CLIENT ALERT | July 8, 2025

Senators Introduce Legislation to Restrict Direct-to-Consumer Drug Advertising

The End Prescription Drug Ads Now Act would prohibit direct-to-consumer advertising and promotion of prescription drugs and biologics.

Key Points:

- The bill would only prohibit direct-to-consumer advertising of approved prescription pharmaceuticals and biologics, sparing medical devices, dietary supplements, cosmetics, over-the-counter drugs, compounded drugs, and other marketed but unapproved drugs.
- The bill targets the holders of approved applications under Section 505 of the Federal Food, Drug, and Cosmetic Act or licenses under Section 351 of the Public Health Service Act, potentially creating an avenue for non-manufacturer entities to continue promoting approved prescription drugs and biologics.
- Secretary Kennedy's long-standing opposition to direct-to-consumer advertising of pharmaceuticals, coupled with potential bipartisan support for the proposed legislation, suggests a favorable legislative environment for change.
- If enacted, the End Prescription Drug Ads Now Act would almost certainly be challenged on constitutional grounds and may not withstand scrutiny under the First Amendment.

On June 12, 2025, Senators Bernie Sanders (I-Vt.) and Angus King (I-Maine) introduced the End Prescription Drug Ads Now Act, with Senators Chris Murphy (D-Conn.), Peter Welch (D-Vt.), Jeff Merkley (D-Ore.), and Dick Durbin (D-Ill.) joining as co-sponsors.[1] If enacted, the bill would amend Section 502 of the Federal Food, Drug, and Cosmetic Act (FDCA) to prohibit direct-to-consumer (DTC) advertising of prescription drugs approved under Section 505 of the FDCA or licensed under Section 351 of the Public Health Service Act.[2]

The bill defines DTC advertising as "any promotional communication targeting consumers, including through television, radio, print media, digital platforms, and social media, for purposes of marketing such a drug."[3] Senator Sanders says the bill would "align the United States with virtually every other country on earth by establishing a ban on direct-to-consumer prescription advertising," which would include "any forms of media, including social media."[4] He notes that this ban "would apply to all drugs and biologics, including those currently on the market."[5]

The bill summary highlights a potential coalition forming to target DTC advertising, noting that Department of Health and Human Services Secretary Robert F. Kennedy Jr. has repeatedly called for banning DTC advertising of prescription drugs, recently imploring voters to "get President Trump back in the White House and me to DTC so we can ban pharmaceutical advertising."[6] Although the bill does not have any Republican co-sponsors, related legislative initiatives to curb pharmaceutical advertising suggest there may be bipartisan support in Congress for the bill.

During the last session of Congress, for example, Senators Durbin and Roger Marshall (R-Kan.) introduced the Protecting Patients From Deceptive Drug Ads Online Act, a bipartisan bill that would have imposed civil penalties on healthcare providers and social media influencers for making false or misleading communications regarding prescription drugs and biologics.[7] Separately, several Republican members of Congress, including Senator Josh Hawley (R-Mo.), introduced the No Handouts for Drug Advertisements Act, which would amend the Internal Revenue Code to prevent companies from deducting expenses relating to DTC advertising of prescription-only drugs in tax filings.[8]

In light of First Amendment protections for truthful, non-misleading speech — including protections for commercial speech — efforts to constrain or limit DTC advertising of prescription drugs and biologics may be more successful than attempts to ban it outright. Despite reductions in staffing and a reported lack of leadership,[9] for example, FDA's Office of Prescription Drug Promotion (OPDP) appears to be continuing its scrutiny of DTC advertising and promotion under its current authority,[10] issuing more enforcement letters already in 2025 than it did throughout 2024.

In addition, the Trump administration is reportedly discussing a policy that would require companies to robustly disclose a drug's side effects in its advertisements.[11] FDA may pursue such an effort by amending its regulations at 21 C.F.R. 202.1(e)(1) to require the "true statement of information in brief summary" to more exhaustively discuss side effects, perhaps for a predetermined period of time in any advertisement or promotional communication.[12]

Testifying before the Senate in May 2025, Secretary Kennedy said that he had conversations about "tax changes" relating to pharmaceutical advertisements with Treasury Secretary Scott Bessent and that he expects to announce a policy advancing this initiative "within the next few weeks."[13] It remains unclear what form such a policy would take from a regulatory perspective, and how it would relate, if at all, to the objectives of the No Handouts for Drug Advertisements Act.

The End Prescription Drug Ads Now Act has been referred to the Senate Committee on Health, Education, Labor, and Pensions (HELP).[14] For the bill to advance to the Senate floor, the Chair of the HELP Committee must introduce the bill to the Committee for a markup session, during which Committee members would review, amend, and debate the bill's provisions. The process would conclude when the Committee agreed, by majority vote, to report the bill to the full Senate chamber for further deliberation.

Senator Bill Cassidy (R-La.) was officially seated as Chair of the HELP Committee on July 1, 2025. Whether he will present the bill to the Committee for markup is unclear.

Conclusion

The End Prescription Drug Ads Now Act seeks to fundamentally change the ways in which drugs and biologics are promoted in the United States. Although there is bipartisan support for change in this area, the bill faces numerous obstacles, including claims that it is unconstitutional. We thus expect opponents of DTC advertising restrictions to continue fighting on multiple fronts, and anticipate that the Trump administration may instead try to restrict DTC advertising via regulatory changes and increased enforcement.

Latham & Watkins will continue to monitor and report on developments related to the bill, similar legislative initiatives, and regulatory actions that seek to limit companies' abilities to promote prescription drugs and biologics.

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Endnotes

[1] End Prescription Drug Ads Now Act, S. 2068, 119th Cong. (2025).

[2] *Id.* § 2(a). Biological products subject to the PHS Act also meet the definition of drugs under the FDCA .

[3] *Id.* § 2(a).

[4] Senator Bernie Sanders, *End Prescription Drug Ads Now Act*, available at https://www.sanders.senate.gov/wp-content/uploads/End-Prescription-Drug-Ads-Now-Act-One-Pager.pdf.

[5] *Id.*

[6] *Id.*

[7] Protecting Patients from Deceptive Drug Ads Online Act, S.5040, 118th Cong (2024).

[8] No Handouts for Drug Advertisements Act, S.1785, 119th Cong. (2025); No Handouts for Drug Advertisements Act, H.R. 3010, 119th Cong. (2025).

[9] *See* Andrea Park, "Senator grills Makary over FDA's ability to regulate drug ads after OPDP cuts," *Fierce Pharma* (May 30, 2025), https://www.fiercepharma.com/marketing/senator-grills-makary-over-fdas-ability-regulate-drug-ads-after-opdp-cuts.

[10] Under FDA's regulatory framework, advertisements for prescription drugs and biologics must be truthful, not misleading, and present a fair balance of risk and benefit information, including a brief summary of side effects, contraindications, and effectiveness. (*See* 21 U.S.C. §§ 352(a), (n)). FDA's regulations specify the conditions under which an advertisement for a prescription drug or biologic is false, lacking in fair balance, or otherwise misleading. (*See* 21 C.F.R. § 202.1(e)(6)). Prescription drug advertisements and promotional communications misbrand a drug if they promote the drug as being better or more effective than actually demonstrated; imply that a drug is safer or has fewer or less severe side effects than demonstrated; claim, without substantial evidence, that a product is better than a competitor's; give a false, misleading, or unbalanced presentation of risk information about a drug product; or promote the product as capable of treating conditions for which FDA has not approved it. (S*ee* 21 C.F.R. § 202.1(e)(6); *see also* FDA, "From the manufacturers' mouth to your ears: Direct to consumer advertising" (last accessed June 27, 2025), https://www.fda.gov/drugs/special-features/manufacturers-mouth-your-ears-direct-consumer-advertising).

[11] Rachel Cohrs Zhang, "RFK Jr.'s Drug-Ad Crackdown Threatens a $10 Billion Market," Bloomberg (June 17, 2025), https://www.bloomberg.com/news/articles/2025-06-17/rfk-jr-plans-crackdown-on-pharma-ads-in-threat-to-10-billion-market.

[12] *See* 21 C.F.R. § 202.1(e)(1).

[13] Senator Josh Hawley, "Hawley Secures RFK Jr.'s Pledge to Review Mifepristone, Support Bill Cracking Down On Big Pharma Ads" (May 15, 2025), at 4:12, https://www.youtube.com/watch?v=c27KZnQ1KI0.

[14] S.2060, End Prescription Drug Ads Now Act, https://www.congress.gov/bill/119th-congress/senate-bill/2068?q=%7B%22search%22%3A%22end+prescription+drug+ads+now+act%22%7D&s=2&r=1.