The truth about that Hims & Hers Super Bowl ad

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What two US Senators (and others, too) are getting wrong about it

The Hims & Hers planned Super Bowl ad buy – and the content of that ad – is noteworthy, but not because it violates any regulations.

Indeed, the ad generally complies with federal law and U.S. Food and Drug Administration guidance, as well as the Alliance for Pharmacy Compounding's recommended Best Practices for Marketing Claims related to compounded drugs. I say more about that below.

Still, it's being pronounced in media stories as misrepresentative, and one even refers to it, incredibly, as 'the Wild West." It is neither.

Yet as a result, U.S. Senators Richard Durbin and Roger Marshall have written to FDA to say the ad "risks misleading patients by omitting any safety or side effect information" and suggest that the agency "take enforcement action against marketing that may mislead patients about this company's products."

It's a perplexing request, *considering that drugmakers run this sort of service-focused, disclosure-free advertising all the time.* More about that below, too.

Because there appears to be confusion about the nature of the ad, the role of compounded drugs, and what regulatory standards apply to their advertising and labeling, here is a primer.

Compounded drugs are not FDA-approved and are not subject to large-scale clinical trials

Unlike FDA-approved drugs, compounded medications do not go through large-scale, double-blind, placebo-controlled clinical trials to establish their safety and efficacy. Instead, these medications are prepared by state-

licensed compounding pharmacies or FDA-registered outsourcing facilities to meet specific patient needs when commercially available options are unavailable or unsuitable.

Because compounded medications are not FDA-approved, they do not carry standardized FDA-required labeling, including side-effect warnings, boxed warnings, or risk evaluation and mitigation strategies (REMS) that apply to approved drugs. However, they are still subject to state board of pharmacy oversight and must comply with USP compounding standards and Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

Unlike FDA-approved drugs, which must comply with strict labeling requirements under the Federal Food, Drug, and Cosmetic Act, compounded medications have different rules for marketing and advertising. Labeling applies to the physical drug container and ancillary written materials (like package inserts) and includes required information for prescribers and patients. In contrast, marketing materials and advertisements must follow separate regulations overseen by the FDA and the Federal Trade Commission (FTC).

Who regulates these advertisements?

- **The FDA** regulates advertising for FDA-approved drugs, ensuring that prescription drug ads are truthful, balanced, and not misleading.
- **The FTC** regulates advertising for non-FDA-approved products, including compounded drugs and dietary supplements. The FTC's focus is on preventing false or deceptive advertising and ensuring that promotional materials accurately describe the product without misleading claims.

This distinction is important because compounded drug advertisements fall under FTC jurisdiction, not the FDA's typical prescription drug advertising rules.

APC's Best Practices for Marketing Compounded Drugs

The Alliance for Pharmacy Compounding has established **Best Practices for Marketing Compounded Drugs** to guide pharmacies in providing accurate and transparent communications to patients and prescribers. One key recommendation is that marketing materials for compounded drugs should include a disclosure that the product is not FDA-approved. This helps ensure patients and healthcare providers understand the regulatory distinction between compounded and manufactured medications.

The Hims ad is consistent with "help-seeking" pharmaceutical advertising

Because the Hims ad does not promote a specific drug or medication, it is not required to provide information about side effects or risks.

Many FDA-approved drug manufacturers produce similar "help-seeking" advertisements, which do not name a specific drug but instead educate patients about a medical condition and encourage them to consult a healthcare provider. These ads avoid direct claims about a particular drug's benefits or risks, making them different from direct-to-consumer drug advertisements, which must include risk disclosures.

Here are just three examples among many:

· **Eli Lilly Disrupts Grammys With a Timely Message About Breast Cancer**

· **Eli Lilly TV Spot, Alzheimers Disease: Hope**

· **My Time to Quit Smoking Commercial - Pfizer (2007)**

If compounding pharmacies or telehealth companies market specific compounded drugs for weight loss, they must ensure their marketing does not mislead consumers about the drug's approval status, safety, or effectiveness. Best practices dictate that any promotion of compounded medications should clearly state that they are compounded, not FDA-approved, and intended for patient-specific needs under a prescriber's guidance.

Hims' Super Bowl ad does not promote a specific drug or medication and therefore is not required to provide information about side effects or risks. Instead, it encouraged viewers to consult with a healthcare provider, which aligns with the FTC's guidelines for non-specific, "help-seeking" advertisements.

APC supports transparent and responsible marketing that accurately informs consumers while adhering to regulatory standards. While compounded drugs play a critical role in ensuring access to customized therapies, they are not FDA-approved, do not undergo large-scale clinical trials, and are not subject to standardized drug labeling requirements.

As the conversation around weight-loss drug marketing continues, we encourage companies promoting compounded medications to adhere to best practices, provide full disclosures where required, and ensure that their advertisements align with FTC guidelines.

While the focus of Hims' Super Bowl ad on drug pricing may push the envelope in terms of the role of compounded drugs in our healthcare system – *I say that's a debate worth having* – it's also perfectly consistent with laws and regulations that allow companies to promote healthcare services without promoting specific drug or needing to make certain disclosures about certain drugs.

I urge Senators Durbin and Marshall to reconsider their letter to FDA in light of this information.

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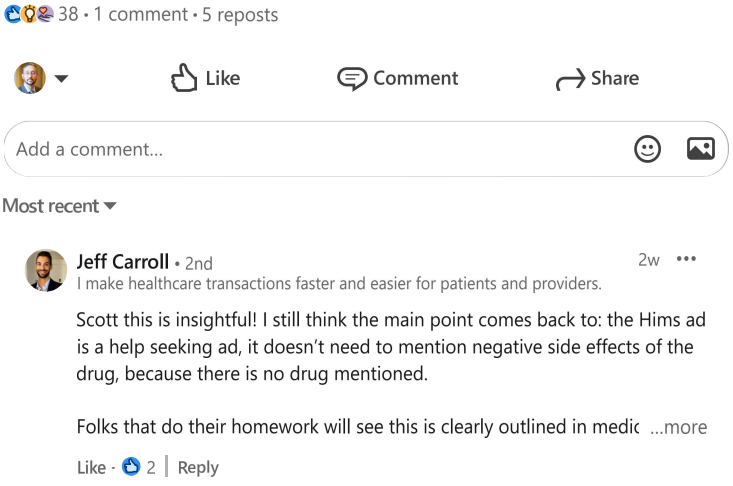

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