FDA Announces “Crackdown on Deceptive Drug Advertising” with Important Implications for Traditional and Digital Media Advertisers

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Last week, the White House issued a memorandum directing the Secretary of Health and Human Services (HHS), Robert F. Kennedy Jr., to take “appropriate action to ensure transparency and accuracy in direct-to-consumer prescription drug advertising.” Shortly thereafter, the Food and Drug Administration (FDA) announced a “crackdown on deceptive drug advertising” and “sweeping reforms to rein in misleading direct-to-consumer pharmaceutical advertisements,” recommitting the agency to aggressive enforcement of existing direct-to-consumer (DTC) pharmaceutical advertising regulations. FDA also indicated the intent to initiate rulemaking to amend existing “loopholes,” with HHS issuing a fact sheet providing additional background and context.

Both Trump and Kennedy have identified DTC pharmaceutical advertising as a priority. In his first administration, Trump’s HHS attempted to require drug manufacturers to list the wholesale acquisition cost in advertisements for any prescription drug over $35, although this rule was eventually struck down by a federal judge who found HHS did not have the authority to regulate price transparency. In a similar vein, Kennedy has long been an outspoken critic of DTC pharmaceutical advertising and has previously called for the all-out ban of the practice.

While the exact scope of the administration’s plans is not clear at this point, the announcement signals a potential sea change with respect to the way pharmaceutical companies will need to engage with consumers – with important implications for traditional and digital media advertisers disseminating such content as well. We break down what you need to know below at this point.

Amending the “adequate provisions” rule: At the heart of FDA’s announcement is the intent to amend the so-called adequate provisions rule, which requires that broadcast DTC pharmaceutical advertisements “[c]ontain a brief summary of all necessary information related to side effects and contraindications, unless adequate provision is made for dissemination of the approved or permitted product labeling in connection with the broadcast presentation.” In 1997, FDA published guidance explaining its position that this requirement could be satisfied through a brief summary of major risks or by directing consumers to a toll-free number or internet address where they could get more information. While both the rule and guidance predated digital and internet advertising for drugs, FDA has consistently applied the same framework for ads made online and in social media.

FDA’s announcement last week suggests that the agency intends to initiate a rulemaking to modify the existing rule and guidance and “return[] to the status quo policy pre-1997,” although details on

the proposal are to-be-determined. Notably, any approach that substantially curtails advertising and/or that imposes more onerous and prescriptive disclosure requirements is likely to face litigation challenges under the First Amendment and commercial free speech doctrines.

Recommitting to aggressive DTC enforcement. In addition to the planned rulemaking, FDA simultaneously announced that it sent thousands of warning letters to pharmaceutical companies regarding misleading advertisements, and issued about 100 cease-and-desist letters to drug manufacturers, mainly focused on allegedly deceptive claims about drug efficacy and side effects. The agency also published a template warning letter which it indicated would be sent to "every single sponsor of an approved drug or biologic." In the HHS fact sheet accompanying the announcement, the agency took issue with the decline in enforcement letters over time – from over 130 annually in the 1990s to only 3 in 2023, notwithstanding massive expenditures in social media advertising.

Expanding oversight to social media and digital advertising. FDA also took issue with Americans' increased reliance on social media and digital channels used to promote pharmaceuticals, which have made it "increasingly difficult for patients to distinguish between evidence-based information and promotional material." To that end, the agency plans to expand oversight to include all social media promotional activities, including:

- Influencer partnerships and sponsored content across all platforms;
- Algorithm-driven targeted advertising and "dark ads";
- AI-generated health content and chatbot interactions;
- Platform-specific promotional strategies designed to evade detection; and
- Emerging digital technologies and promotional methods.

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In an administration that has generally championed deregulation, the announcement sends a clear message to pharmaceutical companies and traditional and digital media advertisers that D2C pharmaceutical advertising practices will be a priority for both regulation and enforcement, although litigation will likely follow closely behind.