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The administration targets direct-to-consumer prescription drug advertising

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On September 9, 2025, the U.S. Food and Drug Administration ("FDA") issued a Press Release (https://bit.ly/3VCjihb) announcing a "crackdown on deceptive drug advertising." Concurrently, the U.S. Department of Health and Human Services ("HHS") published a Fact Sheet (https://bit.ly/4obGZcD) with further detail on FDA's reforms as well as a Press Release (https://bit.ly/4nSpON0) on potential FDA rulemaking.

These statements came shortly after President Trump issued a Memorandum (https://bit.ly/3lHtaDu) directing FDA and HHS to take "appropriate action" against misleading direct-to-consumer ("DTC") prescription drug advertising. FDA Commissioner Martin Makary also published op-eds in the Journal of the American Medical Association (https://bit.ly/4pNF2om) and The New York Times (https://nyti.ms/3Km33T4) explaining the FDA's actions on DTC drug advertising.

HHS Secretary Robert F. Kennedy, Jr. and others connected to the Make America Healthy Again ("MAHA") movement have long criticized DTC drug advertising and supported restrictions or outright bans on such activity. The coordinated announcements from FDA, HHS, and President Trump mark a significant shift from an enforcement and policy standpoint and underscore the administration's adoption of a hostile stance toward DTC prescription drug advertising.

The HHS Fact Sheet announced the following FDA actions aimed at addressing DTC drug advertisements:

- Rulemaking to remove its longstanding "adequate provision" framework, described as a "loophole" undermining "informed patient consent" that has allegedly enabled companies to "hide safety information."
- "Aggressive enforcement" of DTC advertising requirements, beginning with letters to all drug and biologic sponsors notifying them that FDA is no longer "asleep at the wheel," and approximately 100 additional letters to companies targeting specific ads the FDA considers deceptive.
- Closing "digital loopholes" by expanding oversight of online and social media advertising.

These steps are unprecedented in terms of their contemplated scope and raise significant questions about FDA's authority and the future of DTC prescription drug advertising. This article summarizes the latest developments and outlines potential implications for industry.

New administration priorities

In the Memorandum, President Trump directs HHS to strengthen oversight of DTC drug advertising to ensure greater transparency and accuracy. The Memorandum acknowledges that FDA has long required a "fair balance" of risk and benefit information, but claims that current agency practices permit the omission of critical safety details, even as spending on drug advertising continues to grow. The President directs FDA to take appropriate action to enforce prescription drug advertising requirements and otherwise ensure that DTC prescription drug advertising is truthful, non-misleading, and complete.

According to the HHS Fact Sheet, FDA sent a letter to "every single sponsor of an approved drug or biologic" that warns of the agency's renewed attention to advertising requirements.

Pursuant to these directives, HHS and FDA announced sweeping reforms to address allegedly misleading DTC prescription drug advertising. Their statements emphasize the need for increased scrutiny of online advertising, stating that an increased reliance on these channels has "blurred the lines" between editorial content, user-generated media, and paid advertisements, making it difficult for consumers to identify promotional material.

Reforms to the 'adequate provision' requirement for broadcast ads

The HHS Fact Sheet reports that FDA is "initiating rulemaking" to eliminate "the 1997 'Adequate Provision' Loophole," which the agency claims "has enabled pharmaceutical companies to withhold vital safety information in advertisements." As of the publication of this article, FDA has not published any notice of proposed rulemaking.

HHS and FDA highlight 1997 as a pivotal year, but the underlying framework has a longer history. The 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") required that prescription drug advertisements include "a true statement of . . . such other information in brief summary relating to side effects, contraindications, and effectiveness."[1] FDA implemented this "brief summary" requirement when it first adopted prescription drug advertising regulations in 1963.

In 1969, FDA modified these regulations so that broadcast ads (including TV and radio ads) did not need to contain the full "brief summary" of side effects and contraindications if they included the "major" side effects and contraindications of the drug (later referred to as the "major statement") and made "adequate provision" for dissemination of the approved labeling in connection with the ad.[2] Thus, the adequate provision concept has been incorporated in FDA's regulations for over 50 years.

The key development in 1997 was FDA's issuance of a draft guidance for consumer-directed broadcast advertisements that described an approach for how companies could fulfill the adequate provision requirement in DTC broadcast ads, provided that the ads contained the "major statement" of the most important risks of the drug and complied with other FDA advertising requirements like fair balance.[3] FDA then finalized this guidance in 1999.[4]

Notwithstanding this history, the HHS Fact Sheet frames the adequate provision concept as a "loophole that allows pharmaceutical advertisers to hide safety information." HHS argues this approach has hindered informed patient consent, which has had a "clear negative impact on public health."

Thus, FDA plans to engage in rulemaking to "return[] to the pre-1997 status quo" and require full safety information in broadcast prescription drug advertisements. HHS claims that FDA will take this action in a way that "does not unduly burden advertisers" and which will "preserve[] their right to engage in commercial speech under the standards that existed prior to 1997."

Yet HHS's announcement fails to recognize that the "pre-1997 status quo" legally permitted DTC broadcast ads to rely on the approach of presenting the "major statement" of risks in conjunction with "adequate provision" of drug labeling. Prior to the 1997 draft guidance, there was uncertainty among many pharmaceutical companies regarding how to satisfy the adequate provision approach in DTC broadcast ads, but the issuance of the 1997 draft guidance did not mark a change in the underlying legal requirements. As FDA explained in a questions-and-answers document issued in parallel with its 1999 final guidance:

FDA does not agree that it has loosened restrictions on broad cast advertisements, although we have taken steps to make them more feasible. Since being promulgated in the 1960s, the regulations have provided for alternative requirements for broadcast, as compared with print, advertisements.

The atypical characteristics of many of the warning and untitled letters issued by FDA suggest they may have been drafted with the support of AI.

Although product sponsors theoretically had the option of using the adequate provision alternative instead of presenting a brief summary in connection with broadcast advertisements, the absence of formal guidance created uncertainty about how the Agency would treat any particular approach. The result was a broadcast environment confusing to consumers and less than optimal for effectively communicating product information. **Given that there are no legal impediments to such consumer-directed broad cast advertising**, the Agency was obliged to provide appropriate guidance.[5]

As previously noted, FDA has not yet published a proposed rule, so it remains to be seen what precise regulatory change FDA will seek and what justifications will be provided in support of the change. Nevertheless, based on the HHS and FDA announcements to date, the administration's contemplated reforms, if finalized, could fundamentally reshape the regulatory landscape for DTC broadcast ads, resulting in the need for longer ads and much more extensive disclosures of safety information.

Any effort to reform FDA's longstanding regulatory framework in this manner would potentially be subject to legal challenge on constitutional, statutory, and administrative law grounds. For example, reforms to require a recitation of *all* risk information from approved drug labeling in a DTC broadcast ad could amount to a de facto ban on such advertising and would likely be challenged on First Amendment grounds.

Additionally, if FDA attempted to completely eliminate the "major statement plus adequate provision" approach for broadcast ads that has long been authorized by the regulations, it is not clear how FDA would defend such a change as being within its authority, given a 2007 FDCA amendment[6] that prescribed specific requirements for the

major statement for DTC ads in TV and radio format and thus — at least implicitly — recognized that the disclosure of risk information in such ads using the major statement (as opposed to a complete statement of all risks of a drug) is acceptable.

Lastly, depending on the specific reforms proposed and the justifications for them, industry may argue that FDA's actions are otherwise arbitrary and capricious in violation of the Administrative Procedure Act.

Increased FDA enforcement

In the FDA Press Release, the agency criticizes its prior enforcement approach as "increasingly lax and reactive." FDA claims that the number of enforcement letters has declined from more than 130 annually in the late 1990s to only a few in recent years. FDA's Office of Prescription Drug Promotion ("OPDP") and its predecessor office have certainly reduced their enforcement action over the years.

Based on our review, hundreds of warning and "untitled" letters were issued annually between 1997 and 1999 before decreasing in the early 2000s. The number of letters issued each year remained somewhat steady for several years before dipping in 2014. Notably, OPDP enforcement activity did not increase during the first Trump administration.

According to the HHS Fact Sheet, FDA sent a letter to "every single sponsor of an approved drug or biologic" that warns of the agency's renewed attention to advertising requirements. The letter (https://bit.ly/3VCjtcl) has a standard form and does not identify specific promotional violations or reference particular products. Instead, it directs the recipient to review existing materials and remove any noncompliant communications.

In addition, FDA sent more than 100 letters to companies with allegedly deceptive prescription drug advertising. As of the publication of this article, FDA has released 41 untitled letters and 66 warning letters issued on September 9, 2025 target allegedly false and misleading DTC drug advertising. This includes 58 warning letters issued to online pharmacies, telehealth providers, or other entities engaged in compounding, rather than traditional pharmaceutical companies with approved products. The remaining 49 letters (41 untitled letters and 8 warning letters) were issued to traditional pharmaceutical companies.

Most of these 49 letters to traditional pharmaceutical companies specifically focus on television commercials; although a small portion of the letters address other kinds of DTC ads, including sponsored links and video interview segments shown online or on TV. Many of these letters differ from traditional OPDP letters in several key respects.

First, most of the untitled letters do not cite specific statutory or regulatory provisions despite alleging false or misleading advertising. Second, they are signed by the Director of FDA's Center for Drug Evaluation and Research ("CDER") or Center for Biologics Evaluation and Research ("CBER") rather than OPDP or Advertising and Promotional Labeling Branch ("APLB") personnel, and third, many of the untitled letters lack the detailed background information about the product (e.g., the approved indication and key risk information) typically included in such letters.

FDA indicated in its public announcements that this initial enforcement activity relies on the agency's existing authorities. However, FDA also notes it plans to use a "more expansive" interpretation going forward, rather than the "overly cautious approach taken by previous administrations." FDA states that it is already implementing AI tools to proactively surveil and review drug ads. The agency warns that if industry practices do not meaningfully change, "FDA will continue enforcement activity and will return to the 1990s paradigm of issuing hundreds of enforcement letters each year."

Expanded focus on digital advertising and promotion

According to the HHS Fact Sheet, FDA will focus future enforcement on closing "digital loopholes" by expanding oversight to "encompass all social media promotional activities" including influencer partnerships and sponsored consent, algorithm-driven targeted advertising and so-called "dark ads," AI-generated health content and chatbot interactions, platform-specific strategies "designed to evade detection," and other emerging digital technologies and promotional methods.

These focus areas are generally consistent with those highlighted in the MAHA Commission's Make Our Children Healthy Again Strategy Report (https://bit.ly/46vZG3a), which was released the same day and emphasized that FDA, HHS, the Federal Trade Commission, and the Department of Justice will increase their scrutiny of DTC drug advertising, with particular attention to violations involving social media influencers and DTC telehealth companies.

Notably, FDA has no regulations that specifically address social media communications, and the limited number of social media guidances that FDA has issued remain in draft form. Furthermore, FDA has acknowledged in the past that it currently lacks the authority to effectively rein in advertising by telehealth companies and influencers that are not manufacturing or distributing a drug or acting on behalf of a drug's manufacturer, packer, or distributor. As a result, it is not immediately clear how FDA will "close digital loopholes" or "expand oversight" in some of the areas referenced in the HHS Fact Sheet.

Rationale for the administration's new priorities

The administration's statements on DTC drug advertising are premised on assertions that such activity harms public health and that deceptive advertising by pharmaceutical companies is prevalent. Yet numerous references cited in the HHS and FDA announcements rely on arguably stale data and do not

appear to fully support the propositions for which they are cited. By way of example:

- The FDA Press Release relies upon a 2024 review article[7] for the proposition that while 100% of pharmaceutical social media posts highlight drug benefits, only 33% of pharmaceutical social media posts reference potential harms. In support of this proposition, the 2024 review cites a 2015 study,[8] which examined social media posts from top pharmaceutical companies for the period October 2013-September 2014. That 2015 study found that of the 740 pharmaceutical company social media posts within the scope of the review, only1.6% (12/740) of posts included drug product benefit claims, and of those 12 posts, only 33% (4/12) also mentioned drug risks.
- The HHS Fact Sheet points to a study that purportedly found that physicians are 17 times more likely to prescribe drugs specifically requested by patients, with many reporting pressure to maintain patient satisfaction scores even when prescriptions are clinically inappropriate. The referenced study[9] was published in 2003 and relied on physician and patient surveys conducted in 2000 and 2001. The study publication makes no reference to physicians issuing prescriptions based upon "pressure" to maintain patient satisfaction scores, and the authors even state specifically that their study "could not evaluate treatment appropriateness."

As FDA proceeds with potential rulemaking and additional enforcement activity, companies should carefully scrutinize the evidence relied upon by the administration to support its positions.

Implications for the pharmaceutical industry

In the near term, pharmaceutical companies face significant uncertainty about how to respond to FDA's new letters and directives. For example, each sponsor received the same form letter, which did not identify specific products or promotional materials but simply urged application holders to bring materials into compliance. For companies with broad portfolios, this blanket approach creates practical challenges in determining how to structure compliance reviews and prioritize any remedial action that they determine may be appropriate.

Additionally, the atypical characteristics of many of the warning and untitled letters issued by FDA suggest they may have been drafted with the support of AI. Companies responding to such letters should carefully evaluate whether the letters include misstatements of fact or other "hallucinations" or are staking out positions on issues like minimization of risk information or overstatements of efficacy that extend beyond FDA's historical stances.

FDA's future plans raise both legal and practical questions. As described above, any effort to reform the "adequate provision" framework or expand enforcement tools is likely to face constitutional and statutory challenges.

Further, recent reductions to the FDA workforce and budget may undermine the agency's ability to sustain the large-scale enforcement program described in these recent announcements, or even to engage meaningfully with companies that have received warning or untitled letters once responses have been submitted to FDA. FDA has also indicated it may rely more heavily on artificial intelligence to help review advertising materials. Companies will need to monitor whether these tools are used in ways that are consistent with FDA's statutory authority, regulations, and prior guidance.

More broadly, sponsors should expect heightened scrutiny of DTC drug advertising, particularly on social media and other digital platforms. Companies should proactively review their advertising to ensure that risk information is clearly presented, relationships with influencers are transparent, influencer communications comply with FDA requirements, and any noncompliant DTC materials are promptly remediated.

Notes:

[1] Pub. L. No. 87-781, 76 Stat. 780 (1962).

[2] 34 Fed. Reg. 7802 (May 16, 1969); *see*21 C.F.R. § 202.1(e)(1)(i).

[3] 62 Fed. Reg. 43171 (Aug. 12, 1997).

[4] FDA, Guidance For Industry: Consumer-Directed Broadcast Advertisements (Aug. 1999), availableat https://bit.ly/3KHRVzV.

[5] FDA, *Guidance for Industry: Consumer-Directed Broadcast Advertisements: Questions and Answers* (issued Aug. 1999 and last updated Mar. 8, 2001), *available at* https://bit.ly/4mG9tdg (emphasis added).

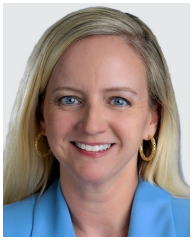
[6] *See* Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85, 121 Stat. 823, 940 (2007).

[7] Mor, J., Kaur, T., Menkes, D. B., Peter, E., & Grundy, Q. (2024). Pharmaceutical industry promotional activities on social media: a scoping review. *Journal of Pharmaceutical Health Services Research*, *15*(4).

[8] Tyrawski J., DeAndrea D.C. (2015), Pharmaceutical Companies and Their Drugs on Social Media: A Content Analysis of Drug Information on Popular Social Media Sites. *Journal of Medical Internet Research*, 17(6):e130.

[9] Mintzes, B., Barer, M. L., Kravitz, R. L., Bassett, K., Lexchin, J., Kazanjian, A., Evans, R. G., Pan, R., & Marion, S. A. (2003). How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *CMAJ: Canadian Medical Association journal*, *169*(5), 405–412.

About the authors

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