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MAHA Targets Social Media in Push for Tighter Controls Over Direct-to-Consumer Pharmaceutical Advertising

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The Make America Healthy Again (MAHA) Commission released the Make Our Children Healthy Again Strategy (MAHA Strategy) this week. The MAHA Strategy, a cornerstone of the MAHA movement championed by Secretary of Health and Human Services Robert F. Kennedy, Jr. and embraced by President Donald Trump in Executive Order 14212, "Establishing the President's Make America Healthy Again Commission," outlines more than 120 initiatives, including one focused on curbing misleading direct-to-consumer (DTC) advertising.

In a strongly worded release from Kennedy and Food and Drug Administration (FDA) Commissioner Martin Makary issued concurrently with the MAHA Strategy, the government announced its intention to restore transparency, accountability and trust in healthcare. Specifically, the **September 9, 2025, announcement** acknowledged that, "Americans … live in a new era of social media," and that "[a]n increasing reliance on digital and social media channels, including undisclosed paid influencer promotion, has blurred the lines among editorial content, user-generated media and pharmaceutical advertising, making it increasingly difficult for patients to distinguish between evidence-based information and promotional material."

The government's statements were critical of FDA's enforcement efforts in this space for the past few decades, calling them "increasingly lax and reactive" despite "widespread violations." Makary committed to utilizing existing legal authorities, including deploying all available enforcement tools, to ensure that industry adheres to the FDA fair balance guidelines, which require advertisements to clearly present serious risks associated with a pharmaceutical product. Along these lines, the Department of Health and Human Services (HHS) also issued a **fact sheet**, highlighting an FDA rulemaking process aimed at closing the "adequate provision loophole" that enables pharmaceutical ads to include a "major risk statement" rather than the full list of contraindications, boxed warnings and precautions in the advertisement.[1]

Trump reinforced these enhanced enforcement efforts in a memorandum to Kennedy and Makary, also issued on September 9, entitled, "**Addressing Misleading Direct-To-Consumer Prescription Drug Advertisements**," which directed Makary to "enforce the Federal Food, Drug, and Cosmetic Act's prescription drug advertising provisions, and otherwise ensure truthful and non-misleading information in direct-to-consumer prescription drug advertisements."

Consistent with this heightened scrutiny of DTC promotion and Trump's memorandum, the **FDA also announced on September 9** that it had dispatched "thousands of letters warning pharmaceutical companies to remove misleading ads" and had issued "approximately 100 cease-and-desist letters to companies" whose advertisements the FDA deemed deceptive. The letters to industry instruct the recipient to "remove any noncompliant advertising and bring all promotional communications into compliance" and reiterate the FDA's view that many materials fail to present a fair balance between a product's risks and benefits. Mirroring the priorities reflected in the MAHA Strategy, FDA's correspondence places particular emphasis on social media-based marketing, including undisclosed influencer promotion.

Kennedy has long expressed skepticism and a desire to limit, if not ban outright, DTC pharmaceutical advertisements. These coordinated actions are consistent with Kennedy's goals, as they outline a broadened enforcement campaign focused on DTC

pharmaceutical promotion that targets social media platforms and influencer partnerships. Per the **HHS fact sheet**, as part of its enhanced oversight, FDA intends to review algorithm-driven "dark ads," artificial intelligence-generated health content, chatbot interactions and other emerging digital technologies.

These recent announcements demonstrate that the current administration can and will enforce the law consistent with its policy priorities. While FDA has in the past sent Warning Letters to sponsors for content posted by social media influencers, the MAHA Strategy could represent a sea change in how FDA reviews such content, as well as the speed with which the agency takes action, as evidenced by the thousands blanketed with Makary's September 9 letters. While the government's focus appears to be on approved drugs and biologics to date, it may also extend to compounded prescription medications, as well as medical devices, as the FDA applies its fair balance guidelines to medical devices per its guidance, "**Presenting Risk Information in Prescription Drug and Medical Device Promotion**".

The strong statements from Trump, Kennedy and Makary warrant a revisiting of industry's approach to advertising and promotion. An enterprise-wide compliance approach that integrates legal, medical and regulatory review of promotional materials remains the most effective safeguard against the growing risk of enforcement actions and reputational harm.

The Cooley team, led by former FDA enforcement attorneys, is here to help. If you have any questions regarding your company's medical product promotion, please reach out to one of us.

Note

1. As of the date of this alert, the proposed rulemaking does not yet appear in the Federal Register.

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