

# Publications

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## Monday Morning (Advertising) Quarterback – Unprecedented Hims & Hers Super Bowl Ad Has Legislators Concerned

The Super Bowl is not just the biggest game of the year for football fans, but it is also one of advertising's biggest nights. Therefore, the FDA lawyers at Polsinelli were not only tuned in to root for the Kansas City Chiefs (as their official law firm partner) but were watching for this year's most creative advertisements.

One commercial started gaining buzz even before kick-off. On Friday, Senators Richard Durbin (D-IL) and Roger Marshall (R-KS) asked the FDA to throw a penalty flag to stop Hims & Hers from marching down the field with their "life-changing" weight-loss solutions ad. According to the letter sent to FDA acting Commissioner Sara Brenner, the senators expressed concern that the Hims & Hers ad "risks misleading patients by omitting any safety or side effect information," about the compounded weight loss drugs that it promotes.

Like other telehealth companies, Hims & Hers utilizes its internet platform to connect consumers to telehealth providers who issue prescriptions in appropriate cases for GLP-1 drugs, which are filled by compounding pharmacies at markedly lower prices than FDA-approved brand name products. GLP-1s are a class of medications that mimic gut hormones that regulate blood sugar and suppress appetite and are known for their weight loss benefits. However, due to insurance restrictions and the high retail price of these medications, they are not easily accessible for individuals seeking to utilize these products for weight loss.

Compounders have taken advantage of the popularity of these medications, which have been on FDA's drug shortage list for several years. When a drug is on the shortage list, pharmacies are permitted to make compounded copies of the drug if they meet specific regulatory requirements outlined in sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). By complying with these conditions, compounded drugs are exempted from several requirements, such as FDA approval and certain labeling conditions. This enables online pharmacies and telehealth companies to produce and sell cheaper versions of the same active ingredient without having to go through the costly FDA approval process.

### Related People

- Stuart M. Pape
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### Related Capabilities

- Food, Drug & Device
- Health Care

As compounded drugs are not “approved” by FDA, these drugs technically have no approved label, indications, or uses. Therefore, pharmacies are exempted from section 502(f)(1) of the FD&C Act requiring adequate directions for use. Similarly, compounded drugs are exempt from the prescription drug advertisement rules outlined in 21 C.F.R. 202.1, which require, among other things, that all advertisements contain a fair balance between information relating to side effects and contraindications and information relating to the effectiveness of the drug. See 21 C.F.R. 202.1(2)(iii).

However, this does not give pharmacies and telehealth companies a “free pass” to run up the score in any way they want, as they are still restricted from making claims related to the therapeutic safety and effectiveness of the drug to remain within this exemption. Online pharmacies are also governed by the same general misbranding provisions under the FD&C Act and Federal Trade Commission rules that prohibit false and deceptive advertising. Therefore, considering the popularity of these platforms and FDA’s outspoken concerns regarding compounded GLP-1 drugs,<sup>1</sup> companies should still consult with regulatory experts before disseminating expensive marketing campaigns in this space.

With the recent change in administration and Robert F. Kennedy, Jr.’s flip-flopping positions on the use of GLP-1s for weight loss, it is unclear whether FDA will seek to rein in telehealth companies promoting GLP-1 drugs. However, just like the “Brotherly Shove” that guided the Eagles to Super Bowl victory, you can either love it or hate it, but until the regulators modify the rules, the Polsinelli lawyers, upon further review, are calling no flag on the play.

[1] See FDA, FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (Dec. 18, 2024).