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Drug Ad Crackdown Demonstrates Admin's Aggressive Stance

By **Nikki Reeves, Heather Banuelos and Gillian Russell** (October 6, 2025, 7:10 PM EDT)


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On Sept. 9, the U.S. Food and Drug Administration issued a press release announcing "sweeping reforms to rein in misleading direct-to-consumer pharmaceutical advertisements,"[1] while simultaneously sending a templated letter[2] to thousands of pharmaceutical companies demanding promotional compliance and over 100 cease-and-desist letters to companies for deceptive advertising related to specific products.

These actions and more were made at the direction of a presidential memorandum and in parallel with similar actions by the U.S. Department of Health and Human Services taken the same day.[3]

"Dear Pharmaceutical Company" Template Letter

The templated letter sent across industry reiterates many of the same concerns highlighted in the press release and serves as notice of the FDA's enforcement approach to all drug application holders, directing removal of all noncompliant advertising and demanding compliance for all promotional communications.

The issuance of thousands of letters at once is reminiscent of similar enforcement actions taken by the Federal Trade Commission against deceptive advertising practices in 2021; however, the FDA's letter condemns direct-to-consumer, or DTC, advertising as a significant public health issue, alleging that it distorts the physician-patient relationship.[4]

The FDA emphasized the following concerns in the "Dear Pharmaceutical Company" letters.

Lack of Fair Balance

The FDA noted a lack of fair balance between drug benefits and risks in drug advertising, even highlighting failure to disclose serious risks and presentation of risk information in a manner that is too difficult for seniors to read or hear.

Use of Digital and Social Media

The FDA expressed particular concern regarding pharmaceutical marketing on digital and social media

channels, including undisclosed paid influencer promotion.

These concerns are not new. In fact, most enforcement letters in the past few decades have focused on minimization and omission of risk information, and FDA and FTC enforcement against digital and social media — including influencers — has long been a trend.

The FDA has maintained several guidance documents on prescription drug promotion related to risk disclosure in social media and broadcast advertising, among others.

Even the FDA's Office of Prescription Drug Promotion has conducted multiple social sciences studies evaluating fair balance and disclosures for influencers. Interestingly, the FDA did not use its own published studies to support its attack on DTC advertising, but rather relied on a review article based on older and less relevant data.

Cease-and-Desist Letters

Beginning Sept. 16, however, the FDA started posting the cease-and-desist enforcement letters on the OPDP's untitled letter webpage[5] and the FDA's warning letter webpages.[6]

As of Oct. 5, the FDA posted a total of 119 enforcement letters as part of recent enforcement activities: 53 untitled letters and 8 warning letters issued to 34 manufacturers, and 58 warning letters to issues to various clinics, telehealth providers and compounding pharmacies of GLP-1 agonists and erectile dysfunction drugs.

Of the 61 letters issued to manufacturers, the majority target DTC television ads, while several others focused on other media modalities, such as newsletters, sales aids, exhibit booth panels, print ads, sponsored links and online videos and webpages.

Although most enforcement letters focused on DTC promotion, promotion to healthcare professionals was also challenged in some letters. The FDA's letters cover a wide range of disease areas, with a notable concentration in oncology, as well as gastroenterology, neurology and psychiatry.

More than 20 letters involve drug products with boxed warnings, underscoring the FDA's focus on higher-risk products and patient safety. In addition to the ongoing focus on fair-balance violations, the FDA also takes issues with unsubstantiated efficacy claims in many letters.

Unlike prior OPDP enforcement letters, which were typically signed by OPDP reviewers and team leaders, the recent letters are signed on behalf of the Center for Drug Evaluation and Research Director George Tidmarsh, likely signaling the increased magnitude and potential consequences of the FDA's enforcement.

The warning letters follow the OPDP's standard format, including a request for corrective communications.

However, the format and style of these letters are reminiscent of older enforcement letters issued by the Division of Drug Marketing, Advertising and Communications, the predecessor to the OPDP, in that they lack the organizational structure that became standard in OPDP letters (e.g., "Background" section that identifies product indications and safety, with separate sections identifying each type of alleged violation).

They also completely omit citations to the Federal Food, Drug and Cosmetic Act and implementing regulations.

While the "Conclusion and Requested Action" section remains largely the same, one sentence has been updated consistent with "cease and desist" language. The new letters now state: "FDA requests that [company] take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above)."

HHS has stated its intent to continue enforcement activity, with a "return to the 1990s paradigm of issuing hundreds of enforcement letters each year," particularly if current enforcement activities do not alter industry approaches.[7]

Thus, we fully anticipate a growing number of enforcement letters beyond this initial set. In fact, the FDA has already posted an additional letter, issued on Sept. 23. Ongoing enforcement will likely be informed by artificial intelligence and other tech-enabled tools that the FDA may use to aggressively and proactively surveil and review drug ads.[8]

Closing the Adequate-Provision Loophole

The FDA and HHS announcements also included a plan to initiate rulemaking to close the "adequate provision" loophole, returning to "the status quo policy pre-1997" for broadcast ads.[9]

It is the government's position that the adequate-provision alternative to providing all safety information has been used as a means to "conceal critical safety risks in broadcast and digital ads, fueling inappropriate drug use and eroding public trust."[10]

As background, in addition to disclosing significant risks in the major statement, FDA regulations require broadcast ads to include a brief summary of all necessary safety information unless an adequate provision is made for dissemination of the approved product labeling.[11]

The major statement, together with adequate provision for product labeling, has been the standard approach adopted by industry for broadcast advertisements for decades. FDA guidance recommends that the adequate provision include four components: a toll-free phone number, concurrent print ad, website and direction to speak with a medical professional.[12]

Calling the adequate provision a loophole suggests that pharmaceutical companies have been skirting risk disclosure; however, the adequate provision has long been permitted by the FDA as one of two possible and legal ways to provide risk information to consumers.

Removing this option will mean that broadcast ads must include a brief summary, which is a more comprehensive list of risks; however, this approach fails to recognize prior research, by the OPDP as well as independent researchers, that concluded that consumers are significantly more likely to consider a drug to be less risky when they hear or read the full list of a drug's potential side effects versus only hearing about the more serious ones.[13]

Indeed, this research prompted the FDA to reevaluate and seek comment on changes to the major statement in 2017. Similar research also supported the FDA's draft guidance for the consumer brief summary in 2014 and 2015, in which the FDA strongly recommends against providing lengthy lists of

risks to consumers in advertising and promotion.[14]

Given the practical limitations to including a brief summary in a 60-90 second television ad, the planned removal of the adequate provision for approved product labeling may be an attempt to eliminate or curtail DTC broadcast ads altogether.

This change will also raise new questions about how the brief summary should be presented in these ads. The FDA only recently finalized rules for the clear, conspicuous and neutral presentation of the major statement, which is a requirement under the FDCA but has not specifically addressed the presentation of the brief summary.[15]

Observations

There is much to unpack from the announcements and enforcement blitz.

As an initial matter, it is worth noting that, while the administration's top-line messaging focuses on concerns about DTC advertising, the cease-and-desist letters were not limited to consumer advertisements.

Among the examples we reviewed, several cited concerns with promotional materials directed to healthcare professional audiences. Accordingly, companies may want to consider taking a fresh look at all promotional communications for their products to ensure compliance.

Further, although HHS Secretary Robert F. Kennedy Jr. has made no secret of his ambition to ban DTC advertising, a direct approach would be untenable under First Amendment precedent.

Thus, the administration appears to want to regulate DTC advertising out of existence, both through aggressive threats of enforcement and by initiating rulemaking to amend the "adequate provision" language in the FDA's regulations.

To justify these actions, the FDA relies on assertions of public health harm when "patients are not seeing a fair balance of information," "serious risks are not clearly presented," and "information is too difficult for seniors to read or hear."

However, the FDA cites to dated studies that were conducted before the agency issued its recent rule establishing standards for what constitutes a clear, conspicuous and neutral presentation of the major statement.

The new requirements went into effect less than a year ago, and it is unclear whether the FDA's data regarding the prevalence of problematic advertisements remains accurate.

Likewise, it is unclear whether social science research would justify changing — or, as the FDA implies, removing — the "adequate provision" language from the regulation.

What would a change mean for the comprehensibility of broadcast advertisements? Could the presentation of the entire brief summary detract from the consumer's understanding of the most serious side effects and contraindications?

To justify regulation of sponsors' speech, the FDA must rely on data that demonstrates why its interest is

substantial, its solution directly advances that interest, and its solution is no more extensive than necessary to serve that interest. The information relied upon by the FDA, thus far, seems to fall short of that constitutional requirement.

How individual pharmaceutical companies respond to the administration's attack on prescription drug promotion will, necessarily, be fact-dependent. Some companies may be on strong footing to push back against the FDA assertions in the cease-and-desist letters.

For instance, if the FDA is now citing concerns with promotional materials that were precleared through the advisory process, a company may assert reliance on prior FDA actions.

Or, if the FDA is asserting that certain promotional statements fall outside the safe harbor provided in the FDA's "consistent with the FDA-required labeling," or CFL, guidance,[16] a company may be able to respond with information explaining why the communication meets the standard or why the company's CFL analysis is reasonable.

However, even when a company's response is legally justified and straightforward, the current administration's general hostility to the pharmaceutical industry will likely factor into companies' decision-making calculus.

Because the administration's aggressive — dare we say, punitive — actions toward the industry go beyond promotional advertising, the legal and business considerations will remain fluid for the foreseeable future.

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[1] FDA News Release, "FDA Launches Crackdown on Deceptive Drug Advertising" (Sept. 9. 2025), available at https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising.

[2] "Dear Pharmaceutical Company" Letter from FDA Commissioner Martin A. Makary (Sept. 9, 2025), available at https://www.fda.gov/media/188616/download?attachment.

[3] Memorandum for the Secretary of Health and Human Services the Commissioner of Food and Drugs re: Addressing Misleading Direct-To-Consumer Prescription Drug Advertisements (Sept. 9, 2025), available at https://www.whitehouse.gov/presidential-actions/2025/09/memorandum-for-the-secretary-of-health-and-human-services-the-commissioner-of-food-and-drugs/. See also HHS Press Release, "HHS, FDA to Require Full Safety Disclosures in Drug Ads" (Sept. 9, 2025), available

at https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency.html; and HHS, Press Room, "Fact Sheet : Ensuring Patient Safety Through Reform of Direct-to-Consumer Pharmaceutical Advertisement Policies," (Sept. 9, 2025) (hereinafter "HHS Fact Sheet"), available at https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency-fact-sheet.html.

[4] FTC New Release, "FTC Puts Hundreds of Businesses on Notice about Fake Reviews and Other Misleading Endorsements" (Oct. 13, 2021), available at https://www.ftc.gov/news-events/news/press-releases/2021/10/ftc-puts-hundreds-businesses-notice-about-fake-reviews-other-misleading-endorsements.

[5] FDA OPDP Untitled Letters, available at https://www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/untitled-letters.

[6] FDA Warning Letters, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[7] HHS Fact Sheet, supra note 3.

[8] See "Dear Pharmaceutical Company" Letter, supra note 2.

[9] HHS Fact Sheet, supra note 3.

[10] FDA News Release, supra note 1.

[11] 21 C.F.R. § 202.1(e)(1)(i)(B).

[12] See FDA Guidance, "Consumer-Directed Broadcast Advertisements" (Aug. 1999), available at https://www.fda.gov/media/75406/download.

[13] See, e.g., Betts KR, et al., Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. Research in Social and Administrative Pharmacy (2017), available at http://dx.doi.org/10.1016/j.sapharm.2017.07.015.

[14] See FDA 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), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/brief-summary-and-adequate-directions-use-disclosing-risk-information-consumer-directed-print.

[15] See 21 C.F.R. § 202.1(e)(1)(ii).

[16] See FDA Guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling— Questions and Answers" (June 2018), available at https://www.fda.gov/media/102575/download.