGS

Under 21 U.S. C. § 352, a drug is deemed to be misbranded “if its labeling is false or misleading in any particular.”¹⁷³ This statute states that false advertising or promotion of compounded drugs is considered a misbranded drug.¹⁷⁴ 21 U.S. C. § 331 states that introducing misbranded drugs into interstate commerce is prohibited.¹⁷⁵ Under 21 U.S. C. § 333, violation of § 331 may lead to penalties of up to \$10,000, imprisonment for up to three years, or both.¹⁷⁶ Although this penalty may seem like the solution to prevent false advertising of compounded drugs, it is not enough to prevent consumer confusion. The solution discussed in this Note is determined to raise consumer awareness on compounded drugs not being affiliated with the brand name and to have a sufficient label stating compounded drugs are not FDA-approved. This will make it less likely for companies selling compounded drugs to get away with not only misbranding compounded drugs, but also get away with not giving enough information about the drug that may lead to consumer confusion. One of the labeling requirements that this Note discusses as a solution is a standard form of disclaimer that the compounded drug is not FDA-approved. In this case, if a consumer ends up facing a severe risk by taking a compounded drug, they do not affiliate it with the original manufacturer that has undertaken the FDA-approval process which tested the original product for its safety and effectiveness. It is currently not a requirement for compounded drugs to be labeled as not FDA-approved, so these drugs will not fall under misbranding under 21 U.S.C. § 352; thus, it is likely that companies will not face penalties under 21 U.S.C. § 333.¹⁷⁷

How can there be stronger regulations concerning the advertising of compounding pharmacies that create copycats of FDA-approved drugs? This is possible by regulating the advertisement and promotions of compounded drugs. Putting restrictions on advertisements of compounded drugs won't violate the First Amendment if the main purpose is to prevent misleading and deceitful

¹⁷³ 21 U.S.C. § 352.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* § 331.

¹⁷⁶ *Id.* § 333.

¹⁷⁷ *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, NAT'L ACADS. OF SCI., ENG'G & MED. (July 1, 2020), <https://www.ncbi.nlm.nih.gov/books/NBK562881/> [https://perma.cc/7LCD-QWCT]; 21 U.S.C. §§ 333, 353(b).

advertisements.¹⁷⁸ Congress must expand on the current regulations, such as the Drug Quality and Security Act, to give the FDA more authority to regulate the advertisement of compounded drugs. As stated before, the purpose of this act is to give the FDA more authority to regulate and monitor the safety of drugs by improving the safety of compounded drugs for patients and by regulating compounding pharmacies.¹⁷⁹ Once given the authority, the FDA must then place limits on advertising and marketing efforts and include penalties for trademark infringement, false advertising, and unfair competition with compounded drugs.

The main concern for manufacturers of FDA-approved brand drugs, like Eli Lilly, is that compounding pharmacies are using their marks in advertising for drugs that are not FDA-approved.¹⁸⁰ Compounding pharmacies do not have to spend a copious amount of money and go through rigorous testing to ensure the safety and quality of their products, and FDA-approved drug manufacturers do not want their products associated with potentially unsafe drugs.¹⁸¹ Also, consumers are more likely to trust a drug if it is labeled as FDA-approved.¹⁸²

The first step Congress should take is to expand on the Drug Quality and Security Act. As stated before, the purpose of this act is to give the FDA more authority to regulate and monitor the safety of drugs by improving the safety of compounded drugs for patients and by regulating compounding pharmacies.¹⁸³ Congress should amend this Act and add a third part to give the FDA the authority to regulate the marketing and promotion of compounded drugs. Congress is already aware of the dangers that compounded drugs pose, which is why the Drug Quality and Security Act was initially enacted.¹⁸⁴ Congress has also expressed its

¹⁷⁸ *Thompson*, 535 U.S. at 367.

¹⁷⁹ See *DQSA – Drug Quality and Security Act (HR 3204)*, *supra* note 100.

¹⁸⁰ *Stim & Hayes*, *supra* note 113.

¹⁸¹ *Id.*; *Lilly Warns Patients About Counterfeit and Compounded Medicines Releases Open Letter and Takes Further Legal Action Against Counterfeit, Fake, Unsafe, and Untested Products*, LILLY INVESTORS (June 20, 2024), <https://investor.lilly.com/news-releases/news-release-details/lilly-warns-patients-about-counterfeit-and-compounded-medicines> [<https://perma.cc/JN9M-KTMR>].

¹⁸² See Aaron S. Kesselheim et al., *Do Patients Trust the FDA?: A Survey Assessing How Patients View the Generic Drug Approval Process*, 26 *PHARMACOEPIDEMIOLOGY & DRUG SAFETY* 694, 694 (2017).

¹⁸³ *DQSA – Drug Quality and Security Act (HR 3204)*, *supra* note 100.

¹⁸⁴ *FDA Issues Final Guidance on Direct-to-Consumer Prescription Drug Advertisements*, *supra* note 94; HASSAN Z. SHEIKH, CONG. RSCH. SERV., R45069,

concern with current issues of drug advertisements that are deceitful, but they have yet to expand the FDA's authority for the regulation of marketing for compounded drugs.¹⁸⁵ By amending the Act to give the FDA more authority, Congress is taking a step towards protecting consumers from deceitful advertisements and the dangers of compounded drugs.

Once given the authority to do so, the FDA must then expand on its current regulations of the advertising of FDA-approved drugs to include compounded drugs. The FDA currently has strict regulations for drug advertising,¹⁸⁶ which may lessen trademark infringement and false advertising claims if they were applied to advertisements for compounded drugs as well.

After being given the authority, the FDA must expand on the current regulations for drug advertising and require all advertising and promotions of compounded drugs to have a standard form of disclaimer stating that it is a compounded drug, it is not FDA-approved, and it has not been tested for its safety, quality, and effectiveness for its intended use. For all advertisements that have a visual component, the disclaimer must always be displayed in a readable font size, and the color must be a clear contrast from the background. For audio-only advertisements, such as the radio or television, there must be an effective audible display stating the disclaimer.

V. CONCLUSION

As of recently, both diabetes/weight loss medicines that Novo Nordisk and Eli Lilly manufacture are no longer on the shortage list.¹⁸⁷ There has now been an upsurge of lawsuits from diabetes drug manufacturers attacking telehealth companies, wellness centers, and medical spas that are continuing to sell compounded versions of tirzepatide and semaglutide.¹⁸⁸ It is only a matter of time

DRUG COMPOUNDING: FDA AUTHORITY AND POSSIBLE ISSUES FOR CONGRESS 1–4 (2018).

¹⁸⁵ *Prescription Drug Advertising*, *supra* note 88.

¹⁸⁶ *Id.*

¹⁸⁷ Claire Bugos, *GLP-1 Drug Shortage Is Over. Why Might These Drugs Soon Be Costlier and Harder to Access?*, *VERY WELL HEALTH* (Nov. 8, 2024), <https://www.verywellhealth.com/glp-1-shortages-ending-8738577> [perma.cc/6LPU-UA6T].

¹⁸⁸ Brendan Pierson, *Lilly Asks to Join Lawsuit Over Compounded Versions of Its Weight-Loss Drug*, *REUTERS* (Jan. 2, 2025), <https://www.reuters.com/business/healthcare-pharmaceuticals/lilly-asks-join-lawsuit-over-compounded-versions-its-weight-loss-drugs-2025-01-02/>

before these drugs are back on the shortage list as the demand for weight loss medicine continues to increase.¹⁸⁹ Novo Nordisk has also informed the Ozempic Medicine Shortage Action Group that there is a limited supply of Ozempic in 2025.¹⁹⁰ Once these drugs do hit the shortage list, it is likely there will be an increase in trademark infringement and false advertising lawsuits.¹⁹¹

Overall, to prevent an abundance of lawsuits that may occur once weight loss and diabetes medication are back on the FDA shortage list, Congress must expand on the Drug Quality and Security Act to give the FDA more authority to add restrictions to the advertising of compounded drugs. The FDA then must require a standard form of disclaimer on compounded drugs stating they are compounded, not FDA-approved, and they have not been tested for their safety, quality, and effectiveness for their intended use. Expanding on current regulations, such as the Drug Quality and Security Act, will assure the protection of consumers and the trademark holders of FDA-approved drugs.

[perma.cc/LK42-ZS4M]; see, e.g., John Kern & Isabella Granucci, *Eli Lilly Strikes Back Against Pharmacy Compounders and Telehealth Platforms*, HOLLAND & KNIGHT (June 13, 2025), <https://www.hklaw.com/en/insights/publications/2025/06/eli-lilly-strikes-back-against-pharmacy-compounders-and-telehealth> [perma.cc/4YSL-DFBW].

¹⁸⁹ Shalina Chatlani, *As Demand for Weight-loss Drugs Rises, States Grapple With Medicaid Coverage*, STATELINE (Jan. 6, 2025), <https://stateline.org/2025/01/06/as-demand-for-weight-loss-drugs-rises-states-grapple-with-medicaid-coverage/> [perma.cc/7NWR-G9S8].

¹⁹⁰ Michael Woodhead, *Ozempic Shortages to Continue Through 2025*, THE LIMBIC (Jan. 17, 2025), <https://thelimbic.com/endocrinology/ozempic-shortages-to-continue-through-2025/> [perma.cc/8XDC-MCRF].

¹⁹¹ See *supra* Part IV.