HaleAdvisors

Safety First

By Zoë Dunn | February 24, 2025

Recent debates surrounding the regulation of compounding pharmacies and telehealth companies have intensified, particularly in light of the recent Hims & Hers Super Bowl advertisement for its compounded GLP-1. Critics argue that these ads mislead consumers about the safety and efficacy of compounded medications, which are not subject to the FDA approval process for prescription drugs. Regulatory bodies and industry experts alike have expressed serious concerns about the potential health risks posed by these products.

The FDA has consistently warned that compounded drugs do not undergo the rigorous testing required for approved pharmaceuticals, making them inherently riskier for consumers. The recent advertisement by Hims & Hers has been labeled as "incredibly irresponsible" by healthcare providers and regulatory professionals, as it fails to disclose critical safety information, including FDA warnings and potential side effects. Furthermore, the ad does not comply with the advertising standards set forth by the FDA and the FTC, raising questions about whether compounded medications are being marketed in a way that puts public health at risk.

The FDA draft guidance *Presenting Risk Information in Prescription Drug and Medical Device Promotion* explicitly requires that prescription drug ads disclose all material risks, communicate clearly that the product is prescription-only, and substantiate any claims made. The Hims & Hers advertisement fails to meet these basic standards, contributing to a dangerous precedent where consumers may not fully understand the risks associated with unapproved compounded medications.

To address growing concerns, a trade association called Alliance for Pharmacy Compounding (APC) created a guideline called *Best Practices for Marketing Compounded Medications*. The APC cautions that pharmacies must avoid making misleading claims regarding safety and efficacy. Notably, research from the JAMA Health Forum[1] has shown that many online sellers of compounded GLP-1 drugs fail to disclose critical safety information, increasing the likelihood of patient harm. Their guidelines strongly discourage marketing based on price comparisons and urge pharmacies to focus on patient-specific needs, drug shortages, and adherence to quality standards. This aligns with the FDA's

[1] Ashwin K. Chetty, BS; Mahima Chillakanti, MS; Reshma Ramachandran, MD, MPP, MHS; et al. Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists. JAMA Health Forum. Published January 17, 2025. Accessed February 24, 2025. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225

stance that compounding should not be used as a cost-saving alternative to commercially available drugs.

To gain an industry perspective, Hale Advisors conducted a highly scientific (wink) LinkedIn survey among pharmaceutical and healthcare professionals, which revealed that 95% of respondents believe that stricter communication regulations are necessary for compounding pharmacies. That's right—95%. If compounding pharmacies were a contestant on a reality show, this would be the part where the audience collectively votes them off the island (or at least votes that they be subject to the same rules as the other contestants). This overwhelming consensus underscores the widespread concern that the current regulatory framework does not sufficiently protect consumers from misleading marketing practices.

Adding to the regulatory pressure, on February 21 the FDA announced that semaglutide, the active ingredient in weight loss drugs Ozempic® and Wegovy®, is no longer in short supply. Under U.S. regulations, compounding pharmacies are permitted to manufacture approximations of branded drugs when the reference drug is in shortage. With the FDA now reclassifying the semaglutide shortage as "resolved," compounded versions of semaglutide will no longer be permitted under current regulations. This decision is a significant setback for manufacturers of compounded semaglutide and telehealth companies that have built a market around selling cheaper alternatives to branded weight-loss drugs.

The FDA has given compounding pharmacies until April or May, depending on their regulatory status, to stop compounding, distributing, or dispensing semaglutide injection products. This shift is expected to significantly impact the compounding industry and telehealth companies like Hims & Hers, which saw its stock tumble 25% following the announcement.

Many healthcare professionals argue that the demand for weight-loss drugs remains high and that potential future shortages could impact patient access. Even the FDA acknowledged that "patients and prescribers may still see intermittent and limited localized supply disruptions." Additionally, affordability concerns persist, as compounded GLP-1 medications typically cost under $200 per month, while branded alternatives like Ozempic and Wegovy can exceed $1,000 per month. Some experts worry that patients unable to afford branded medications may turn to unregulated or counterfeit products, further complicating the issue.

The FDA's announcement serves as a reminder that safety and transparency must always come first. Compounding pharmacies have a role to play in patient care, but they must adhere to the highest regulatory standards to ensure public trust. And let's be honest, if you're selling medicine like it's a late-night infomercial, you might be doing it wrong.

Given the serious health implications, regulatory agencies and broadcasting companies must take action to ensure that compounded medications are marketed responsibly and in full compliance with the existing FDA guidance or even the APC best practices. Strengthening oversight in this area is crucial to safeguarding public health and maintaining trust in the pharmaceutical industry. Patients deserve full transparency when it comes to their health, and we should accept nothing less. Because at the end of the day, when it comes to medicine, we should be making decisions based on science—not on who has the flashiest commercial.

About the Author
Zoë Dunn has spent her career shaping how the life sciences industry looks at risk and marketing. She is the president and CEO of Hale Advisors, bringing to bear more than 20 years' experience in advertising and promotion governance strategy, as well as deep expertise in digital and omnichannel marketing and modular content readiness. Last year, Zoë penned the essential reference "Navigating the shift to omnichannel marketing" for *Regulatory Focus*, the peer-reviewed journal of RAPS, the Regulatory Affairs Professionals Society. She loves a good debate and can be contacted at zoe@haleadvisors.com.

About Hale Advisors
Hale Advisors is a consulting company focused on marketing governance for the life sciences. Hale has created the industry's best practice for managing advertising and promotion regulatory risk while creating organizational readiness for innovations such as omnichannel marketing, modular content, and GenAI. Founded in 2010, Hale has worked with 18 of the top 25 pharmaceutical companies. Twice named an *MM+M* "Best Place to Work," Hale Advisors is proud to be a WBENC-certified woman-owned business. Learn more at haleadvisors.com or follow along on LinkedIn.