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The Nucleus: Life Sciences Regulation and Enforcement Updates

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Joint FDA/HHS Initiative Targeting Direct-to-Consumer Pharmaceutical Advertising Garners Much Attention, but Legal Basis and Likely Impact Are Unclear

Executive Summary

- **What is new:** On September 9, 2025, HHS and FDA announced a new initiative to close a purported loophole in FDA's regulations regarding the adequate provision of safety information in direct-to-consumer pharmaceutical advertising.
- **Why it matters:** Direct-to-consumer advertising is likely to come under increased scrutiny, but whether FDA will follow through with, or succeed in implementing, regulatory changes remains to be seen.
- **What to do next:** Companies may want to ensure robust review processes are in place for all direct-to-consumer advertising, including social media advertising, and stay tuned to see whether any further regulatory activity occurs.

On September 9, 2025, the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) announced a new initiative to close what the agencies describe as a "loophole" in requirements regarding the adequate provision of safety information in pharmaceutical advertising.

Through a combination of a White House memorandum, press release, fact sheet and myriad letters to industry, FDA and HHS began an assault on direct-to-consumer (DTC) pharmaceutical advertising. The goal of this coordinated effort is to attempt to require pharmaceutical companies to disclose all safety information in DTC ads, rather than the "clear, conspicuous, and neutral" major information statement that is currently mandated and codified under the federal Food, Drug, and Cosmetic Act (FD&C Act).

These actions make clear that the Trump administration does not believe that the current state of pharmaceutical advertising complies with the FD&C Act. Instead, FDA and HHS leadership believe that a return to the pre-1997 regulatory state will restore order for DTC advertising.

This is a major departure from previous FDA policy on DTC advertising, which was most recently updated at the end of 2024. To fully understand the implications of these announcements, it is important to first consider how the regulation of pharmaceutical advertising has evolved since 1997.

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Stepping Back: A Brief History of DTC Advertising Regulation

DTC advertising of prescription drugs underwent a dramatic shift beginning in 1997, with the release of FDA's draft guidance on broadcast advertising of pharmaceuticals. Prior to the issuance of this guidance, most DTC promotion was limited to print media because FDA had never clarified how to fulfill 21 CFR Part 202.1's requirement that broadcast advertisements include "a brief summary of all necessary information related to side effects and contraindications, unless adequate provision" was made for approved product labeling to be disseminated in connection with a broadcast ad.

FDA's guidance, finalized in 1999, further clarified how broadcast advertisements could meet regulatory standards, particularly with respect to disclosing a drug's major side effects and contraindications (known as the "major statement"). These clarifications opened the door to modern broadcast pharmaceutical advertising.

Congress and FDA subsequently responded to concerns about the adequacy and clarity of these disclosures. Through the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress amended Section 502(n) of the FD&C Act to require that the major statement in television and radio advertisements be presented in a "clear, conspicuous, and neutral manner."

This statutory mandate, effective in 2008, augmented FDA's existing authority by not only requiring inclusion of risk information but also dictating how that information must be conveyed so consumers are not misled.

In 2010, FDA issued a proposed rule to define standards for clarity, prominence and neutrality, emphasizing factors such as plain language, understandable audio delivery, legible text and avoidance of distracting visuals or sounds. This rule was not finalized until November 2023 (with an effective date of November 2024), but manufacturers have been putting it into practice voluntarily for some time.

As a result, DTC pharmaceutical advertisements have evolved to offer even more conspicuous safety information in a manner that complies with the statutory requirements.

Substance and Potential Impact of FDA's and HHS' New Activities

Taken together, the developments since 1997 mark a significant evolution: from FDA's initial guidance enabling more widescale broadcast DTC ads, to statutory and regulatory standards ensuring that risk information is communicated fairly, accurately and in a manner designed to protect public health.

As such, a return to pre-1997 standards for pharmaceutical advertising arguably represents a loss of the past 28 years of policy progress and refinement the agency has made in this area.

The basis for FDA's actions is also less than clear: While the implementation of the final rule on DTC advertising standards is less than a year old, much of the social science FDA cites in its recent announcements about the deleterious effects of pharma-ceutical advertising is from the early 2000s. These dated publications could not take into account the changes that have occurred in DTC advertising practices under FDAAA or FDA's proposed or final rule, all of which have taken effect since 2008.

The announcements from HHS and FDA list specific actions FDA will take to address DTC pharmaceutical advertising:

1. Rulemaking to remove the 1997 "adequate provision" loophole.
2. Aggressive enforcement of DTC violations.
3. Closing digital loopholes by expanding regulatory oversight to encompass social media promotional activities.

Action Item 1 – Updating FDA's Regulations on Prescription Drug Advertising

While regulations and guidance currently define the standard for the adequate provision of safety information, the concept of the major statement is codified in the statute.

Therefore, FDA cannot, as is implied in its announcement and fact sheet, move entirely away from allowing safety information to be summarized in advertising without congressional action to amend Section 502(n) of the FD&C Act. Any attempt to do so would conflict with the statutory requirement that such a major statement of safety information be included in DTC ads.

Moreover, to actually complete the required rulemaking process, FDA would have to issue a proposed rule, take public comment, finalize the rule (presumably with an implementation date in the future) and withstand litigation that would inevitably ensue because of the conflict with the statute and likely First Amendment defenses.

It is unclear if FDA has considered other stakeholders who may be affected by the reduction in pharmaceutical advertising in trying to navigate the rulemaking process. Media channels, including broadcast media and streaming, rely heavily on revenue from pharmaceutical ad buys. Professional sports are also often supported by pharmaceutical advertising revenue.

Beyond the pharmaceutical industry, the downstream players that benefit from pharmaceutical ad-buying may have a strong opinion about what FDA is doing here and may file public

comments or even join in any potential litigation. We have seen a similar trajectory play out in other recent FDA decisions, with the public response to agency actions leading to the temporary firing of FDA staff and immediate reversal of FDA's policy position.

To date, we have not seen FDA under the Trump administration follow policy pronouncements with formal regulatory action, and pursuing such action takes a significant period of time. It remains to be seen whether FDA will actually undertake formal rulemaking around DTC advertising and, if so, whether it ultimately will be successful in implementing its proposed change through rulemaking.

Even if the agency succeeds in amending 21 CFR Part 202.1, the statutory requirement under Section 502(n) would persist, leaving manufacturers with a potential avenue to convey safety information in DTC advertising and creating a direct conflict between the statute and FDA's implementing regulations.

Action Item 2 – Aggressive Enforcement

FDA's announcement was coupled with letters to "every single sponsor of an approved drug or biologic" directing them to "remove any noncompliant advertising and bring all promotional communications into compliance." The letter also notes that FDA is "demand[ing] compliance with the FD&C Act and FDA implementing regulations and requires companies to remove any and all DTC prescription drug advertising that violates the law."

While FDA's announcement describes the letters as "warning" and "cease-and-desist" letters, their wording is far from standard for FDA's ordinary administrative enforcement warning and untitled letters. In addition to sending "warning" letters to all sponsors, FDA announced that it is separately sending "cease-and-desist" letters to specific companies with "deceptive" ads, with FDA making clear that it is taking "a more expansive reading of its authorities" than prior administrations.

Under any legal construct where the standard is open to interpretation, there can be mistakes or even bad actors that flout the legal requirements. However, the implication of FDA's recent letters is that every recipient manufacturer has ads that fail to comply with legal requirements.

Notably, the Office of Prescription Drug Promotion (OPDP) is authorized to provide advisory opinions for broadcast pharmaceutical advertisements before they are placed on the market. While FDA does not review every pharmaceutical ad before it is released, it is common practice in industry to seek a voluntary opinion before launching a major ad campaign.

OPDP's advisory review process presumably would flag ads that do not comply with the law. As such, FDA's apparent assumption that every pharmaceutical manufacturer is potentially releasing noncompliant advertising seems inconsistent with common industry practice and the reality of current DTC advertising.

Action Item 3 – Increased Scrutiny of Social Media Advertising

FDA has actively monitored social media compliance for many years, as reflected by the fact that many of the untitled and warning letters issued by OPDP in the past few years have been related to influencer content and other social media-based marketing.

The Federal Trade Commission (FTC) has also implemented guidance regarding the clear and prominent disclosure for sponsored social media advertising, thereby helping to reduce consumer confusion about the origin of influencer content.

FDA's recent announcement suggests it intends to further expand scrutiny of social media activity. Notably, the Make America Healthy Again (MAHA) strategy, released concur-rently with the DTC advertising announcements, further underscores that the Department of Justice (DOJ), FDA and FTC will prioritize enforcement efforts related to social media marketing, reflecting a coordinated, multiagency approach to oversight in this space.

Companies evaluating what to make of FDA's flurry of advertising-related activity may want to pay particular attention to the focus on social media advertising. To the extent companies do not already have robust "medical, legal, regulatory" review (commonly referred to as "MLR" review) processes that encompasses all social media advertising, especially sponsored content and postings by influencers, now may be the time to put such processes in place, enhance existing processes as needed and review all current social media content to ensure it is compliant.

While FDA's announcements — and the resulting news headlines — pay significant attention to broadcast advertising, social media is often what tips FDA off to problems in the advertising and promotion space.

Takeaways

Despite FDA's ominously worded letters to industry, there are no immediate consequences to the agency's announcements, and the current regulatory framework still stands.

That said, it may be prudent for pharmaceutical manufacturers with marketed products or that intend to launch a product soon to ensure that rigorous promotional review processes are in effect and that all ads have been reviewed.