

FIXING TRANSPARENCY IN PHARMACEUTICAL ADVERTISING

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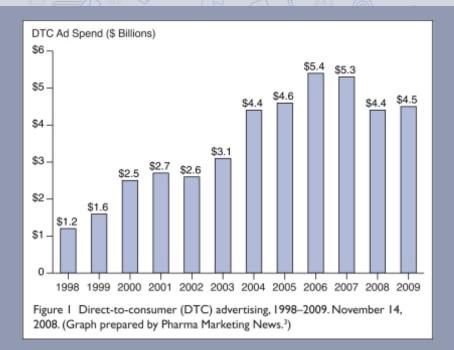
Direct-to-Consumer (DTC) pharmaceutical advertisements have become more popular and have expanded across millions of homes across the nation. These ads raise concerns about transparency, patient understanding, and the influence of marketing decisions on healthcare. While these ads can increase public awareness, their presentation often minimizes risks and strains the doctor-patient relationship. Existing regulatory rules have not kept up with the pace of modern advertising. This memo evaluates the limitations of current policy framework, the competing interests of pharmaceutical companies, and the constitutional constraints that make a full ban legally challenging. It proposes targeted policy solutions including disclosure requirements, strengthened enforcement mechanisms, and more monitoring of digital advertising. These reforms aim to ensure that DTC marketing informs rather than misleads and restoring trust back into the healthcare system.

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## INTRODUCTION

Direct-to-consumer (DTC) pharmaceutical advertisements are the promotion of pharmaceutical drugs that may need an intermediary, such as a doctor, directly to patients through TV, radio, print, etc. (Choi & Lee, 2007). Consumer and patient advocates have long raised concerns about the prevalence and nature of DTC pharmaceutical advertising in the United States. These advertisements can include OTC medication, vitamins, and supplements, but the most polarizing subject is those that include prescription medications. (Choi & Lee, 2007) Advertisements account for a large share of healthcare spending, which, in turn, has driven the price of prescription drugs over the years. Considering this, the practices of the advertisements have been under scrutiny in recent decades for how they present the drugs and their risks, and ultimately how that is shaping the healthcare system. The landscape of big-budget advertising complicates the regulations that have otherwise been advocated for in the industry.



# CURRENT POLITICAL DEVELOPMENTS

The first pharmaceutical advertisement in the US appeared in the early 1980s, and a boom in those commercials happened in the 1990s. (Koinig, Diegelmann, & Bidmon, 2022)
Following this rise in 1997, the FDA established "adequate provision" This provided a guideline allowing advertising to provide a brief mention of the risks of the medication as long as they provide an external link to a full disclosure, usually in the form of a phone number or website. (Koinig, Diegelmann, & Bidmon, 2022)



Pg. 12-13, "Reader's Digest", October, 198

In 1997, 1.3 billion was spent on advertising with 79,000 ad occurrences, and by 2016, 6 billion was spent on 4.6 million occurrences. (Main, Argo, & Huhmann, 2004) This clause makes producing ads more favorable for drug producers because all contraindications, box warnings, and general precautions make advertisements less appealing to advertisers. (Koinig, Diegelmann, & Bidmon, 2022)

In recent developments, there has been popular support on both sides of the aisle for stricter regulations on DTC advertisements. On Sept. 9, 2025, President Donald Trump released a memorandum, instructing the Department of Health and Human Services to ensure transparency and accuracy in DTC advertisements by increasing information on associated risks. On the same day, the Make America Healthy Again Commission (MAHA), chaired by Robert F. Kennedy Jr., released a report stating the FDA, HHS, FTC, and DOJ need to increase oversight and enforcement for violations of the DTC advertisement laws. Also, on June 12, 2025, Senators Bernie Sanders (I-Vt) and Angus King (I-Maine) introduced a bill for an all-out ban on prescription drug ads. (Faget et al.)

### WHAT WE KNOW:

## THE EFFECTS OF DTC PHARMACEUTICAL ADVERTISEMENTS

#### PATIENTS:

The gradual increase of prescription drug use for Americans has been partially credited to the rise in pharmaceutical advertisements. (Main, Argo, & Huhmann, 2004) Which has overall changed the landscape of patient-provider relationships, because of the fact that healthcare providers are mediators in the prescription process (Choi & Lee, 2007). Patients may approach providers with drug request and limited understanding of how appropriate the request is for their condition and alternative treatments (Choi & Lee, 2007). This dynamic forces providers to navigate between patient self advocacy and their professional discretion.

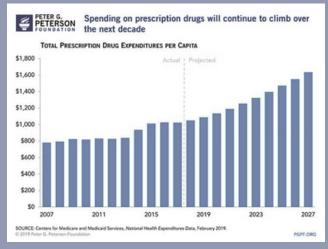




Serena Williams' advertising campaign for Telehealth company, Ro advocated against the stigma surrounding the use of GLP-1s through

#### **HEALTHCARE INDUSTRY:**

The overall increase of DTC advertisements have had notable effects on the healthcare industry as a whole. The inclusion of marketing for prescription drugs contribute to higher costs for consumers. This has raised questions about the overall spending on advertisements within the context of the American healthcare system because of widespread objections and concerns to resource allocation in an already strained healthcare system.



# STAKEHOLDERS AND ROLE OF THE GOVERNMENT

#### STAKEHOLDERS:

The main stakeholders present in this policy problem can be seen in terms of the private sector, being the pharmaceutical companies. They derive power from private investors /investments and are profit-driven.

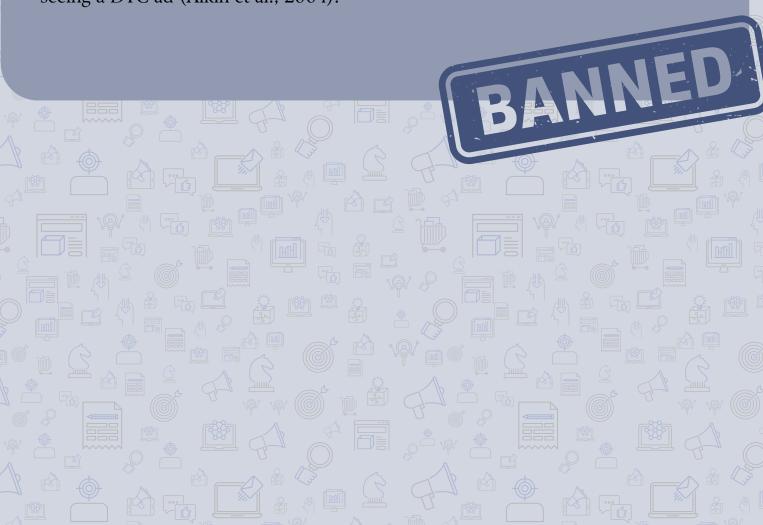
Additionally, the public sector includes the government and the authority it exerts and the people and the general public.

#### **ROLE FOR GOVERNMENT:**

The role of the government in addressing this policy issue would first be to establish what is considered appropriate or sufficient disclosure and situate that standard within a mandate or legislature. Ultimately, the role of the government is to decide how much intervention is needed to protect patients and the healthcare system and how much freedom drug companies will be afforded to advertise prescription drugs directly to consumers. The government has the role of establishing methods of enforcement and of overall regulation of the industry.

## IS A BAN THE RIGHT PATH?

- Under current U.S. law, a total ban faces constitutional obstacles since the advertising of prescription drugs is considered commercial speech.
- The regulation of commercial speech is constrained under the Federal Food, Drug, and Cosmetic Act (FDCA) and the First Amendment laws, as well as the Central Hudson Gas and Electric Corp. v. Public Service Commission test, which requires regulation to be no more restrictive than necessary to serve an interest (Central Hudson Gas & Elec. V. Public Svc. Comm'n, 447 U.S. 557 (1980), n.d.; The First Amendment and Direct-To-Consumer (DTC) Prescription Drug Ads, 2025).
- Advertising has also served to benefit the public by increasing awareness of treatable conditions and encouraging patients to communicate with their physicians.
- About 43% of patients in one survey said they sought further information after seeing a DTC ad (Aikin et al., 2004).



## POLICY SOLUTIONS

### 1. Enhance Transparency

- In line with President Trump's memorandum issued Sept. 9, 2025, directing Department of Health and Human Services (HHS) and the FDA to ensure DTC prescription drug ads provide full safety warnings are not misleading (Memorandum for the Secretary of Health and Human Services the Commissioner of Food and Drugs, 2025)
- Proposal: amend the FDCA (or adopt a new regulation under it) requiring that all prescription drug DTC advertisements explicitly display risk information and summary labeling in the ad itself, not just through "adequate provision" links.

## 2. Strengthen Enforcement

- Mandate that the FDA issue tiered penalties for violations.
  - Administrative penalties for first-time offenders
  - Larger fines or injunctions for repeat or blatant violations
- Expand FDA monitoring system to detect misleading content early on. The HHS fact sheet clearly mentions closing digital loopholes. (Direct-To-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format Final Rule Questions and Answers, 2023)
  - Monitoring social media posts, telehealth platforms, pharma-linked ad campaigns, etc.)
- Require companies to submit periodic public reports on their advertising expenditures by advertising medium, drug, and compliance metrics

## POLICY IMPLICATIONS

## **Legal Implications**

These proposals focus on transparency and enforcement, so they are more likely to withstand First Amendment scrutiny for commercial speech. Regulations must be tailored so they aren't violating the Central Hudson Gas and Electric Corp. v. Public Service Commission, Central Hudson Gas & Elec. V. Public Svc. Comm'n, 447 U.S. 557 (1980), n.d.) test

## **Cost implications**

FDA will require more resources for monitoring digital ads and issuing enforcement. However, it is possible that these costs could outweigh reductions in inappropriate prescribing, wasteful spending, and patient harm.

## **Industry Pushback**

Pharmaceutical firms may argue that these regulations will restrict drug innovation and public awareness of treatments.

#### **Public Health Benfits**

Improved transparency can increase informed decision making amongst the patient population.

## CONCLUSION

Pharmaceutical advertising remains a powerful force in shaping patient perception, prescribing patterns, and healthcare spending. Without increased transparency and accountability, these advertisements risk undermining public trust and the integrity of decision-making. By reinforcing disclosure standards, and holding companies accountable, policymakers have the power to close the gap between marketing and medicine. By adopting these measures, Congress and federal agencies can ensure that pharmaceutical marketing informs rather than misleads, advancing both consumer protection and public health.



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