FDA Discloses 75 Letters Over Misleading TV Ads

Sep 17, 2025, 11:48 AM EDT

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(Inside Health Policy)

Updated Story

FDA on Tuesday (Sept. 16) released 40 -- but not all of the roughly 100 -- cease-and-desist letters it sent last week, along with 35 warning letters, flagging pharmaceutical TV ads it says are “false and misleading” and violate the Federal Food, Drug, and Cosmetic Act, as part of a broader advertising crackdown.

Major companies that received the letters are AstraZeneca, Pfizer, Bristol-Myers Squibb, AbbVie, Amgen, Novartis, Boehringer Ingelheim. Telehealth companies like Hims & Hers also received letters.

Signed by FDA drug center chief George Tidmarsh, the letters ask companies to submit their rationale and any supporting evidence within 15 working days if they believe their products do not violate the FD&C Act.

FDA’s cease-and-desist letters are framed as an enforcement concern and an opportunity to respond -- the agency notes the issues flagged may not be exhaustive, and says it’s the sponsor’s responsibility to comply with the FD&C Act and implement regulations. If the companies fail to correct the ad or adequately justify it, the agency could escalate enforcement actions, which range from additional letters to potential injunctions or other sanctions.

Eli Lilly received three letters tied to two local TV interviews in Ohio and Oklahoma, as well as an ABC special hosted by Oprah Winfrey focusing on obesity and anti-obesity drugs. Pfizer received a letter about its ulcerative colitis treatment Velsipity, while AstraZeneca received letters regarding its cancer drugs Calquence and Truqap, as well as its asthma medication Fasenra.

Boehringer Ingelheim also received three letters for its TV commercial on its diabetes drug Jardiance. FDA says the ad's fast-paced choreography, scene changes, music and oversized movie-themed props "compete for the consumer's attention" and undermine viewers' ability to comprehend the drug's indications and limitations of use. The agency also criticized the legibility of the on-screen major statement, noting font size, contrast and placement make required safety and usage information hard to read.

The agency warns that the mix of sound and visuals created a misleading impression about efficacy. The letter argues the ad's compelling imagery -- from a man catching popcorn mid-air to a dog in 3D glasses -- creates a false impression of Jardiance's benefits by distracting from the audio and on-screen text that contain the drug's actual indications and limits.

FDA announced Tuesday (Sept. 9) it is moving to rewrite its advertising rules by targeting the "adequate provision loophole" policy established in 1997, which regulators say has allowed drugmakers to downplay key safety risks in TV and online ads, contributing to misuse and undermining public confidence.

FDA said that enforcement will extend beyond traditional media, encompassing social media posts, influencer content and telehealth promotions. The agency noted it will prioritize "egregious violations demonstrating harm" and said it is deploying artificial intelligence tools to surveil and review ads proactively.

The pharmaceutical industry lobby group Pharmaceutical Research and Manufacturers of America (PhRMA) pushed back on FDA's plan, saying it could undercut patient access to key health information.

"PhRMA member companies are committed to responsible advertising and look forward to weighing in on the FDA's planned rulemaking," the group said in a statement Thursday (Sept. 11). "This move by the FDA will make it harder for patients to access valuable information they need to have meaningful conversations with their doctors. Truthful and non-misleading direct-to-consumer advertising is protected under the First Amendment and has documented evidence of advancing patient awareness and engagement."

While not banning prescription drug ads -- which is prohibited under the First Amendment -- FDA now seeks to enforce “fair balance” requirements, ensuring benefits and risks are presented with equal clarity.

Legal experts predict the enforcement campaign could spark legal challenges, particularly as FDA appears intent on resurrecting decades-old requirements and interpreting “fair balance” and “major statement” in a far more aggressive manner.

Makary’s op-ed on DTC ads

In a *JAMA* op-ed published Sept. 12, FDA Commissioner Martin Makary called FDA’s latest enforcement actions against pharmaceutical advertisements “overdue,” arguing that decades of weak oversight have created a public health crisis. Makary criticized direct-to-consumer (DTC) ads for flooding U.S. consumers with often misleading promotional content, distorting the patient-doctor relationship, and driving demand for drugs regardless of clinical necessity.

Makary noted that the United States is one of only two countries globally allowing direct-to-consumer drug ads. He noted that 1997 FDA regulatory change relaxed advertising restrictions, unleashing a marketing “free-for-all” that drove spending on pharmaceutical advertising up nearly 800% within a decade and often created misleading impressions of drug efficacy.

According to Makary, flashy TV ads -- featuring patients laughing, dancing, or engaging in entertaining scenarios -- overshadow risk information presented in fine print, creating “a distraction by design.” Research shows direct-to-consumer drug advertising increases prescription requests, elevates clinician prescribing rates and contributes to inappropriate use, even when physicians question the clinical necessity of the medication.

Makary cited studies showing that direct-to-consumer drug ads account for roughly a third of the increase in U.S. drug spending since 1997, with lower-benefit drugs disproportionately promoted. He argued that billions spent on advertising prioritizes demand creation over research and development, placing a financial burden on patients and contributing to overtreatment.

The op-ed points to the “adequate provision” loophole, which allows companies to present risk information in vague statements and redirect consumers to websites or hotlines, often omitting key safety details.

Makary also warned about social media influencer campaigns and online pharmacy ads, which routinely highlight benefits while downplaying risks, further blurring the line between entertainment and medical guidance.