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| RESEARCH ARTICLE

Direct-to-Consumer Prescription Drug Advertising in the United States: A Narrative Review of Clinical, Public-Health, Ethical, and Economic Implications

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| ABSTRACT
Background**.** Direct-to-consumer advertising (DTCA) of prescription drugs is permitted in only two high-income countries — the United States and New Zealand — and represents a multi-billion-dollar component of the U.S. health-care environment. Recent policy debates and proposals have focused on whether and how to tighten regulatory oversight of DTCA, particularly as digital and social-media promotion have grown. Approach. This narrative review and policy analysis synthesizes peer-reviewed empirical research, government reports, and primary regulatory documents addressing DTCA's effects on patient and clinician behavior, public health, ethics, and the health-care economy. Key Findings. Across multiple study designs, DTCA increases information seeking, patient requests, and prescribing of advertised products, with measurable effects on diagnosis rates and class-level utilization. Patients who specifically request a DTCA-promoted drug receive a prescription substantially more often than those who do not. Higher promotional spending tends to be directed toward branded products with comparatively low added clinical benefit. Modeling analyses suggest that meaningful changes in DTCA spending translate into measurable, though modest, changes in national prescription drug spending. Conclusions. DTCA is a clinical, ethical, public-health, and economic phenomenon, not merely a marketing practice. Clinicians can mitigate harms through structured response to ad-driven requests and shared decision-making. Health systems can integrate DTCA awareness into clinician education and decision support. Policymakers continue to weigh a range of options, including stricter risk-presentation standards, broader oversight of digital promotion, and fiscal levers such as limits on tax deductibility for DTCA expenditures.

| KEYWORDS
Direct-to-consumer advertising; prescription drugs; pharmaceutical marketing; health policy; FDA; medical ethics; public health; health-care utilization.

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1. Introduction

Direct-to-consumer advertising (DTCA) of prescription drugs occupies an unusual position in modern medicine. The United States and New Zealand are the only countries that allow full, branded product-claim DTCA, whereas most other high-income countries either prohibit prescription drug advertising to the public entirely or allow only restricted forms such as reminder ads or disease-awareness campaigns (Mintzes, 2012). DTCA in its modern broadcast form expanded rapidly in the United States after the U.S. Food and Drug Administration (FDA) issued draft guidance in 1997 that effectively allowed broadcast advertisements to satisfy risk-disclosure requirements through a brief "major statement" of risks combined with so-called "adequate provision" of full risk information through other channels. Industry spending on DTCA grew several-fold over the following two decades to roughly $9.6 billion by 2016 (Schwartz & Woloshin, 2019), and DTCA has remained a multi-billion-dollar enterprise since.

Unlike most clinical interventions, DTCA acts before the clinical encounter. It shapes whether a patient seeks care, what they expect, and which products they associate with their symptoms. For practicing clinicians, DTCA is therefore a daily reality:

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patients arrive with brand-name requests, and the encounter is already partly scripted. For public-health professionals and ethicists, DTCA raises foundational questions about information quality, autonomy, and the alignment between marketing intensity and clinical value. For health-system leaders and payers, it contributes meaningfully to drug spending and administrative workload.

Regulatory and policy debates over DTCA have intensified in recent years. The FDA finalized a long-pending rule on the "clear, conspicuous, and neutral" presentation of broadcast risk information in 2023 (U.S. Food and Drug Administration, 2023a, 2023b). Recent federal discussions have also highlighted persistent concerns about misleading promotion and the difficulty of applying rules designed for traditional broadcast media to digital and social-media channels. Calls to ban DTCA outright, or to limit the tax deductibility of DTCA spending, continue to appear in legislative and policy discussion. This article reviews what is known about DTCA's clinical, public-health, ethical, and economic effects, and situates that evidence within the broader policy debate.

2. Background: Regulation and Spending

Modern U.S. DTCA dates from the late 1990s, when FDA draft guidance allowed broadcast advertisements to satisfy disclosure requirements through a brief major statement of major risks together with "adequate provision" of full risk information through other channels such as websites and toll-free numbers. Television became the dominant DTCA channel, and industry spending grew several-fold within two decades (Schwartz & Woloshin, 2019).

Spending is large and concentrated. The U.S. Government Accountability Office (GAO) reported that approximately $17.8 billion was spent on DTCA across 553 drugs from 2016 through 2018, with about two-thirds of that spending devoted to roughly 39 brand-name drugs (U.S. Government Accountability Office, 2021). Over the same three-year period, Medicare and beneficiaries spent $560 billion on prescription drugs, of which about $324 billion was on drugs with DTCA (U.S. Government Accountability Office, 2021).

The principal contemporary regulatory anchor is the FDA's 2023 final rule, which established five standards under which the major statement in broadcast advertisements is considered to be presented in a clear, conspicuous, and neutral manner: consumer-friendly language; audio at least as understandable as the rest of the advertisement; no audio or visual elements that interfere with risk comprehension; concurrent dual-modality presentation of audio and on-screen text on television; and readable text formatting (U.S. Food and Drug Administration, 2023a, 2023b). Industry compliance was required by late 2024.

Digital and social-media promotion remains the most challenging frontier. Short-form video, scrolling feeds, influencer-style content, and algorithmically targeted advertising create persistent fair-balance problems, and the "adequate provision" model designed for broadcast television maps poorly onto these formats. Recent regulatory discussion has emphasized the need for format-specific oversight in this space.

3. Effects on Patient Behavior and Prescribing

The empirical literature consistently shows that DTCA changes patient behavior and prescribing, with effects that extend beyond the advertised brand.

Information seeking and patient requests. A 2020 systematic review of 38 studies of DTCA in the patient–prescriber encounter found that exposure to DTCA was associated with greater information seeking, more patient questions, and more patient-initiated requests for advertised products (DeFrank et al., 2020). The review noted that such requests can be appropriate when underuse exists, but can also lead to prescriptions for medications patients did not need.

Translation of requests into prescriptions. When patients ask for an advertised drug by name, prescribing rates rise substantially. A widely cited cross-sectional study found that physicians were considerably more likely to write a prescription when patients specifically requested an advertised medication, often despite ambivalence about clinical appropriateness (Mintzes et al., 2002). Subsequent reviews of point-of-service studies have reported that DTCA-driven requests are accommodated in a majority of encounters and increase prescribing volume, with appropriateness judged variable (Becker & Midoun, 2016).

Effects on diagnosis and class-level use. DTCA can shift diagnosis rates and class-level utilization, not only brand share. Niederdeppe and colleagues (2013) found that exposure to televised statin advertising was associated with a higher likelihood of being diagnosed with high cholesterol and of statin use, including among lower-risk patients. A JAMA analysis by Layton and colleagues (2017) linked DTCA for testosterone products to higher rates of testosterone testing and treatment initiation in U.S.

men, consistent with class-level demand effects from heavy promotion. A study of asthma medication advertising similarly identified an association with increased prescription sales and asthma-related health-care use (Daubresse et al., 2015).

Misalignment with clinical value. A 2023 cross-sectional analysis published in JAMA examined manufacturer promotional spending for top-selling U.S. branded drugs and found that products with lower added therapeutic benefit ratings received a disproportionately higher share of promotional spending devoted to DTCA (DiStefano et al., 2023). In other words, the products most heavily marketed to consumers are not, on average, those judged to deliver the greatest incremental clinical value — an inversion that has both clinical and ethical significance.

System-level spending effects. Modeling analyses of national prescription drug spending suggest that meaningful changes in DTCA spending translate into measurable, though modest, changes in overall drug expenditures (Congressional Budget Office, 2024). Although DTCA is one of many drivers of drug spending, the effect is meaningful at the scale of national pharmaceutical expenditures.

4. Clinical, Public-Health, and Ethical Implications

4.1 Clinical encounters

DTCA shapes the daily texture of clinical practice. Patients arrive with brand-name requests that may or may not match their condition. Handled well, such conversations open productive dialogue and can support shared decision-making. Handled poorly, the same encounter can collapse into a transactional exchange in which the clinician either prescribes a low-value product to satisfy the patient or dismisses the request without addressing the underlying concern. Both outcomes erode the therapeutic relationship and have been documented in physician surveys (Becker & Midoun, 2016; DeFrank et al., 2020).

4.2 Public-health implications

At the population level, DTCA is double-edged. Proponents argue that it raises awareness of underdiagnosed and undertreated conditions and supports treatment-seeking; critics argue that it medicalizes ordinary experience, promotes high-cost branded therapies over equivalent generics, and accelerates uptake of products whose long-term risk profiles are not yet fully understood (DeFrank et al., 2020; Layton et al., 2017; Niederdeppe et al., 2013). The net public-health effect is product- and population-specific and not uniformly positive or negative.

4.3 Equity considerations

DTCA exposure is not evenly distributed. Television viewing patterns, language, digital access, and platform algorithms all shape who sees which advertisements. Patients with greater health literacy may be better equipped to contextualize advertising claims, while patients with less access to longitudinal primary care may be more reliant on advertising-mediated information. These asymmetries can widen rather than narrow disparities in care, particularly when heavy promotion is concentrated on high-cost branded products with limited incremental benefit (DiStefano et al., 2023).

4.4 Ethical implications

DTCA intersects with all four classical principles of biomedical ethics.

- **Autonomy.** DTCA can support autonomy by giving patients vocabulary with which to participate in decisions about their care. It can also distort autonomy when persuasive content selectively emphasizes benefits, when production values create implicit endorsements, or when patients confuse advertising with clinical guidance. Autonomy-supporting information is full, balanced, and tailored; advertising is by design selective and persuasive.
- **Beneficence.** DTCA arguably advances beneficence when it prompts evaluation that uncovers untreated disease. It works against beneficence when it accelerates exposure to therapies with marginal added benefit or to products whose risk profile is not yet fully characterized.
- **Non-maleficence.** Risks include adverse drug effects from medications a patient might not otherwise have taken, diagnostic cascades triggered by ad-driven evaluations, and downstream costs that can compromise other dimensions of care.
- **Justice.** When promotional spending concentrates on lower-value brands, the broader population — including patients who never request the advertised drug — bears the resulting cost through premiums, taxes, and constrained system resources (Congressional Budget Office, 2024; DiStefano et al., 2023; U.S. Government Accountability Office, 2021).

Two brief scenarios illustrate the ethical texture of DTCA-driven care.

Scenario 1. A 58-year-old man with mild, well-controlled type 2 diabetes asks his primary-care clinician for a recently advertised glucose-lowering agent he has seen during sports broadcasts and is drawn to its cardiovascular-benefit messaging. The clinician must decide whether to honor the request, redirect to an evidence-based first-line option, or use the conversation to revisit the

patient's overall cardiovascular risk. The ethical task is not simply to refuse or to comply, but to translate an advertising-shaped request into a clinically grounded, autonomy-respecting plan.

Scenario 2. A parent brings a school-aged child to clinic asking about a medication advertised on a parenting-focused social-media feed for a behavioral concern that does not meet diagnostic criteria. The clinician must navigate parental anxiety, the child's interests, the limits of evidence in pediatric off-label use, and the family's autonomy — all while contending with an advertisement that has framed the encounter before it began.

These scenarios are routine, not exceptional. They demonstrate that DTCA is not a distant policy issue but a recurring feature of clinical ethics in everyday practice.

5. Economic and Health-System Implications

Effects on drug spending. Beyond the GAO finding that more than half of Medicare drug spending in 2016–2018 was on advertised drugs (U.S. Government Accountability Office, 2021), modeling analyses link incremental DTCA spending to incremental national drug spending (Congressional Budget Office, 2024). Because DTCA is concentrated on a small set of high-cost branded products (DiStefano et al., 2023; U.S. Government Accountability Office, 2021), even modest elasticities translate into meaningful absolute dollar effects.

Effects beyond pharmacy spending. DTCA also generates effects in the medical (non-pharmacy) part of total cost of care. Patients who see an advertisement and seek evaluation may receive diagnostic testing, specialty referral, and follow-up visits even when the advertised brand is not ultimately prescribed. Class-level effects documented for statins, testosterone, and asthma therapies illustrate how broad the spillover can be (Daubresse et al., 2015; Layton et al., 2017; Niederdeppe et al., 2013).

Administrative burden. DTCA-driven demand can generate prior-authorization submissions, appeals, patient calls, and clinician documentation work. These activities consume clinician time, slow access for other patients, and add operational cost without direct clinical benefit.

Tax-policy considerations. Pharmaceutical advertising spending is currently deductible as an ordinary business expense in the United States. Proposals to deny that deduction have been discussed in Congressional Research Service briefings and in policy analyses, and represent a fiscal lever that does not require restricting speech (Guenther, 2022). The magnitude of any prescribing or spending effect from such a change would likely be class- and product-specific.

6. Limitations

This article is a narrative review and policy analysis, not a systematic review conducted under PRISMA standards. It draws on published English-language literature, primary regulatory documents, and government reports, and inevitably reflects choices about which evidence to emphasize. Reported DTCA spending figures vary by source, channel definition, and year, and are not always directly comparable. Causal inference is limited by the nature of available data; randomized exposure to advertising at the population level is not feasible, and quasi-experimental designs depend on identifying assumptions. Several of the most influential studies are based on data that pre-date the rapid growth of digital and social-media promotion, so contemporary effects may differ in magnitude or distribution. The U.S. regulatory and political environment around DTCA is evolving, and specific policy details may change after publication.

7. Conclusion

Direct-to-consumer advertising of prescription drugs is not a peripheral marketing phenomenon. It is a clinical force that shapes patient expectations and prescribing, a public-health force that influences awareness and medicalization, an ethical force that intersects with every classical principle of biomedical ethics, and an economic force that contributes meaningfully to U.S. drug spending.

The most heavily promoted drugs are, on average, not those judged to deliver the greatest incremental clinical value (DiStefano et al., 2023). This misalignment is the central tension of contemporary DTCA and the reason it warrants sustained attention from clinicians, ethicists, public-health professionals, and policymakers — not only from regulators and payers.

Practical responses are available at every level of the system. Clinicians can convert ad-driven requests into structured, autonomy-respecting conversations. Health systems can integrate DTCA-aware education and decision support into routine care. Policymakers continue to weigh complementary directions, including stricter risk-presentation standards, broader oversight of

digital promotion, and fiscal levers such as limits on the tax deductibility of DTCA spending. The aim is not to silence DTCA but to align it more closely with patient welfare, clinical evidence, and equitable access to high-value care.

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