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WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Honorable Senator Dick Durbin

Honorable Senator Roger Marshall

United States Senate

Washington, DC 20002

February 27, 2025

Dear Senators Durbin and Marshall,

We write to respond to the statement by the Alliance for Pharmacy Compounding (APC) that responds to your requests for information about the claims in the Hims & Hers Super Bowl advertisement (Advertisement).[1] APC has asserted that the Advertisement "generally complies with federal law" and FDA guidance and "does not violate any regulations". They have also asserted that the Federal Trade Commission has jurisdiction over these advertisements. Their statements represent an inaccurate understanding of the applicable law and regulations.

First, the Advertisement does not comply with federal law. The Advertisement misleads consumers about the potential health risks, side effects, and contraindications of drugs for "weight loss", which is not an FDA-approved indication for use for all patient populations for glucagon-like peptide-1 receptor agonist (GLP-1) drugs. The Federal Food, Drug, and Cosmetic Act (FDCA) provides that "if the advertising or promotion of a compounded drug is false or misleading in any particular", then the drug is misbranded.[2] Importantly, this FDCA misbranding provision does not require a particular person to be responsible for the false or misleading advertising or promotion of a compounded drug. As a result, a telehealth company, technology platform, manufacturer, packer, distributor or any other person can misbrand a compounded drug under the FDCA. Likewise, the FDCA's list of prohibited acts states simply that the "misbranding of any … drug" is a prohibited act.[3] The Advertisement does not comply with the FDCA because the Advertisement misbrands drugs, and it is a violation of the FDCA to misbrand a drug, to introduce a misbranded drug into interstate commerce, and to deliver a misbranded drug for introduction into interstate commerce.[4]

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[1] Statement by Alliance for Pharmacy Compounding CEO Scott Brunner on Request by Senators Durbin and Marshall to FDA About Claims in Hims & Hers Super Bowl Ad (Feb. 7, 2025).

[2] 21 U.S.C. § 352(bb). Additionally, if the labeling of a drug is false or misleading in any particular, the drug is misbranded. 21 U.S.C. § 352(a)(1). *See also* Hims & Hers Health, Inc., Form 10-K for the Fiscal Year Ended Dec. 31, 2024 (stating "FDA regulations relating to the advertising and promotion of prescription … drugs, including prescription compounded drugs, also require that promotional materials for prescription drugs not be false or misleading. Failure to comply with FDA requirements can result in a prescription drug being deemed misbranded under the FDCA.").

[3] 21 U.S.C. § 331(b). Under 21 U.S.C. § 379a, there is a presumption that the connection with interstate commerce exists in any action to enforce the FDCA with respect to drugs.

[4] *See, e.g.*, 21 U.S.C. § 331(a) – (c). The FDA also determined on February 21, 2025, that the shortage of semaglutide injection products has been resolved and that the agency may take action against compounders for

The FDCA also provides that prescription drug advertising for any prescription drug distributed or offered for sale must contain a "true statement" of "information in brief summary relating to the side effects, contraindications, and effectiveness" of a drug.[5] The FDCA and FDA regulations also require that prescription drug television advertisements provide a major statement relating to side effects and contraindications in a "clear, conspicuous, and neutral manner."[6] The FDCA and FDA regulations do not exempt compounded drug advertisements from such requirements, and the Advertisement did not provide this required information to consumers.[7] It is also a violation of the FDCA to disseminate a television advertisement without complying with the FDA's requirements for television advertisements.[8] The FDCA and FDA regulations provide for the submission of television advertisements "for a drug" to the FDA for review before the television advertisement is disseminated, and compounded drugs are drugs under the FDCA.[9] The FDCA's section on pharmacy compounding sets forth specific sections of the FDCA that do not apply to compounded drug products; the FDCA's television advertisement requirement is not one of these very limited FDCA sections.[10]

Second, the Advertisement does not comply with FDA regulations. FDA regulations for prescription drug advertisements apply to compounded drugs and only contain a limited exception for certain compounded drugs which is not applicable to the Advertisement.[11] The APC has asserted that because the Advertisement is a "help-seeking" advertisement that does not promote a specific drug or medication, it is not required to provide information about side effects or risks. The Advertisement would not fall within FDA's description of help-seeking advertisements, which are those that "describe a disease or condition but do not recommend or suggest a specific drug treatment."[12] The Advertisement recommends the use of drugs for specific diseases and conditions: to combat obesity and overweight and for weight loss.[13] Importantly, none of Ozempic, Mounjaro, Saxenda or Wegovy are FDA-approved for general weight loss in all populations.[14] As a result, the Advertisement is advertising an unapproved, off-label use for specific diseases and conditions. The Advertisement also recommends and suggests the use of specific drugs (e.g.,

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violations of statutory and regulatory requirements. FDA, FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize, https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[5] 21 U.S.C. § 352(n).

[6] *Id.*; 21 C.F.R. § 202.1(e)(1)(ii).

[7] *See* 21 U.S.C. §§ 353a(a), 353b(a).

[8] 21 U.S.C. §§ 331(kk), 353c; 21 C.F.R. § 202.1(e), (j).

[9] 21 U.S.C. §§ 353c, 321(g)(1), (p); 21 C.F.R. § 202.1.

[10] *See* 21 U.S.C. §§ 353a(a), 353b(a).

[11] 21 C.F.R. § 202.1.

[12] FDA, Basics of Drug Ads, https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads#help_seeking.

[13] All three terms are used in the commercial.

[14] *See, e.g.*, Ozempic Highlights of Prescribing Information (Jan. 28, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209637s025lbl.pdf; Mounjaro Highlights of Prescribing Information (Nov. 1, 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215866s010s015s 022lbl.pdf; Wegovy Highlights of Prescribing Information (Nov. 27, 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s 015lbl.pdf. Wegovy is FDA-approved to reduce excess body weight and maintain weight reduction long term in: adults and pediatric patients aged 12 years and older with obesity, and adults with overweight in the presence of at least one weight-related comorbid condition. *Id.*

compounded Ozempic and Wegovy) provided by Hims & Hers.[15] As a result, the advertisement is a drug product claim advertisement that must comply with FDA laws and regulations. Additionally, FDA regulations also prohibit reminder ads for drugs that have boxed warnings.[16] Since Ozempic, Mounjaro, Saxenda, and Wegovy have boxed warnings as a result of a risk of thyroid c-cell tumors, FDA regulations do not permit reminder advertisements for such drug products.[17]

Third, the Advertisement does not comply with FDA guidance. FDA withdrew its draft guidance on "help-seeking" advertisements in 2015.[18] FDA issued a subsequent, final guidance that states that compounded drug products intended for use in humans must not have "labeling, advertising, and promotion" that is "false or misleading", and, as noted above, the Advertisement is misleading with respect to side effects, contraindications, and effectiveness.[19] FDA's guidance also states that if "an individual or firm compounds a drug product that does not meet the conditions" of the FDCA, including those regarding labeling, advertising, and promotion, then the individual or firm that "compounds the drug product may also be subject to a warning letter, seizure of product, injunction, and/or criminal prosecution for violations of the FDCA".[20]

Fourth, the APC has argued that "compounded medications have different rules for marketing and advertising" and that the Federal Trade Commission (FTC) "regulates advertising for non-FDA approved products, including compounded drugs". This is inaccurate and contrary to what Hims & Hers has expressly stated in its public filings with the Securities and Exchange Commission:

- "FDA may also bring enforcement actions for false or misleading advertising and promotion of prescription drugs, including compounded drugs";
- "[T]he promotion and advertising of these compounded drugs is subject to FDA regulation"; and
- "FDA regulates all labeling and advertisements for prescription … drugs. FDA prohibits false or misleading promotional statements and has broad authority to determine whether a

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[15] The annual report filed by Hims & Hers describes the company's compounded injectable semaglutide drugs that are part of the company's "weight loss specialty": "In May 2024, we began offering access to GLP-1s, first in the form of compounded injectable semaglutide and in August 2024, in the form of branded (or FDA-approved) injectable semaglutide, as part of our weight loss specialty. … all doses of semaglutide marketed under the trade names Ozempic and Wegovy became listed as available on the FDA's Drug Shortage List as of October 30, 2024. On February 21, 2025, the FDA resolved the semaglutide shortage, which could constrain our ability to continue providing access to compounded semaglutide on our platform once our current inventory has been sold." Hims & Hers Health, Inc., Form 10-K for the Fiscal Year Ended Dec. 31, 2024.

[16] 21 C.F.R. § 202.1(e)(2)(i).

[17] *See, e.g.*, Ozempic Highlights of Prescribing Information, Mounjaro Highlights of Prescribing Information, and Wegovy Highlights of Prescribing Information, *supra* note 14.

[18] FDA, Withdrawal of Draft Guidance Documents Published Before December 31, 2013, 80 Fed. Reg. 26059, 26060 (May 6, 2015).

[19] 21 U.S.C. §§ 352(a), (bb), 321(n); FDA Guidance, Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (June 2016), at 7.

[20] The FDA Guidance cites *Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 405 (5th Cir. 2008), which states that "compounded drugs are in fact 'new drugs' as defined by [21 U.S.C.] § 321(p) but are exempt from the requirements of [21 U.S.C.] §§ 351(a)(2)(B), 352(f)(1), and 355 if and only if they comply with the conditions set forth in [21 U.S.C.] § 353a".

> communication is 'false or misleading', including taking into account whether a communication fails to disclose material facts in light of the representations made. These restrictions may be more limiting for compounded products as compared with FDA-approved products regarding efficacy and safety claims".[21]

Congress has granted FDA the authority to ensure that prescription drugs are safe and effective for the uses in the drug's labeling and has given FDA the explicit authority to oversee compounded drugs.[22] Under a 1971 Memorandum of Understanding with the FTC, FDA exercises primary responsibility for prescription drug advertising.[23] While compounded medications have different rules for "labels", which are "written, printed or graphic matter upon the immediate container" of a drug[24], compounded drugs are subject to the same FDCA requirements as prescription drugs for labeling, advertising, and promotion.[25]

Finally, the APC has asserted that "labeling applies to the physical drug container and ancillary written materials (like package inserts)". The APC has incorrectly defined "labeling". The FDCA defines "labeling" broadly to mean "all labels" and "other written, printed or graphic matter".[26] The FDA and the Supreme Court have broadly interpreted "labeling" to apply to marketing and advertising materials, including advertisements.[27]

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[21] Hims & Hers Health, Inc., Form 10-K for the Fiscal Year Ended Dec. 31, 2024.
[22] Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 302 (2019); *see, e.g.*, 21 U.S.C. §§ 353a, 335a-1, 353b(a).
[23] Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) 9,851 (1971); *see also* 21 C.F.R. § 202.1(l)(1)(defining advertisements subject to 21 U.S.C. § 352(n) to include advertisements broadcast through medica such as television).
[24] 21 U.S.C. § 321(k).
[25] 21 U.S.C. §§ 352(a), (bb), 321(n); FDA Guidance, Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (June 2016), at 7; *see also* FDA, Final Rule, Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format, 88 Fed. Reg. 80958, 80961 (Nov. 21, 2023)(stating "since 1938 (for labeling) and 1976 (for advertising), [21 U.S.C. § 352(n)] has reflected the principle that disclosing material facts that include the 'consequences' of using the drug to which labeling or advertising relates is key to ensuring that such communications are not misleading").
[26] 21 U.S.C. § 321(m).
[27] *See, e.g.*, Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 303-04 (2019) ("Although we commonly understand a drug's 'label' to refer to the sticker affixed to a prescription bottle, in this context the term refers more broadly to the written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription bottle when the drug is handed to the patient at the pharmacy."); PLIVA, Inc. v. Mensing, 564 U.S. 604, 615 (2011) ("The FDA argues that Dear Doctor letters qualify as 'labeling'. … we defer to the FDA."); Kordel v. United States, 335 U.S. 345, 348-350 (1948) ("[W]e conclude that the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported. … The second clause [of 21 U.S.C. § 321(m)] – 'accompanying such article' – has no specific references to packages, containers or their contents as did a predecessor statute. … No physical attachment one to the other is necessary. … Every labeling is in a sense an advertisement. The advertising which we have here performs the same function as it would if it were on an article or on the containers or wrappers. As we have said, physical attachment or contiguity is unnecessary under [21 U.S.C. § 321(m)]".).

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We look forward to further dialogue with you both regarding the urgent need for FDA to take action against compounded drug advertisements that fail to comply with FDA laws, regulations, and guidance.

Sincerely,

Shabbir J. Imber Safdar, CFE
Executive Director
Partnership for Safe Medicines