

CAPITOL STREET

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Pharma DTC Ad Regulations Coming (FDA, FTC, DOJ)

FDA to Release Non-Opioid Pain Guidance Sept 10

Relevant Companies



»» Our Take & Next Up

DTC advertising regulations are in development at HHS, per today's MAHA report and Presidential memo. Today, President Trump released a memorandum for HHS and the FDA to address direct-to-consumer prescription drug advertising [here](#). The directive focuses on side effect disclosure and lax standards in advertisements. We believe that HHS and FDA will likely seek stakeholder input before the release of new regulations guiding DTC advertising transparency (on social media and side effect reporting) in late 2025/2026.

»» Key Points

Also today, the MAHA Commission released the "Make Our Children Healthy Again Strategy" continuing to outline the administration's priorities on food, agriculture, FDA, and chronic disease research [here](#). Notably, the report highlights the administration's stance on direct-to-consumer (DTC) drug advertising, NIH research priorities, a new vaccine framework, FDA focus areas, and data transparency and modernization targets.

DTC DRUG ADS

President Trump formally directed HHS and FDA to address DTC drug advertising with today's [memoranda](#). The President's directive focuses on side effect disclosures and increased scrutiny on what is considered a "balanced" advertisement. It directs the HHS Secretary to increase DTC transparency of side effects and FDA Commissioner to enforce drug advertising regulations.

Based on the directive and MAHA report, DTC advertising regulations are coming (likely for social media and enhanced side effect disclosures). The MAHA report notes that multiple agencies including the FDA, HHS, FTC, and DOJ will increase oversight and enforcement of direct-to-consumer (DTC) prescription drug advertising laws. During his Senate Finance [hearing](#) last week, RFK Jr. continued to support addressing DTC drug advertising. The report states that the administration will target misleading and deceptive advertising, particularly on social media and digital platforms.

Currently, there is considerable flexibility in how this risk information can be conveyed. Drug manufacturers must still disclose all of the important risks in a product claim advertisement, but they need not provide all of that information in a single commercial segment and may just provide links to resources. As a reminder, the FDA cannot pre-review the ads, only those on the market and commercial speech doctrine likely limits what the FDA can do.

FDA

The FDA will release draft guidance for non-opioid pain medications tomorrow. Commissioner Makary stated that in line with MAHA goals, the FDA is set to release draft guidance for the development of non-opioid medications tomorrow. In January 2025, the FDA approved a first-in-class non-opioid analgesic, to treat moderate to severe acute pain in adults. As a reminder, the FDA issued draft guidance on the development of non-opioid analgesics for acute pain in 2022.

Supplemental NDA/BLAs for repurposed drugs could see increased clinical trial support from the FDA, amidst ongoing review process concerns. The report states that the NIH and FDA will jointly investigate opportunities to strengthen the use of repurposed drugs (drugs already approved) for new treatments of chronic disease, while collaborating on clinical trial designs.

The EPA, FDA, and NIH have all committed to using New Approach Methodologies (NAMs) moving forward. NIH will launch a new Office of Research Innovation, Validation, and Application to develop, validate, and scale NAMs, and serve as an interagency coordination hub.

Other FDA priorities (domestic manufacturing pre-check, CRL letters, rare diseases, national priority review vouchers) were highlighted by Commissioner Makary at a MAHA briefing here. The FDA is pushing forward on transparency and drug review-focused initiatives including:

- Streamline review of domestic manufacturing through FDA PreCheck (2 phase review). See our analysis here.
- Real-time release of complete response letters (CRL) shortly after they are issued.
- New proposed review program for ultra rare disease therapies. See our analysis here.
- Ongoing implementation of the Commissioner's National Priority Voucher (CNPV) program. See our program expectations here.

NIH

NIH priorities are shifting with the upcoming Initiative on chronic disease. The NIH will also launch a new Whole-Person-Health approach to chronic disease prevention research and leverage collective expertise across the agency.

The administration is aiming for data modernization with the development of a Real World Data Platform (RWDP). Secretary Kennedy has increasingly focused on access to real-time data (increased transparency) and wearable tech for health information. The report announced that the NIH will link multiple datasets, such as claims info, electronic health records, and wearables data, into a single integrated dataset to research causes and treatments for the chronic disease crisis.

VACCINES

The White House Domestic Policy Council and HHS will develop a new vaccine framework that aims to change vaccination schedules and policy norms. According to the MAHA Strategy report, the framework will focus on (1) ensuring America has the best childhood vaccine schedule; (2) addressing vaccine injuries; (3) modernizing American vaccines with transparent, gold-standard science; (4) correcting conflicts of interest and misaligned incentives; and (5) ensuring scientific and medical freedom.

Vaccine injuries remain a key focus and present ongoing liability concerns for vaccine manufacturers. HHS, in collaboration with NIH, will investigate vaccine injuries through a new vaccine injury research program at the NIH Clinical Center. This ties in with the ongoing risk of changes to the National Vaccine Injury Compensation Program (VICP), which provide financial compensation to individuals who were injured by a covered vaccine. We could see autism be added to VICP as a vaccine injury. See high points from our vaccine webinar on August 5 [here](#).

The report does not address the Advisory Committee on Immunization Practice (ACIP), despite the pending meeting on Sept 18-19 ([here](#)). HHS Secretary RFK Jr. is poised to add seven new members to ACIP ([here](#)), some of whom have controversial views on COVID-19. Seven other previously added members with mixed records on vaccines gathered at ACIP's June meeting. At the meeting, ACIP voted against thimerosal in flu vaccines and signaled they would further scrutinize the childhood vaccine schedule and established vaccines (our take [here](#)). Recall, RFK also defended his vaccine policies at the SFC hearing on Sept. 4 ([here](#)).

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