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FDA Begins Crackdown on Direct-to-Consumer Pharmaceutical Advertising

FDA's two-part strategy for reining in DTC advertisements involves greater enforcement combined with rulemaking to require more risk information in broadcast advertisements.

Enforcement Letters

- The US Food and Drug Administration (FDA) issued a flurry of letters to manufacturers in early September 2025 following a presidential memorandum directing FDA to "take appropriate action to enforce the Federal Food, Drug, and Cosmetic Act's prescription drug advertising provisions, and otherwise ensure truthful and non-misleading information in direct-to-consumer prescription drug advertisements." In turn, the Department of Health and Human Services (HHS) and FDA committed to a "more expansive reading" of FDA's enforcement authorities, "in contrast to the overly cautious approach taken by previous administrations."
- Consistent with this pledge, FDA sent more than 100 enforcement letters to pharmaceutical companies and compounding firms. The letters allege that certain promotional communications and direct-to-consumer (DTC) advertisements are false and misleading.
- FDA has also committed to leveraging AI and other tech-enabled tools to support this effort.
- FDA intends to "close digital loopholes" by expanding its oversight to encompass "all social media promotional activities," including influencer partnerships and sponsored content across all platforms.
- Companies will be watching carefully to assess whether FDA issues enforcement letters articulating standards that differ from the existing framework.

FDA Rulemaking

- FDA announced its intention to conduct rulemaking that would require broadcast advertisements for prescription drugs and biologics to present a "brief summary" of information relating to a drug's side effects, contraindications, and effectiveness.
- Under current FDA guidance, a "major statement" conveying a drug's most important safety risks and instructions for viewers to access a drug's full prescribing information — the "adequate provision loophole," as FDA describes it — are sufficient to meet disclosure obligations.

- A rulemaking could take a year or more to finalize and interested parties will have the opportunity to provide comment. Any final agency action will likely be challenged on First Amendment grounds for impermissibly burdening commercial speech.

Architecture Behind the DTC Advertisement Enforcement Effort

On September 9, 2025, President Trump signed a presidential memorandum that directs HHS to increase "the amount of information regarding any risks" associated with the use of prescription drugs and instructs FDA to "take appropriate action to enforce the Federal Food, Drug, and Cosmetic Act's prescription drug advertising provisions."[1] HHS and FDA announced that same day in simultaneous news releases that FDA would begin a "crackdown on deceptive drug advertising."[2] HHS also published a fact sheet accompanying its news release, further detailing the actions FDA will take, which include conducting "rule-making to close the 'adequate provision' loophole to ensure risk disclosure" and "stepping up enforcement action of DTC pharmaceutical ads."[3]

Part I: Increased Enforcement via Untitled and Warning Letters

In the September 9 announcements, FDA promised "[a]ggressive enforcement of DTC violations."[4] Thereafter, FDA sent a letter to every sponsor of an approved drug or biologic directing them to "remove any noncompliant advertising from the market and bring all promotional communications into compliance."[5] Additionally, FDA issued approximately 100 "cease-and-desist" letters to companies regarding allegedly "deceptive ads."[6] The cease-and-desist letters referenced in the September 9 announcements were initially nonpublic, but FDA has since made them available on its website as warning letters and untitled letters. While we will continue to evaluate these letters, our initial observations include:

- All of the September 9 enforcement letters citing DTC promotional content were issued at the center-level by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) and signed at the director-level by either Dr. Tidmarsh or Dr. Prasad, respectively. This is a departure from prior enforcement practices. CDER's Office of Prescription Drug Promotion (OPDP) or CBER's Advertising and Promotional Labeling Branch (APLB) customarily issue enforcement letters regarding allegedly violative promotional content, with OPDP and APLB leadership signing such letters. This change in authorship suggests that FDA may be following different internal procedures in developing and vetting misbranding allegations for promotional content.

- Only a handful of the warning letters issued on September 9 involved DTC video advertisements, while the overwhelming majority related to online promotional content for compounded GLP-1 products. Of the warning letters regarding DTC video advertisements, FDA alleged misbranding violations due to overstatements of efficacy and failure to adequately present risk information; some of the allegedly false or misleading content dates back as far as March 2024.

- Untitled letters were the primary mechanism FDA used to target DTC video content. FDA's most common basis for alleging a misbranding violation was its concern about exaggerated efficacy or benefits. Some of FDA's analyses asserted that certain claims lacked adequate support from clinical evidence. Others cited misalignment between the benefits highlighted in the advertisement and the advertised product's approved indication in its FDA-approved prescribing information (PI), as well as the clinical data included in the PI.
- The enforcement letters also focus on visual presentations that purportedly distract from the major statement, such that the presentation was not in a clear, conspicuous, and neutral manner as required under 21 CFR 202.1(e)(1)(ii). Many letters cited to distracting visual presentations during the major statement, and several untitled letters cited these presentations as the sole basis for a misbranding violation.
- Some, but not all, of the enforcement letters cited a failure to submit promotional content under Form FDA-2253 — an important reminder that reviewing promotional content submitted under Form FDA-2253 is one of FDA's few surveillance mechanisms.

FDA announced that its wave of enforcement against DTC advertisements used "AI and other tech-enabled tools to proactively surveil and review drug ads."[7] Relying on AI could help FDA compensate for reduced staff in OPDP, but it may increase the risk that the enforcement letters contain errors and factual inaccuracies. Whether and how the Agency relied on these tools and implemented human oversight is unclear, but the simultaneous issuance of dozens of enforcement letters requiring responses to OPDP within 15 business days also means that OPDP will experience a significant influx of materials to review in the near-term. Time will tell whether OPDP will rely on AI and other technologies to facilitate its review of these responses, but companies should expect that closure letters may take additional time given resource limitations in OPDP.

Going forward, FDA has committed to continuing its use of AI and other tech-enabled tools and "aggressively deploy[ing] its available enforcement tools." FDA's news release suggests that the Agency plans to rely on untitled letters and warning letters as the primary mechanism of enforcement, stating that FDA anticipates ramping up enforcement activity to "hundreds of enforcement letters each year" if its initial actions do not "sufficiently alter DTC advertising behavior."[8] FDA has not specified what would constitute sufficiently altered DTC advertising behavior.

In general, FDA's enforcement letters and Commissioner Makary's statements suggest that FDA intends for its crackdown — and, in particular, its rulemaking to eliminate the adequate provision loophole — to deter companies from DTC advertising by making compliance impracticable.[9]

Part II: Rescinding the Adequate Provision Loophole

Unlike print advertisements, broadcast advertisements that contain a major statement are not required to contain a brief summary of all necessary information related to the side effects and contraindications of

the drug if "adequate provision is made for dissemination of the approved or permitted product labeling in connection with the broadcast presentation."[10] The major statement refers to the presentation of the advertised product's most important risks, including its major side effects and contraindications.[11] In 2007, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) to require that the major statement be presented in a clear, conspicuous, and neutral manner. Congress also directed FDA to issue regulations interpreting this standard.[12] In November 2023, FDA finalized a rulemaking to comply with this directive, establishing regulations specifying the criteria that must be met for a major statement to satisfy the clear, conspicuous, and neutral manner standard.[13]

FDA's current regulatory framework for broadcast advertisements enables sponsors to communicate this content in a manner that is both practical and informative. The adequate provision regulation, coupled with the major statement framework, informs viewers of the drug's most important risks while instructing them where to find more information about the drug in its PI.[14] Although FDA's adequate provision regulation has been in effect for many decades, FDA attributes its origin to 1997 — the year FDA published draft guidance outlining FDA's interpretation of how industry could fulfill the adequate provision requirement.[15] Commissioner Makary characterizes the publication of this draft guidance as a "regulatory change,"[16] although it is unclear why given that the guidance is interpretive. Notably, the guidance is still operative; it was finalized in August 1999 and, to date, has not been rescinded.

FDA's news release and the HHS fact sheet indicate that FDA plans to amend its regulation at 21 C.F.R. § 202.1(e)(1)(i)(b) to remove the text that allows sponsors to make "adequate provision ... for the dissemination of the approved or permitted product labeling in connection with the broadcast presentation."[17] As a result, broadcast advertisements would be required to contain a "brief summary of all necessary information related to side effects and contraindications."[18] Broadcast advertisements would thus need to disclose each specific side effect and contraindication contained in the product's approved labeling, a result that both HHS and FDA have acknowledged would likely make the advertisements prohibitively long and expensive.[19]

Expanded Social Media Oversight

FDA announced that it will close digital loopholes by expanding its oversight of DTC advertising to encompass all social media promotional activities.[20] This effort, according to FDA, will include monitoring "algorithm-driven targeted advertising" and "dark ads," "platform-specific promotional strategies designed to evade detection," "influencer partnerships and sponsored content across all platforms," "AI-generated health content and chatbot interactions," and "emerging digital technologies and promotional methods."[21] It remains to be seen whether FDA will follow its existing guidance under any such expansion of its social media oversight, such as its guidance discussing the use of social media platforms with character space limitations or on correcting independent third-party misinformation, and whether FDA will update any of these guidances.

Analysis

By taking a more "expansive" view of its existing authorities, FDA could overreach

Prescription drug advertisements are required to present a "fair balance" of risk and effectiveness information.[22] FDA's regulations describe numerous ways in which an advertisement may violate this requirement, such as by suggesting that a drug has less serious side effects or contraindications than its labeling indicates.[23] FDA's regulations are also clear that an advertisement is not lacking in fair balance "if the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety."[24] Similarly, broadcast advertisements are not false and misleading if they include a major statement of key risks in a clear, conspicuous, and neutral manner under FDA's regulatory framework that became effective last year.[25]

Prescription drug advertisements and promotional communications are thus subject to a detailed and well-established statutory and regulatory framework to which FDA must adhere so long as the framework remains. Stakeholders will want to closely observe whether FDA tries to expand its authorities via enforcement letters before it has changed the existing regulatory architecture, as this would present a predicament for companies. On the one hand, courts have held that warning letters and untitled letters are not final agency action and cannot be challenged judicially.[26] At the same time, these letters are generally publicly available and can have significant knock-on effects for companies who receive them.

Requiring information in brief summary for broadcast advertisements would conflict with the major statement framework

In the fact sheet accompanying the joint news releases, FDA and HHS describe the major statement as "vague" and assert that, even when it is combined with instructions for how patients can access an advertised product's full PI, it "denies patients vital safety information required for them to make an informed decision."[27] According to Commissioner Makary, the issue is that neither Congress nor FDA have defined "major," allowing companies to "choose what to include or omit."[28]

These statements represent a dramatic change in position from FDA's description of the major statement in the final rule that went into effect last year. As part of that rulemaking, FDA established requirements that would ensure DTC broadcast advertisements "convey a truthful and non-misleading net impression about the advertised drug, including its risks, and that consumers are better informed when they participate in healthcare decision making."[29] In fact, FDA stated that it intended for these new regulations to "convey a truthful and non-misleading net impression about the advertised drug" and to "remedy the lack of business incentive for prescription drug firms to effectively communicate the risks of their products to consumers."[30] In order to change its position on the major statement framework, FDA will need to both acknowledge and offer a reasonable basis for such a change.

More fundamentally, requiring broadcast advertisements to disclose information in brief summary conflicts with the statutory provision that expressly permits major statements in broadcast advertisements, which Congress enacted in 2007.[31] The information to include in brief summary includes "each specific side

effect and contraindication ... contained in required, approved, or permitted labeling."[32] By contrast, the information in a major statement includes the "presentation of the drug's most important risks."[33] Requiring both would thus likely affect viewer comprehension, conflicting with the statutory provision that implicitly indicates that summarizing risk information is permissible. It would also be at odds with FDA's carefully considered regulatory framework for major statements. Indeed, FDA has said that including exhaustive, lengthy lists of all the risk information from a drug's prescribing information in an advertisement "detract[s] from, and make[s] it difficult for, consumers to comprehend and retain information about the more important risks."[34]

The HHS fact sheet attempts to preemptively address a First Amendment challenge

Under the Supreme Court's *Central Hudson* framework, the government may impose restrictions on commercial speech that directly advance a substantial government interest and are no more extensive than necessary to serve that interest.[35] Courts also evaluate compelled commercial speech under the more relaxed standard in *Zauderer*,[36] but HHS and FDA seem to recognize that a court would likely review any final rule under *Central Hudson*. Specifically, in the fact sheet, they state that the proposed rulemaking "goes to the core government interests of protecting the public from deception and protecting public health—as supported by voluminous evidence of public harm under the current system; and does not unduly burden advertisers, by preserving their right to engage in commercial speech under the standards that existed prior to 1997."[37]

As HHS and FDA acknowledge, however, requiring information in brief summary previously deterred pharmaceutical companies from broadcast advertising altogether.[38] Further, and as noted above, FDA has said that it believes overwhelming consumers with all of the risk information and technical language in a drug's PI "may serve to detract from consumers' comprehension of the information or from the likelihood of consumers reading material in its entirety."[39] FDA will likely need to address these points to satisfy the four-part test under *Central Hudson.*

Conclusion

Companies should prepare for heightened scrutiny of DTC advertisements and promotional communications more generally. Given the downstream effects that can follow receipt of an untitled letter or warning letter, companies may consider taking a fresh look at existing and planned DTC advertisements and promotional communications to ensure they are aligned with the company's risk tolerance given FDA guidance in the recently issued letters.

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Endnotes

[1] Memorandum for the Secretary of Health and Human Services the Commissioner of Food and Drugs re: Addressing Misleading Direct-to-Consumer Prescription Drug Advertisements (Sep. 9, 2025), https://www.whitehouse.gov/presidential-actions/2025/09/memorandum-for-the-secretary-of-health-and-human-services-the-commissioner-of-food-and-drugs/.

[2] FDA News Release, *FDA Launches Crackdown on Deceptive Drug Advertising* (Sep. 9, 2025), https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising (FDA News Release); HHS Press Office, *HHS, FDA to Require Full Safety Disclosures in Drug Ads* (Sep. 9, 2025), https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency.html (HHS News Release).

[3] HHS, Fact Sheet: Ensuring Patient Safety Through Reform of Direct-to-Consumer Pharmaceutical Advertisement Policies, https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency-fact-sheet.html (Fact Sheet).

[4] Fact Sheet.

[5] *See* FDA, Ltr. to "Pharmaceutical Company," Sep. 9, 2025, available at https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising (emphasis removed).

[6] *Id.*

[7] *Id.*

[8] Fact Sheet.

[9] CNBC Television, *FDA Commissioner Dr. Makary: Deceptive drug ads have 'distorted the doctor-patient relationship'*, YOUTUBE, at 1:35-1:43, https://www.youtube.com/watch?v=Ow_uBPp9bg0.

[10] 21 C.F.R. § 202.1(e)(1)(i)(B).

[11] 21 U.S.C. § 352(n).

[12] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, title IX, § 121 Stat. 823, 940 (Sep. 27, 2007).

[13] *See* 21 C.F.R. § 202.1(e)(1)(ii).

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

[15] FDA, *Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements* (July 1997); FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (Aug. 1999), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consumer-directed-broadcast-advertisements.

[16] Martin A. Makary, MD, MPH, JAMA, *The FDA's Overdue Crackdown on Misleading Pharmaceutical Advertisements*, JAMA (Sep. 12, 2025), https://jamanetwork.com/journals/jama/fullarticle/2839061 (JAMA Article).

[17] *See* HHS Fact Sheet.

[18] *See* 21 C.F.R. § 202.1(e)(1)(i)(B).

[19] Fact Sheet.

[20] Fact Sheet.

[21] *Id.*

[22] 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(5)(ii).

[23] 21 C.F.R. § 202.1(e)(6)(i).

[24] *Id.* § 202.1(e)(5)(ii).

[25] *Id.* § 202.1(e)(1)(ii).

[26] *See Holistic Candlers & Consumers Ass'n v. FDA,* 770 F.Supp.2d 156, 160-62 (D.D.C. 2011), *aff'd* 664 F.3d 940, 945-946 (D.C. Cir. 2012).

[27] Fact Sheet.

[28] JAMA Article.

[29] 88 Fed. Reg. 80960.

[30] *Id.* at 80959-80960.

[31] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(d)(3)(A), 121 Stat. 823, 940 (2007) (codified at 21 U.S.C. § 352(n)).

[32] 21 C.F.R. § 202.1(e)(3)(iii).

[33] FDA, *Drug Advertising: A Glossary of Terms*, https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#major_statement.

[34] FDA, *Revised Draft Guidance: Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs* (Aug. 2015), Rev. 2, at 4, available at https://www.fda.gov/files/drugs/published/Brief-Summary-and-Adequate-Directions-for-Use---Disclosing-Risk-Information-in-Consumer-Directed-Print-Advertisements-and-Promotional-Labeling-for-Prescription-Drugs.pdf (FDA Revised Draft Guidance).

[35] *Central Hudson Gas & Elec. Corp. v. Public Svc. Comm'n*, 447 U.S. 557, 566 (1980).

[36] *Zauderer v. Off. Of Disciplinary Couns. Of Sup. Ct. of Ohio*, 475 U.S. 626, 651 (1985).

[37] Fact Sheet.

[38] *Id.*

[39] FDA Revised Draft Guidance.