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Kyle A. Diamantas, J.D.
Acting Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Citizen Petition to Ban Direct-To-Consumer (DTC) Advertising of Human Prescription Drugs

Dear Acting Commissioner Diamantas,

Public Citizen, a consumer advocacy organization with more than one million members across every state, respectfully petitions the Food and Drug Administration (FDA) to ban direct-to-consumer (DTC) advertising of prescription drugs pursuant to § 502(n) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 352(n), and implementing regulations at 21 C.F.R. § 202.1.

Public Citizen has long been concerned about DTC advertising of prescription drugs and its adverse effects on informed medical decision-making. Since September 1998, Public Citizen,

through its Health Research Group, has submitted multiple comments and letters to the FDA, opposing DTC advertising and urging the agency to strengthen regulation of DTC advertising.[1,2]

When the first DTC advertisement aired on television in the early 1980s,[3,4] the FDA did not have explicit rules addressing DTC advertising. Soon thereafter, however, the agency began requiring DTC advertisements to meet the same requirements as advertisements directed at physicians, which included full disclosure of the drug's side effects, contraindications, precautions, and warnings (referred to as a "brief summary"). Due to the considerable amount of airtime needed to comply with this requirement, broadcast DTC advertising was extremely rare. In fact, the brief summary requirement "created a de facto barrier to the broadcast advertising of prescription drugs."[5]

However, in 1997, the FDA loosened these requirements through its "Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements."[6] The guidance stated that companies could substitute the brief summary with a "major statement" of risks and direct viewers towards additional information about a drug's efficacy and safety, whether through a website, a toll-free number, a print insert, or through their pharmacist or physician.[7] The pharmaceutical industry quickly capitalized on this regulatory shift, airing DTC advertisements that omitted or minimized important safety information by sharing this information in another format or location. As a result, broadcast DTC advertising expanded rapidly. Decades later, the negative public health consequences remain clear.

As explained below, DTC advertisements often mislead consumers because they are designed to persuade rather than to inform or educate patients. These advertisements also often employ emotional manipulation techniques or visual distractions to highlight information about a drug's benefits while minimizing information about a drug's risks. When DTC advertisements "work," they do so by interfering with the doctor-patient relationship, persuading physicians to prescribe medications they would not have otherwise prescribed. As such, DTC advertisements offer no measurable public health benefit. Worse, they undermine informed medical decision-making,

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[1] Public Citizen. Public Citizen's Health Research Group's comments on: Food and Drug Administration: Attitudinal and behavioral effects of direct-to-consumer advertising of prescription drugs. September 28, 1998. https://www.citizen.org/wp-content/uploads/1460.pdf. Accessed July 15, 2026.
[2] Public Citizen. Drug promotion. https://www.citizen.org/article/drug-promotion/. Accessed July 15, 2026.
[3] Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. *JAMA.* 2019 Jan 1;321(1):80-96.
[4] Scott D. The untold story of TV's first prescription drug ad. *Stat News.* December 11, 2015. https://www.statnews.com/2015/12/11/untold-story-tvs-first-prescription-drug-ad/. Accessed July 15, 2026.
[5] Donohue J. A history of drug advertising: the evolving roles of consumers and consumer protection. *Milbank Q*. 2006;84(4):659-699.
[6] Federal Register. Draft guidance for industry. Consumer-directed broadcast advertisements. August 12, 1997.
[7] Donohue J. A history of drug advertising: the evolving roles of consumers and consumer protection. *Milbank Q*. 2006;84(4):659-699.

influence prescribing practices, erode trust in the patient-prescriber relationship, and impose substantial costs on the U.S. healthcare system.[8,9]

In September 2025, the FDA announced a "crackdown" on deceptive drug advertising, including plans for rulemaking on DTC advertising and stronger enforcement, with the goal of returning to the pre-1997 environment, when such advertising was rare.[10,11] Since the announcement, the FDA has issued an increased number of cease-and-desist and warning letters to pharmaceutical manufacturers regarding DTC advertising.[12,13] The agency has asked Congress for additional statutory authority to deem drugs misbranded if advertisements lack "fair balance and create[s] a misleading impression regarding FDA approval, the scope of the FDA-approved indication(s) and the limitations of use, or the drug's efficacy and benefits, including by making or suggesting overstated representations that are not supported."[14] The FDA also "proposes revising the prescription drug advertising regulation to require DTC ads broadcast through media such as radio and television to disclose all relevant risk and safety information to consumers within the confines of the ad itself rather than referring consumers to an external source where they can request the full FDA-approved labeling."[15]

Greater enforcement and proposed strengthening of existing regulations, with uncertain effectiveness, is not an adequate substitute for a ban on DTC advertising. Warning letters simply react to violations that have already occurred; they do not constitute a proactive approach to remedy the harms of DTC advertising. Because the FDA does not preapprove DTC advertisements, DTC advertisements that violate agency standards may air for months or years

[8] Food and Drug Administration. FDA launches crackdown on deceptive drug advertising. September 9, 2025. https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising. Accessed July 15, 2026.
[9] Government Accountability Office. Prescription drugs: Medicare spending on drugs with direct-to-consumer advertising. May 18, 2021. https://www.gao.gov/products/gao-21-380. Accessed July 15, 2026.
[10] Food and Drug Administration. FDA launches crackdown on deceptive drug advertising. September 9, 2025. https://www.fda.gov/news-events/press-announcements/fda-launches-crackdown-deceptive-drug-advertising. Accessed July 15, 2026.
[11] Department of Health and Human Services. Fact sheet: Ensuring patient safety through reform of direct-to-consumer pharmaceutical advertisement policies. September 9, 2025. https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency-fact-sheet.html. Accessed July 15, 2026.
[12] Food and Drug Administration. Letter to industry. September 9, 2025. https://www.fda.gov/media/188616/download?attachment. Accessed July 15, 2026.
[13] Food and Drug Administration. Untitled letters. June 2, 2026. https://www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/untitled-letters. Accessed July 15, 2026.
[14] Department of Health and Human Services. Fiscal Year 2027: Food and Drug Administration. https://www.fda.gov/media/191778/download?attachment. Accessed July 15, 2026.
[15] Office of Information and Regulatory Affairs. Agency Rule List- 2026. Department of Health and Human Services. July 3, 2026. https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&csrf_token=6AA0C4539953D73B327F5AE790D82958298203F80CCB1590A83286A2F971A01B8688A2D6202963D3FED0DC9246D3BC228C6E. Accessed July 15, 2026.

before warning letters are issued. And even if perfectly enforced, DTC regulations cannot solve the harms of DTC advertising, because those harms are inherent in the advertising itself.

Nearly all other developed nations, including Canada, Australia, the United Kingdom, and those of the European Union, have long prohibited DTC advertising for prescription drugs that include medical claims. Only two developed countries, the United States and New Zealand, allow unfettered DTC advertising of prescription medications.[16] In Canada, for example, DTC advertisements of prescription drugs are prohibited except for "reminder" advertisements that identify products by their brand name but do not include claims about therapeutic uses, benefits, or safety. The Canadian Food and Drugs Act and Canada's Food and Drug Regulations explicitly forbid advertising that communicates the purpose, efficacy, or safety of prescription drugs directly to the public. The Canadian regulatory authority — Health Canada — enforces this framework to prevent misleading and/or promotional messaging that could drive inappropriate demand for prescription medicines.[17]

The European Union and the United Kingdom go even further, strictly prohibiting DTC advertising of prescription drugs to the public and limiting promotional communications to healthcare professionals only.[18,19,20] Longstanding restrictions on DTC advertising in most developed countries reflect the minimal informational value that is typical of the advertisements, which tend to misinform patients and induce inappropriate prescribing. There is no evidence that consumers in countries that ban DTC advertisements suffer any adverse health effects.

In the sections that follow, the petition (1) discusses the harm DTC advertising of prescription drugs causes in the U.S. to patients, physicians, the economy, and the healthcare system; (2) evaluates the principal arguments in favor of DTC advertising and their shortcomings; and (3) demonstrates the need for a ban on DTC advertising.

[16] Menkes DB, Mintzes B, Lexchin J. Direct-to-consumer advertising: a modifiable driver of overdiagnosis and overtreatment. *BMJ Evid Based Med.* 2024 Nov 22;29(6):423-425.
[17] Health Council of Canada. Direct-to-consumer advertising of prescription drugs in Canada. January 2006. https://publications.gc.ca/collection_2007/hcc-ccs/H174-3-2006E.pdf. Accessed July 15, 2026.
[18] European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use. https://eur-lex.europa.eu/eli/dir/2001/83/oj/eng. Accessed July 15, 2026.
[19] Velo G, Moretti U. Direct-to-consumer information in Europe: the blurred margin between promotion and information. *Br J Clin Pharmacol*. 2008;66(5):626-628.
[20] Medicines and Healthcare products Regulatory Agency. Guidance: Advertise your medicines. Updated April 11, 2025. https://www.gov.uk/guidance/advertise-your-medicines. Accessed July 15, 2026.

A. ACTION REQUESTED

Public Citizen requests that the FDA, pursuant to § 502(n) of the FDCA, promptly ban DTC advertising of prescription drugs.

B. STATEMENT OF GROUNDS

1. Statutory and Regulatory Background

The FDCA prohibits the sale of misbranded drugs. Section 352, which defines misbranding, provides that DTC advertising renders a product misbranded unless the advertisement includes:

> "a true statement of (1) the established name [as elsewhere defined], printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 371(a) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088 […].'"[21]

The statute further requires that DTC advertising of prescription drugs on television or radio include a major statement relating to side effects and contraindications "presented in a clear, conspicuous, and neutral manner."[22]

FDA regulations provide further specificity regarding permissible DTC advertising of prescription drugs. The regulations require that DTC advertisements include a "true statement" of information relating to the drug's side effects, contraindications, and effectiveness.[23] An advertisement violates this section if:

1) "It is false or misleading with respect to side effects, contraindications, or effectiveness; or
2) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by section 502(n) of the act and this information is not fairly balanced by a

[21] 21 U.S.C. § 352(n).
[22] *Id*.
[23] 21 C.F.R. 202.1(e) (5).

presentation of a summary of true information relating to side effects and contraindications of the drug; […]

3) It fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement."[24]

In December 2023, as directed by the Food and Drug Amendments Act of 2007, the FDA amended its regulations to establish standards for determining whether the major statement in DTC television and radio advertisements is presented in a clear, conspicuous, and neutral manner.[25] Accordingly, the current regulation sets out five standards that television and radio DTC advertisements must meet to satisfy this requirement and ensure that consumers will fully understand the drug's risks. Specifically, the regulation requires that the major statement:

1) Is presented in consumer-friendly language that is readily understandable;
2) Delivers audio disclosures at a volume, pace, and clarity comparable to the rest of the advertisement;
3) Presents information using both audio and text formats;
4) Displays text in legible fonts with appropriate size, placement, and contrast; and
5) Avoids distracting elements, such as background music or competing visuals, that interfere with comprehension.[26]

The FDA does not review or approve DTC advertisements before they are disseminated to the public, except in rare instances, for example as part of a compliance action. Although pharmaceutical companies can voluntarily submit advertisements before they are aired to request agency feedback, most advertisements are submitted to the agency at the same time as they first appear on television, radio, the internet, or any other platform.[27, 28] As a result, companies can release advertisements that do not conform with FDA regulations before the agency is even aware of the advertisements.

If the FDA finds that an advertisement does not comply with its regulations, the agency has several options. First, it can send a letter explaining that the advertisement is deficient and

[24] *Id*.
[25] Food and Drug Administration. 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. Guidance for industry. December 2023. https://www.fda.gov/media/175074/download. Accessed July 15, 2026.
[26] 21 C.F.R. § 202.1(e)(1)(ii).
[27] Food and Drug Administration. OPDP frequently asked questions (FAQs). May 31, 2024. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-frequently-asked-questions-faqs. Accessed July 15, 2026.
[28] Food and Drug Administration. Prescription drug advertising. Questions and answers. June 19, 2015. https://web.archive.org/web/20260317133545/https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers. Accessed July 15, 2026.

requesting that the company cease the advertisement.[29] Second, the FDA can require a pharmaceutical company to publish a corrective advertisement. Finally, the agency can take enforcement actions, such as filing a case in court to request an injunction prohibiting further dissemination of the advertisement or bringing criminal charges.

2. Evidence of Harm to Patients

A substantial body of peer-reviewed evidence demonstrates that DTC advertising: (1) misleadingly presents the benefits and risks of medications, thereby distorting patients' understanding of drug safety and effectiveness; (2) uses favorable imagery to manipulate consumers' emotions; (3) contributes to the overdiagnosis of disease and overprescription of medications; (4) erodes the patient-clinician relationship; and (5) promotes low-value medications and medications whose benefits and harms are uncertain.

2.1 Misleading Presentation of the Benefits and Risks of Medications

FDA regulations do not require that DTC advertisements include quantitative benefit data in DTC advertisements, such as absolute risk reduction or response rates.[30] As a result, prescription drug manufacturers can selectively frame efficacy and safety information, thereby overstating benefits and understating risks, and misleading patients.

In a study assessing 97 DTC advertisements published in 2018, researchers found that none of the advertisements presented quantitative evidence of the drug's safety risks, and only one-quarter described the drugs' efficacy in quantitative terms.[31] This lack of information leaves patients misinformed. A 2004 study found that participants shown a table that displayed quantitative outcome data rated the drug's effectiveness lower than those who viewed the same advertisement without quantitative data.[32] That said, even advertisements that contain data about drugs' risks and benefits generally will not adequately inform consumers, as the general population lacks statistical training and is prone to undervaluing or misjudging risk.[33,34] The general population's lack of statistical training and the undervaluing or misjudging of risk are

[29] *Ibid.*
[30] Food and Drug Administration. Presenting quantitative efficacy and risk information in direct-to-consumer (DTC) promotional labeling and advertisements. Guidance for Industry. December 2023. https://www.fda.gov/media/169803/download. Accessed July 15, 2026.
[31] Klara K, Kim J, Ross JS. Direct-to-consumer broadcast advertisements for pharmaceuticals: Off-label promotion and adherence to FDA guidelines. *J Gen Intern Med*. 2018 May;33(5):651-658.
[32] Woloshin S, Schwartz LM, Welch HG. The value of benefit data in direct-to-consumer drug ads. *Health Aff*. 2004;23(Suppl1):W4-234.
[33] Hoffmann TC, Del Mar C. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. *JAMA Intern Med*. 2015 Feb;175(2):274-286.
[34] Schwartz LM, Woloshin S, Black WC, et al. The role of numeracy in understanding the benefit of screening mammography. *Ann Intern Med*. 1997 Dec 1;127(11):966-972.

important reasons why prescription medicines are only available by prescription from a physician or other licensed healthcare professional.

Moreover, although DTC advertisements largely — but not always — follow FDA guidelines,[35,36] the response of pharmaceutical manufacturers has aptly been described as "generally attentive to the letter of the law but too often dismissive of the spirit" and "boundary testing."[37] For instance, manufacturers often present drug information using visual or auditory distractions, small fonts strategically placed, as well as specific word choices that downplay the product's harms and emphasize its benefits. FDA guidance, however, requests the fair balance of risk-benefit information, and agency regulations require the major statement to be presented in a clear, conspicuous, and neutral manner.[38]

The rise of digital and social-media-based drug promotion has exacerbated these risks.[39,40,41] In recent years, internet-based DTC advertising channels — including targeted advertising algorithms, interactive campaigns, and collaborations with social media influencers (which consumers often fail to recognize as pharmaceutical advertising) — have become important marketing strategies.[42] Internet-based DTC advertising allows pharmaceutical companies to employ more targeted approaches with even less oversight. Internet and social-media based drug advertising has become widespread and appears especially prone to misleading or deceiving consumers.[43]

Ensuring that drug advertisements adequately inform consumers is especially difficult in the context of character-limited communications, such as "tweets" and Instagram posts.[44] Moreover, social media posts containing DTC advertisements can be shared easily on social media

[35] Mulinari S, Ozieranski P. Unethical pharmaceutical marketing: a common problem requiring collective responsibility. *BMJ.* 2023 Sep 19;382:e076173.
[36] Kesselheim AS, Mello MM. Prospects for regulation of off-label promotion in an era of expanding commercial speech protection. *NCL Rev*. 2014;92:1539.
[37] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[38] 21 C.F.R. § 202.1.
[39] Zenone M, Kenworthy N, Maani N. The social media industry as a commercial determinant of health. *Int J Health Policy Manag 2023;12:6840.*
[40] Mor J, Kaur T, Menkes DB, et al. Pharmaceutical industry promotional activities on social media: a scoping review. *Journal of Pharmaceutical Health Services Research*. 2024 Nov;15(4):rmae022.
[41] Pomeranz JL, Hanson E, Mozaffarian D. Regulating direct-to-consumer prescription drug advertising in the United States. *Milbank Q*. 2026 Mar;104(1):13-47.
[42] Willis E, Delbaere M. Patient influencers: The next frontier in direct-to-consumer pharmaceutical marketing. *J Med Internet Res*. 2022 Mar 1;24(3):e29422.
[43] Dave S, Reed S, Woloshin S. The FDA and FTC need to crack down on TikTok and Instagram influencers pitching prescription drugs. *Stat News.* January 22, 2024. https://www.statnews.com/2024/01/22/fda-ftc-tiktok-instagram-influencers-advertising-prescription-drugs/. Accessed July 15, 2026.
[44] Sullivan HW, O'Donoghue AC, Mannis S, et al. Character-space-limited online prescription drug communications: Four experimental studies. *Res Social Adm Pharm.* 2022 Dec;18(12):4092-4099.

platforms, often without context or the necessary information about risks and benefits.[45] Researchers have cautioned that internet-based DTC advertising has "great potential for the public to be exposed to misleading or dangerous information," while also noting that monitoring such content is not feasible.[46] The harms of misleading internet-based DTC advertisements stripped of necessary information about the risks and benefits of medications is a continuing and growing problem.[47,48]

Despite the ubiquity of social media and the importance of internet-based DTC advertising, the agency has not exercised adequate oversight or issued adequate guidance on the topic.[49,50] The FDA's draft guidelines for internet-based DTC advertising were published in 2014 and have not been updated since.[51] The guidelines are vague and do not clarify, for instance, how the FDA will enforce its regulations in the context of video-based platforms such as TikTok or direct messages on platforms such as Instagram. Because of the sheer volume of posts, the FDA cannot effectively monitor digital marketing practices. Between 2017 and 2023, the FDA's Office of Prescription Drug Promotion sent 40 warning letters, only seven of which addressed sponsored social media posts.[52] As artificial intelligence (AI)-guided advertising approaches that incorporate patients' preferences and purchasing histories are increasingly used, effective monitoring by the agency will become even more infeasible.[53]

In September 2025, the FDA acknowledged that the lack of regulation of DTC advertisements on social media is a "digital loophole[s]."[54] Nonetheless, the FDA has not expanded its oversight to include all social media promotional activities, such as sponsored content, influencer partnerships, and AI-generated health content. But even if or when the agency finally monitors

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[45] Tyrawski J, DeAndrea DC. Pharmaceutical companies and their drugs on social media: a content analysis of drug information on popular social media sites. *J Med Internet Res*. 2015 Jun 1;17(6):e130.
[46] *Ibid*.
[47] Dave S, Reed S, Woloshin S. The FDA and FTC need to crack down on TikTok and Instagram influencers pitching prescription drugs. *Stat News.* January 22, 2024. https://www.statnews.com/2024/01/22/fda-ftc-tiktok-instagram-influencers-advertising-prescription-drugs/. Accessed July 15, 2026.
[48] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[49] Pomeranz JL, Hanson E, Mozaffarian D. Regulating direct-to-consumer prescription drug advertising in the United States. *Milbank Q*. 2026 Mar;104(1):13-47.
[50] Dave S, Reed S, Woloshin S. The FDA and FTC need to crack down on TikTok and Instagram influencers pitching prescription drugs. *Stat News.* January 22, 2024. https://www.statnews.com/2024/01/22/fda-ftc-tiktok-instagram-influencers-advertising-prescription-drugs/. Accessed July 15, 2026.
[51] Food and Drug Administration. Internet/social media platforms with character space limitations – presenting risk and benefit information for prescription drug and medical devices. Draft guidance. June 2014. https://www.fda.gov/media/88551/download. Accessed July 15, 2026.
[52] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[53] Tyrawski J, DeAndrea DC. Pharmaceutical companies and their drugs on social media: a content analysis of drug information on popular social media sites. *J Med Internet Res*. 2015 Jun 1;17(6):e130.
[54] Department of Health and Human Services. Fact sheet: Ensuring patient safety through reform of direct-to-consumer pharmaceutical advertisement policies. September 9, 2025. https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency-fact-sheet.html. Accessed July 15, 2026.

social media, the sheer volume of advertisements makes effective monitoring impossible. The FDA will simply not be able to keep up with the advent of AI-driven personalized marketing and influencer-driven DTC advertisements.

2.2 Emotional Manipulation and Selective Imagery

DTC advertisements often rely on emotionally persuasive narratives and favorable imagery. For example, DTC advertisements often show people engaged in healthy and recreational activities with friends and family or talk vaguely about patients regaining control over their lives.[55] In these ways, the advertisements appeal to patients' emotions, distract them, and distort their perceptions of a drug's benefits and risks.[56]

For example, a 2018 content analysis of prime-time DTC advertisements aired in 2004 and 2016 found that most advertisements contained positive emotional appeals (94.4% and 94.1%, respectively). Meanwhile, the percentage of factual information presented about the advertised conditions had decreased (from 82.0% in 2004 to 77.4% in 2016), including information about prevalence and risk factors.[57] And studies show that exaggerated imagery in advertisements makes a difference. For example, two experimental studies reported in a 2021 article demonstrated that participants who saw images that exaggerated drug benefits were significantly more likely to overestimate drug efficacy than those who saw accurate images or no images.[58]

Moreover, a 2021 visual content analysis of risk statements in DTC television advertisements found that the advertisements showed different visual content during the recitation of the major statement than during other portions of the advertisements.[59] Specifically, the major statement portion of the advertisements contained more motion and more complex and positive imagery. The authors concluded that their findings "strongly suggest that DTCA is intentionally structured in a way that will visually distract consumer attention during the narrated major statement."[60]

Similarly, a 2018 study that assessed DTC advertisements aired on television between 2015 and 2016 — before the FDA's 2023 regulation requiring the presentation of the major statement in a

[55] Applequist J, Ball JG. An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Ann Fam Med*. 2018 May;16(3):211-216.
[56] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[57] Applequist J, Ball JG. An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Ann Fam Med*. 2018 May;16(3):211-216.
[58] Sullivan HW, O'Donoghue AC, Lynch M, et al. Visual images of prescription drug benefits in direct-to-consumer television advertisements. *Patient Educ Couns*. 2021 Sep;104(9):2240-2249.
[59] King J, Koppenhafer L, Madrigal R. Look, puppies! A visual content analysis of required risk statements embedded in direct-to-consumer pharmaceutical advertising. *Journal of Public Policy & Marketing.* 2021 Jan;40(1):45-61.
[60] *Ibid.*

clear, conspicuous, and neutral manner[61] — found that during the presentation of safety risks all advertisements employed distracting visuals, such as dancing actors or frequent scene changes.[62] And 79% of the reviewed advertisements displayed text unrelated to product safety during the audio statement of the risk information.

Distracting visuals and emotional appeals are signature aspects of DTC advertisements. These features exaggerate the drugs' benefits and impede consumers from absorbing informative content and engaging in rational healthcare decision-making.

2.3 Overdiagnosis of Disease and Overprescription of Medications

DTC advertising has skewed prescribing in the United States. Patients exposed to drug advertisements are significantly more likely to request specific medications, leading to overdiagnosis and overprescription, including inappropriate prescribing, off-label prescribing, or both. DTC advertisements thus harm patients and increase healthcare costs.[63,64]

Prescription drug use increased from 39.0% of the population between 1988 and 1994 to 49.9% of the population between 2017 and 2020, according to a 2025 Department of Health and Human Services publication.[65] This increase is due in part to DTC advertisements. Studies have repeatedly demonstrated that patient requests can profoundly affect physicians' prescribing behavior.[66] For example, patients who requested an advertised drug were almost 17 times more likely to receive a prescription than those who did not, according to a 2003 study.[67]

In an influential 2005 study, patient actors visited family physicians or general internists seeking treatment for major depression or adjustment disorder.[68] The patient actors either (1) mentioned an advertisement and made a specific request for a brand-name drug; (2) made a request for a drug that "might help;" or (3) made no request. The patient actors who made a request (whether

[61] 21 C.F.R. § 202.1(e)(1)(ii).
[62] Klara K, Kim J, Ross JS. Direct-to-consumer broadcast advertisements for pharmaceuticals: Off-label promotion and adherence to FDA guidelines. *J Gen Intern Med*. 2018 May;33(5):651-658.
[63] Kesselheim AS, Mello MM. Prospects for regulation of off-label promotion in an era of expanding commercial speech protection. *NCL Rev.* 2014;92:1539.
[64] Patel NG, Hwang TJ, Woloshin S, et al. Therapeutic value of drugs frequently marketed using direct-to-consumer television advertising, 2015 to 2021. *JAMA Netw Open*. 2023 Jan 3;6(1):e2250991.
[65] Department of Health and Human Services. Fact sheet: Ensuring patient safety through reform of direct-to-consumer pharmaceutical advertisement policies. September 9, 2025. https://www.hhs.gov/press-room/hhs-fda-drug-ad-transparency-fact-sheet.html. Accessed July 15, 2026.
[66] DeFrank JT, Berkman ND, Kahwati L, et al. Direct-to-consumer advertising of prescription drugs and the patient-prescriber encounter: A systematic review. *Health Commun.* 2020 May;35(6):739-746.
[67] Mintzes B, Barer ML, Kravitz RL, et al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *CMAJ*. 2003;169(5):405-412.
[68] Kravitz RL, Epstein RM, Feldman MD, et al. Influence of patients' requests for direct-to-consumer advertised antidepressants: A randomized controlled trial. *JAMA*. 2005 Apr 27;293(16):1995-2002.

specific or general) were significantly more likely to receive a diagnosis and to be prescribed an antidepressant.

In a second 2005 study that showed a link between DTC advertising and inappropriate prescribing, the authors used survey and administrative data to assess whether prescribers were more likely to prescribe nonsteroidal anti-inflammatory drugs (NSAIDs) for pain and inflammation or a newer and more costly subclass called cyclooxygenase-2 inhibitors (COX-2).[69] Patients who saw a COX-2 drug advertisement and asked their doctor for a brand-name drug were substantially more likely to be prescribed the newer drug, even when a traditional NSAID would have been more appropriate. Moreover, boosted by DTC advertisements, the use of COX-2 inhibitors, specifically rofecoxib, marketed as Vioxx, which was later withdrawn from the market because of serious safety concerns, led to a massive number of avoidable deaths, as discussed below.

A controlled longitudinal study published in 2008 found that DTC advertisements influenced prescribing not only in the United States but also in Canada, where patients were exposed to such advertisements through media including television and the internet.[70] The study included three drugs. Cross-border DTC advertisements for the selective serotonin receptor agonist tegaserod, marketed as Zelnorm, for the treatment of irritable bowel syndrome in women were associated with increased use in Canada. This increase, driven by DTC advertising, was particularly problematic because tegaserod was later withdrawn from the market in the United States and Canada due to cardiovascular safety concerns.[71]

Two video-based experiments published in 2014 demonstrated that requests for oxycodone or celecoxib to treat chronic knee osteoarthritis or symptoms suggesting sciatica led to suboptimal care.[72] In the experiments, patient actors either made a request for a specific drug or something to help with pain management. Those who had made specific requests were more likely to receive the requested drug than those who did not, even though prescribing either drug could lead to more adverse event complications compared to alternative treatment options.

DTC advertising also contributes to overdiagnosis, self-diagnosis and patient misinterpretation of symptoms, which in turn may lead to unnecessary diagnostic testing.[73] Increased exposure to statin advertisements was associated with higher odds of "high cholesterol" diagnosis and a

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[69] Spence MM, Teleki SS, Cheetham TC, et al. Direct-to-consumer advertising of COX-2 inhibitors: effect on appropriateness of prescribing. *Med Care Res Rev*. 2005 Oct;62(5):544-559.
[70] Law MR, Majumdar SR, Soumerai SB. Effect of illicit direct to consumer advertising on use of etanercept, mometasone, and tegaserod in Canada: controlled longitudinal study. *BMJ.* 2008 Sep 2;337:a1055.
[71] Madia VN, Messore A, Saccoliti F, et al. Tegaserod for the treatment of irritable bowel syndrome. *Antiinflamm Antiallergy Agents Med Chem*. 2020;19(4):342-369.
[72] McKinlay JB, Trachtenberg F, Marceau LD, et al. Effects of patient medication requests on physician prescribing behavior: results of a factorial experiment. *Med Care*. 2014 Apr;52(4):294-299.
[73] Menkes DB, Mintzes B, Lexchin J. Direct-to-consumer advertising: a modifiable driver of overdiagnosis and overtreatment. *BMJ Evid Based Med*. 2024 Nov 22;29(6):423-425.

higher rate of statin use, according to a 2013 study. However, the increase in statin use was primarily among individuals with a low cardiovascular risk, for whom the potential harms of the medication outweighed the potential benefits.[74] A 2017 study that assessed the association between DTC advertisements and statin use reported similar results.[75] DTC advertisements for statins were associated with increased statin sales and more frequent medical visits for "high cholesterol," but only among those aged 18 to 45 years, an age group with lower cardiovascular risk relative to older adults.

2.4 Erosion of the Patient-Physician Relationship

Proponents of DTC advertisements often argue that these advertisements are informative and educational for consumers, which in turn encourages people to seek care for previously undiagnosed conditions, thereby facilitating communication with physicians or other prescribers and promoting beneficial prescribing.[76] The promotional features of DTC advertisements, however, undermine any informative value. Indeed, the prominence and cost of these advertisements reflect that their primary goal is to create consumer demand,[77] not to inform and educate patients.[78]

Despite FDA regulations requiring that the presentation of the major statement be done in a clear, conspicuous, and neutral manner,[79] pharmaceutical manufacturers often use music and imagery in DTC advertising to distract viewers and readers from substantive content, including the important disclosures required by FDA regulations.[80] The information conveyed in DTC advertisements is often low-value, incomplete, or misleading.[81,82]

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[74] Niederdeppe J, Byrne S, Avery RJ, Cantor J. Direct-to-consumer television advertising exposure, diagnosis with high cholesterol, and statin use. *J Gen Intern Med*. 2013 Jul;28(7):886-893.
[75] Chang HY, Murimi I, Daubresse M, et al. Effect of direct-to-consumer advertising on statin use in the United States. *Med Care*. 2017 Aug;55(8):759-764.
[76] Alpert A, Lakdawalla D, Sood N. Prescription drug advertising and drug utilization: The role of Medicare Part D. *J Public Econ*. 2023 May;221:104860.
[77] Franquiz MJ, McGuire AL. Direct-to-consumer drug advertisement and prescribing practices: Evidence review and practical guidance for clinicians. *J Gen Intern Med*. 2020 May;36(5):1390-1394.
[78] Applequist J, Ball JG. An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Ann Fam Med*. 2018 May;16(3):211-216.
[79] 21 C.F.R. § 202.1(e)(1)(ii).
[80] King J, Koppenhafer L, Madrigal R. Look, puppies! A visual content analysis of required risk statements embedded in direct-to-consumer pharmaceutical advertising. *Journal of Public Policy & Marketing.* 2021 Jan;40(1):45-61.
[81] Menkes DB, Mintzes B, Lexchin J. Direct-to-consumer advertising: a modifiable driver of overdiagnosis and overtreatment. *BMJ Evid Based Med.* 2024 Nov 22;29(6):423-425.
[82] Klara K, Kim J, Ross JS. Direct-to-consumer broadcast advertisements for pharmaceuticals: Off-label promotion and adherence to FDA guidelines. *J Gen Intern Med*. 2018 May;33(5):651-658.

Relying on information in DTC advertisements may have important consequences. Consumers, believing that they are well informed, may not seek additional, more reliable health information[83] or may visit their physician or other clinician specifically to request advertised drugs based on biased or misleading information.[84] Clinical encounters influenced by DTC advertisements may shift away from evidence-based counseling and prescribing toward consumer-driven preferences swayed by marketing. DTC advertisements prompt patients to make specific requests for brand-name drugs that their clinicians would not otherwise prescribe to them.

Although adequate data are not yet available on how digital DTC advertisements specifically influence clinical visits,[85] empirical evidence has long confirmed concerns about the effects of DTC advertisements on the relationship between patients and physicians or other prescribers. In a national survey of physicians and households published in 2004, most physicians expressed negative views about DTC advertisements, noting that the advertisements rarely provided adequate information regarding drug costs, comparative effectiveness, or adverse effects.[86] Physicians reported that DTC advertising led to increased patient requests for advertised drugs and altered patient expectations, thereby complicating or interfering with clinical decision-making. Physicians also reported that DTC advertisements diverted valuable consultation time away from diagnostic and therapeutic considerations and toward managing misconceptions generated by promotional material.

A 2020 systematic review that included 38 studies published between 1982 and 2017 identified similar concerns, with many doctors reporting pressure to prescribe drugs that patients requested.[87] According to a nationally representative web survey of 1,744 U.S. adults, also published in 2020, 76% of respondents said they were likely to ask their clinicians about advertised drugs, and 23% stated that they were likely to switch clinicians if they did not receive the requested brand name drug.[88] A 2020 evidence review found that when patients request a specific drug, physicians complied 39% to 77% of the time, even though the physicians themselves considered nearly half of those prescriptions potentially clinically inappropriate.[89]

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[83] Almasi EA, Stafford RS, Kravitz RL, et al. What are the public health effects of direct-to-consumer drug advertising? *PLoS Med*. 2006 Mar;3(3):e145.
[84] Applequist J, Ball JG. An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Ann Fam Med*. 2018 May;16(3):211-216.
[85] DeFrank JT, Berkman ND, Kahwati L, et al. Direct-to-consumer advertising of prescription drugs and the patient-prescriber encounter: A systematic review. *Health Commun*. 2020 May;35(6):739-746.
[86] Robinson AR, Hohmann KB, Rifkin JI, et al. Direct-to-consumer pharmaceutical advertising: Physician and public opinion and potential effects on the physician-patient relationship. *Arch Intern Med.* 2004;164(4):427–432.
[87] DeFrank JT, Berkman ND, Kahwati L, et al. Direct-to-consumer advertising of prescription drugs and the patient-prescriber encounter: A systematic review. *Health Commun.* 2020 May;35(6):739-746.
[88] Sullivan HW, Aikin KJ, Berktold J, et al. Direct-to-consumer prescription drug advertising and patient-provider interactions. *J Am Board Fam Med*. 2020 Mar-Apr;33(2):279-283.
[89] Franquiz MJ, McGuire AL. Direct-to-consumer drug advertisement and prescribing practices: Evidence review and practical guidance for clinicians. *J Gen Intern Med*. 2020 May;36(5):1390-1394.

In summary, although physicians have an ethical and professional duty to act in their patients' best interests, the pressure to prescribe medications patients request after seeing an advertisement is substantial, and physicians frequently comply. Physicians' ability to act on their best medical judgment is diminished when patients arrive at office visits with advertisement-induced notions about which drugs should be prescribed.[90,91]

2.5 Promotion of Low-Value Medications or Medications with Uncertain Benefits or Harms

Evidence indicates that DTC advertising disproportionately promotes drugs with limited clinical benefit or uncertain post-market safety profiles. Fewer than one-third of DTC television advertising spending for the 73 top-advertised drugs from 2015 to 2021 was on medications with high therapeutic value, according to a cohort study published in 2023. The remaining 71.3% of DTC advertising spending was for drugs with low added benefit.[92] A cross-sectional analysis of the 134 highest-selling drugs in the United States, also published in 2023, found that companies spend more on DTC advertising for drugs with lower added clinical value.[93] According to the researchers, this spending pattern may "reflect a strategy to drive patient demand for drugs that clinicians might be less likely to prescribe because either there are several similarly effective alternative treatments available or there is a more effective alternative available."[94]

U.S. consumers also often make incorrect assumptions about the drugs the FDA approves. A 2011 randomized controlled trial found that more than half of consumers had at least one misconception about FDA drug approvals.[95] For example, 39% of consumers mistakenly believed that only "extremely effective" drugs are approved by the FDA and one-quarter mistakenly believed that drugs are only approved if they are not associated with serious adverse events. Of particular concern, 17% of consumers believed that drugs with serious adverse effects cannot be featured in DTC advertisements at all.

The benefits and long-term safety risks of newly approved drugs is generally uncertain because approval is often based on relatively short trials with few carefully selected participants. For example, a cross-sectional study published in 2020 found that approval of 109 new drugs and biologics between 2015 and 2017 was based on a median of only 467 trial participants.[96] The

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[90] *Ibid.*
[91] Menkes DB, Mintzes B, Lexchin J. Direct-to-consumer advertising: a modifiable driver of overdiagnosis and overtreatment. *BMJ Evid Based Med*. 2024 Nov 22;29(6):423-425.
[92] Patel NG, Hwang TJ, Woloshin S, et al. Therapeutic value of drugs frequently marketed using direct-to-consumer television advertising, 2015 to 2021. *JAMA Netw Open*. 2023 Jan 3;6(1):e2250991.
[93] DiStefano MJ, Markell JM, Doherty CC, et al. Association between drug characteristics and manufacturer spending on direct-to-consumer advertising. *JAMA.* 2023;329(5):386–392.
[94] *Ibid.*
[95] Schwartz LM, Woloshin S. Communicating uncertainties about prescription drugs to the public: a national randomized trial. *Arch Intern Med.* 2011 Sep 12;171(16):1463-1468.
[96] Zhang AD, Puthumana J, Downing NS, et al. Assessment of clinical trials supporting US Food and Drug Administration approval of novel therapeutic agents, 1995-2017. *JAMA Netw Open*. 2020 Apr 1;3(4):e203284.

study also found that the proportion of indications approved based on data from at least two pivotal clinical trials had decreased.

Although the long-term efficacy and safety of drugs is generally not adequately established at the time of approval, many newly approved drugs are heavily advertised. Some of these drugs are later found to have no clinical benefit.[97]

More concerningly, several heavily advertised drugs have been recalled for safety reasons. As previously mentioned, one of the most egregious examples is the COX-2 inhibitor rofecoxib, marketed as Vioxx, which was approved in 1999 and was one of the most heavily advertised drugs while on the market.[98]Although the manufacturer reportedly was aware of increased cardiovascular risks associated with this pain reliever as early as 2000, it continued spending more than $100 million annually on advertisements that allegedly misrepresented the drug's harms.[99] According to the California Department of Justice, the "aggressive television advertising convinced hundreds of thousands of consumers to seek Vioxx prescriptions before the drug's risks were fully understood."[100] Indeed, a 2006 study that examined the prescribing behavior of physicians between 2000 and 2002 found that advertisements increased the number of physician visits and the number of prescriptions for Vioxx.[101] When the drug was withdrawn from the market in 2004, more than 80 million patients had been prescribed the drug, which may have been associated with thousands of acute myocardial infarctions and sudden cardiac deaths in the United States that might have otherwise not occurred.[102]

3. Evidence of Harm to the Economy and the Healthcare System

DTC advertising for prescription drugs imposes substantial economic burdens on the U.S. healthcare system by driving higher drug spending, inflating drug prices, and shifting state and federal healthcare expenditures toward drugs that are frequently advertised to consumers.

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[97] Schwartz LM, Woloshin S. Communicating uncertainties about prescription drugs to the public: a national randomized trial. *Arch Intern Med.* 2011 Sep 12;171(16):1463-1468.
[98] Topol EJ. Failing the public health-rofecoxib, Merck, and the FDA. *N Engl J Med*. 2004 Oct 21;351(17):1707-1909.
[99] Horton R. Vioxx, the implosion of Merck, and aftershocks at the FDA. *Lancet*. 2004 Dec 4-10;364(9450):1995-1996.
[100] State of California Department of Justice. $58 million Merck settlement to change deceptive TV drug advertisement. May 20, 2008. https://oag.ca.gov/news/press-releases/58-million-merck-settlement-change-deceptive-tv-drug-advertisements. Accessed July 15, 2026.
[101] Bradford WD, Kleit AN, Nietert PJ, et al. How direct-to-consumer television advertising for osteoarthritis drugs affects physicians' prescribing behavior. *Health Aff* (Millwood). 2006 Sep-Oct;25(5):1371-1377.
[102] Graham DJ. Testimony of David J. Graham, MD, MPH, Nov. 18, 2004. *Senate Committee on Finance*, *108th Cong.* (2004 November 18), https://www.finance.senate.gov/imo/media/doc/111804dgtest.pdf. Accessed July 15, 2026.

In a 2024 report, the Congressional Budget Office stated that a 10% change in DTC advertising expenditures was associated with a 1% to 2.3% change in prescription drug spending.[103] In 1993, spending on DTC advertising was only about $150 million.[104] Since then, spending has dramatically increased. After the FDA relaxed its DTC advertising regulations, annual spending grew from approximately $1.3 billion in 1998 to $8 billion in 2024.[105,106]

In 2021, the Government Accountability Office found that the drugs with the highest Medicare spending were also those with the highest DTC advertising expenditures.[107] For instance, of the $560 billion in Medicare Parts B and D spending between 2016 to 2018, 58% was spent on drugs advertised directly to consumers.

The financial implications extend beyond marketing budgets. Under the Internal Revenue Code, pharmaceutical companies may deduct advertising expenditures as ordinary business expenses. This means that the tax code therefore subsidizes DTC advertising. In this way, the public indirectly finances campaigns that encourage inappropriate prescribing.

Elevated DTC advertising spending is associated with pricing practices that compound the economic burden on the healthcare system. For example, CSRxP (the Campaign for Sustainable Rx Pricing, a bipartisan coalition of healthcare professionals[108]) has highlighted that, for blockbuster drugs such as apixaban, marketed as Eliquis, aggressive DTC advertising was combined with regular price hikes.[109] The price increases resulted in monthly costs more than doubling over a decade, which ultimately led to therapies being unaffordable for many patients and higher claims costs for insurers.

Taken together, the evidence demonstrates that DTC advertising is not merely a marketing expense. Rather, DTC advertising drives systemic inefficiency, inflated drug prices, increased taxpayer costs, and misaligned therapeutic priorities.

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[103] Congressional Budget Office. Alternative approaches to reducing prescription drug prices. October 2024. https://www.cbo.gov/publication/60812. Accessed July 15, 2026.
[104] Alpert A, Lakdawalla D, Sood N. Prescription drug advertising and drug utilization: The role of Medicare Part D. *J Public Econ*. 2023 May;221:104860.
[105] Scott D. The untold story of TV's first prescription drug ad. *Stat News.* December 11, 2015. https://www.statnews.com/2015/12/11/untold-story-tvs-first-prescription-drug-ad/. Accessed July 15, 2026.
[106] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[107] Government Accountability Office. Prescription drugs: Medicare spending on drugs with direct-to-consumer advertising. May 18, 2021. https://www.gao.gov/products/gao-21-380. Accessed July 15, 2026.
[108] The Campaign for Sustainable RX Pricing. About. https://www.csrxp.org/about/. Accessed July 15, 2026.
[109] The Campaign for Sustainable RX Pricing. Dose of reality: Big Pharma's two decades of price hikes and advertising binging on ten drugs eligible for Medicare negotiation. September 20, 2023. https://www.csrxp.org/dose-of-reality-big-pharmas-two-decades-of-price-hikes-and-advertising-binging-on-ten-drugs-eligible-for-medicare-negotiation/. Accessed July 15, 2026.

4. Arguments Supporting DTC Advertisements Lack Merit

4.1. Banning DTC advertising complies with the First Amendment

Proponents of DTC advertising have argued that a ban would violate the First Amendment, which states, in part: "Congress shall make no law… abridging the freedom of speech." DTC advertising, however, is commercial speech, which receives only limited First Amendment protection. And because DTC advertising is often misleading, and because banning it would advance a substantial government interest, a ban would comply with the First Amendment.

First, the First Amendment does not protect commercial speech that is false or misleading.[110] As discussed above, DTC advertisements are often misleading because they omit or distort critical safety information or exaggerate therapeutic benefits.[111,112] Importantly, even when DTC advertisements are technically compliant with FDA regulations, they distort patients' perceptions and understanding of drug risks and benefits.[113,114] That is, DTC advertising is inherently false and misleading, and poses problems that cannot be cured by stronger regulation and enforcement:

- Manipulative and emotional appeals that downplay risks are inherent in DTC advertising.
- Quantitative data on risks and benefits are commonly missing, and, even more importantly, the public is not equipped to assess quantitative risks and benefits. In the United States direct sales of prescription drugs to consumers are illegal.
- The FDA cannot possibly monitor and enforce compliance given the abundance of social media posts and other DTC advertisements, especially AI-generated individualized marketing messages.

Second, even if the advertisements were not inherently misleading, a ban is constitutionally permissible because it would directly advance substantial government interests, facilitating the ability of patients to make informed, evidence-based medical decisions, preserving the integrity of the patient-prescriber relationship, and curbing unnecessary healthcare expenditures. Because DTC advertisements undermine these government interests, as described above, prohibiting DTC advertising would, instead, help advance them.

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[110] Central Hudson Gas & Elec. v. Public Svc. Comm'n, 447 U.S. 557 (1980).
[111] Pomeranz JL, Hanson E, Mozaffarian D. Regulating direct-to-consumer prescription drug advertising in the United States. *Milbank Q*. 2026 Mar;104(1):13-47.
[112] Maker of "female Viagra" deceives women with misleading radio ad. *Worst Pills, Best, Pills.* December 2020. https://www.worstpills.org/newsletters/view/1369. Accessed July 15, 2026.
[113] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[114] Sullivan HW, O'Donoghue AC, Lynch M, et al. Visual images of prescription drug benefits in direct-to-consumer television advertisements. *Patient Educ Couns*. 2021 Sep;104(9):2240-2249.

Finally, consumers have an interest in access to information about drug benefits and risks. In contrast to the situation in 1997, when the FDA loosened DTC advertising requirements, reliable information about prescription medications is readily available to consumers through other means. A ban on DTC advertising would therefore not affect patients' access to trustworthy and balanced information, including FDA-approved prescribing information and medication guides available online, as well as information from physicians and pharmacists.

4.2. Existing DTC advertising regulations are inadequate to achieve government and public interests

Banning DTC advertising would not be more extensive than is necessary to serve the important government and public interests at stake. Experience with DTC advertisements shows that measures short of a ban will not achieve these important interests. Regulations intended to prevent the harms associated with DTC advertisements have proven inadequate, as study after study has shown. After-the-fact enforcement, whereby companies are told to remove misleading or noncompliant advertising only after patients have been exposed to the advertisements, has not served the government and public interests.[115]

The growth of DTC advertising makes the current approach increasingly inadequate for regulating television advertisements, digital advertisements, and social-media-based drug promotion.[116,117,118] The sheer volume of content, as well as the ease with which social media posts can be generated and shared, makes effective FDA oversight impossible.

Problematic advertisements frequently remain in circulation for months or years before they are reviewed, during which time they may reach millions of consumers and substantially influence prescribing behavior.[119] Once an advertisement reaches a consumer, retrospective enforcement cannot undo that exposure.

FDA enforcement action typically requires only withdrawal or modification of the offending advertisement, without the imposition of monetary penalties or other sanctions that would be better deterrents. Enforcement limitations are compounded by ongoing budgetary and staffing constraints at the FDA, which significantly restrict the agency's capacity to conduct sustained,

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[115] Pomeranz JL, Hanson E, Mozaffarian D. Regulating direct-to-consumer prescription drug advertising in the United States. *Milbank Q*. 2026 Mar;104(1):13-47.
[116] Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. *JAMA*. 2019 Jan 1;321(1):80-96.
[117] Willis E, Delbaere M. Patient influencers: The next frontier in direct-to-consumer pharmaceutical marketing. *J Med Internet Res*. 2022 Mar 1;24(3):e29422.
[118] Mor J, Kaur T, Menkes DB, et al. Pharmaceutical industry promotional activities on social media: a scoping review. *Journal of Pharmaceutical Health Services Research*. 2024 Nov;15(4):rmae022.
[119] Kesselheim AS, Jetelina KK. 9 answers to burning questions about pharmaceutical ads. *Stat News.* September 13, 2025. https://www.statnews.com/2025/09/13/pharmaceutical-ads-rfk-jr-fda-enforcement-questions-answered/. Accessed July 15, 2026.

proactive oversight, particularly in an era dominated by increasing digital, social media, and algorithmically targeted advertising. In short, the current regulatory framework for DTC advertising has structural limitations. Reliance on post-market enforcement is insufficient to ensure that DTC advertisements are fair, accurate, and protect public health.

4.3. Physicians or other prescribers as learned intermediaries are insufficient to protect patients

Prescription drugs are different from other advertised products because they require a physician or other prescriber to prescribe a medication before a consumer can purchase the drug. As learned intermediaries, physicians and other prescribers are trained to evaluate a drug's risks, benefits, and appropriateness for individual patients. Before deciding whether to prescribe a medication, physicians should discuss their recommendations with the patient and exercise their professional expertise, considering patient history, diagnosis, and other relevant factors.

Advocates of DTC advertising argue that DTC advertising is not harmful because the product is only available to a patient if a physician or other prescriber provides a prescription. This argument ignores the fact that DTC advertisements alter the patient-physician relationship by encouraging patients to pressure physicians to prescribe drugs that may not be clinically indicated, do not have well-established safety profiles, or otherwise do not represent the optimal course of care. As the studies discussed above show, physicians may recognize that a drug a patient has requested is not optimal but nonetheless prescribe it, due to concerns about patient satisfaction, retention, or potential conflict.[120] The advertisements thus undermine the clinician's role by pitting the physician's expert opinion against advertising-driven consumer preferences.

At the same time, pharmaceutical manufacturers generally need not worry about liability to patients for harm caused by the drug because manufacturers may be shielded from liability by the "learned intermediary doctrine."[121] The doctrine, under which the physician as intermediary, rather than the drug manufacturer, bears the primary responsibility to the patient, assumes a traditional medical setting where patients receive information about treatment options mainly from their physicians. However, given the ubiquity of broadcast and increasingly internet-based DTC advertising, the learned intermediary doctrine "now provides perverse incentives to companies to aggressively market their drugs without consequence."[122]

A prohibition on DTC advertising is thus necessary to restore the integrity of the relationship between the patient and physician or other prescriber, reinforce the role physicians or other

[120] Franquiz MJ, McGuire AL. Direct-to-consumer drug advertisement and prescribing practices: Evidence review and practical guidance for clinicians. *J Gen Intern Med*. 2020 May;36(5):1390-1394.
[121] Thornton RG. The learned intermediary doctrine and its effects on prescribing physicians. *BUMC Proceedings.* 2003 Jul;16(3):359-361.
[122] Pomeranz JL, Hanson E, Mozaffarian D. Regulating direct-to-consumer prescription drug advertising in the United States. *Milbank Q*. 2026 Mar;104(1):13-47.

prescribers as intermediaries, and safeguard the public from the commercial pressures that distort medical decision-making.

4.4. The harms of DTC advertisements outweigh the benefits

Proponents of DTC advertising sometimes argue that such advertisements can have beneficial effects on prescribing.[123,124] DTC advertising, however, typically promotes brand-name drugs before generic alternatives enter the market, as discussed above. In general, DTC advertising is for expensive drugs and may include medications without well-established benefit-risk profiles, significant safety concerns, or low clinical value.[125,126,127] DTC advertising also diverts attention from alternatives to medications, such as healthy lifestyle changes.[128] Moreover, increased prescribing associated with DTC advertising has been documented among groups of people at low risk for the diseases for which the medications are being prescribed.[129]

Proponents of DTC advertisements have also suggested that the advertisements are associated with increased medication adherence. Although some studies suggest that DTC advertising can have beneficial effects on medication adherence, other studies suggest that it has detrimental effects.[130]

Claims that DTC advertising increases clinical visits, potentially resulting in the detection of undiagnosed or unrelated health conditions, also do not withstand scrutiny. A DTC advertisement is seldom the only reason why a patient schedules a medical visit.[131] As discussed above, such visits are typically driven by demand for the prescription drug that is being advertised, increasing the risks of overdiagnosis and overprescribing and interfering with the relationship between the patient and the physician or other prescriber.[132]

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[123] Alpert A, Sood N. Assessing the case against direct-to-consumer drug advertisements. *JAMA Health Forum*. 2025 Nov 7;6(11):e255325.
[124] Alpert A, Lakdawalla D, Sood N. Prescription drug advertising and drug utilization: The role of Medicare Part D. *J Public Econ*. 2023 May;221:104860.
[125] Patel NG, Hwang TJ, Woloshin S, et al. Therapeutic value of drugs frequently marketed using direct-to-consumer television advertising, 2015 to 2021. *JAMA Netw Open*. 2023 Jan 3;6(1):e2250991.
[126] Parekh N, Shrank WH. Dangers and opportunities of direct-to-consumer advertising. *J Gen Intern Med*. 2018 May;33(5):586-587.
[127] Zhang AD, Puthumana J, Downing NS, et al. Assessment of clinical trials supporting US Food and Drug Administration approval of novel therapeutic agents, 1995-2017. *JAMA Netw Open*. 2020 Apr 1;3(4):e203284.
[128] Applequist J, Ball JG. An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Ann Fam Med*. 2018 May;16(3):211-216.
[129] Chang HY, Murimi I, Daubresse M, et al. Effect of direct-to-consumer advertising on statin use in the United States. *Med Care*. 2017 Aug;55(8):759-764.
[130] DeFrank JT, Berkman ND, Kahwati L, et al. Direct-to-consumer advertising of prescription drugs and the patient-prescriber encounter: A systematic review. *Health Commun*. 2020 May;35(6):739-746.
[131] *Ibid.*
[132] Parekh N, Shrank WH. Dangers and opportunities of direct-to-consumer advertising. *J Gen Intern Med*. 2018 May;33(5):586-587.

Finally, DTC advertising cannot be justified based on its informational value to patients. DTC advertisements often have low informational value and may include biased or misleading claims, as also discussed above.[133,134] More reliable and balanced sources of information are readily available.

5. Conclusion

Substantial and credible evidence demonstrates that DTC advertising of prescription drugs significantly harms patients, undermines the patient-prescriber relationship, inflates healthcare costs, and erodes the integrity of the U.S. healthcare system. These harms outweigh any purported benefits of DTC advertising and cannot be sufficiently mitigated through existing or updated federal regulations or enhanced FDA enforcement.

We respectfully request that the FDA exercise its authority under § 502(n) of the FDCA and related provisions to ban DTC advertising of human prescription drugs. Banning DTC advertisements would align U.S. policy with international best practices, protect the public from misleading and harmful drug promotion, and promote rational, evidence-based prescribing.

C. ENVIRONMENTAL IMPACT

We claim a categorical exclusion from the requirement to submit an environmental assessment or environmental impact statement under 21 C.F.R. § 25.30.

D. ECONOMIC IMPACT

This information will be submitted only when requested by the Commissioner.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies and includes representative data and information known to the petitioner that are unfavorable to the petition.

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[133] Kravitz RL. Health care ramifications of pervasive direct-to-consumer prescription drug advertising. *Annu Rev Public Health.* 2026 Apr;47(1):479-497.
[134] Applequist J, Ball JG. An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Ann Fam Med*. 2018 May;16(3):211-216.

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