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Omolayo T. Umaru *

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Re-Thinking 'Product Claim' DTCA in the United States: Implications for Regulation and Public Health

Omolayo T. Umaru

Department of Pharmaceutical Care & Health Systems, College of Pharmacy, University of Minnesota, Minneapolis, USA; umaru002@umn.edu

Abstract

The United States is one of only two countries worldwide that permits direct-to-consumer advertising (DTCA) of prescription drugs, yet policy debates treat this practice as a monolithic construct. Insufficient distinction has been made among DTCA's three regulatory categories: help-seeking, reminder, and "Product Claim" advertisements. This paper argues that "Product Claim" advertisements - which explicitly name drugs, identify conditions, and make therapeutic claims - require distinct regulatory evaluation due to their unique combination of brand promotion and clinical messaging. Unlike help-seeking advertisements that primarily raise disease awareness, "Product Claim" ads may disproportionately influence prescribing patterns, healthcare spending, and medication adherence through mechanisms including brand-driven demand, displacement of generic alternatives, and prescribing pressure during clinical encounters. These advertisements reach millions of consumers before regulatory enforcement can address misleading claims, creating a structural gap between promotional impact and oversight capacity. Current regulatory safeguards, including "fair balance" requirements and post-market enforcement, may be insufficient to address population-level effects specific to this category. The rise of digital platforms and targeted advertising further amplifies reach and personalization, intensifying concerns about appropriate boundaries for pharmaceutical promotion**.** A category-specific analytical framework would enable more targeted policy evaluation and strengthen alignment between pharmaceutical promotion and evidence-based prescribing. Empirical research examining prescribing trends, cost impacts, and therapeutic substitution following "Product Claim" ad exposure could inform more effective regulatory approaches.

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1. Introduction

Direct-to-consumer advertising of prescription drugs is prohibited in nearly every developed nation - except the United States and New Zealand (AlShammari et al., 2020). Yet debate surrounding this exceptional practice suffers from a critical blind spot: it treats DTCA as monolithic when important distinctions exist among its three regulatory categories. Help-seeking advertisements, reminder advertisements, and "Product Claim" advertisements differ fundamentally in structure and impact (FDA, 2015). Many cited benefits of DTCA - such as disease awareness and stigma reduction - derive primarily from help-seeking advertisements (Eisenberg et al., 2022; Cortina, 2020), while the most substantial criticisms - including brand-driven demand, displacement of generics, prescribing pressure, and medication discontinuation - appear concentrated within the "Product Claim" category (Shmerling, 2022;

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Polen et al., 2009). Failing to distinguish among these categories risks misaligned policy evaluation and regulatory oversight.

"Product Claim" advertisements explicitly name a drug, identify the condition it treats, and present both benefits and risks (FDA, 2015). Unlike help-seeking advertisements, which focus primarily on symptom recognition, or reminder advertisements, which reinforce brand awareness without clinical claims, "Product Claim" advertisements combine persuasive branding with clinical assertions regarding efficacy and safety. This combination creates distinct behavioral and market dynamics that warrant isolated examination. The present analysis focuses on the regulatory framework and population-level implications specific to "Product Claim" DTCA within the United States, arguing that this category's unique characteristics justify targeted policy scrutiny separate from broader debates about pharmaceutical advertising.

In the United States, the Federal Trade Commission regulates advertising of over-the-counter drugs, whereas the U.S. Food and Drug Administration (FDA) oversees prescription drug advertising (FDA, 2015). This regulatory architecture was significantly shaped by the Kefauver-Harris Drug Amendments of 1962, which strengthened consumer protection and transferred oversight from the FTC to the FDA in recognition that therapeutic claims require scientific substantiation and specialized regulatory scrutiny. However, as discussed below, structural limitations in FDA enforcement may be particularly consequential for "Product Claim" advertisements, which reach mass audiences before corrective action can occur.

2. Regulatory Context and Public Health Impact

"Product Claim" advertisements explicitly name a drug, identify the condition it treats, and present both benefits and risks (FDA, 2015). Unlike help-seeking advertisements, which focus primarily on symptom recognition, or reminder advertisements, which reinforce brand awareness without clinical claims, "Product Claim" advertisements combine persuasive branding with clinical assertions regarding efficacy and safety. The FDA requires that these advertisements present a "fair balance" between benefit and risk information and prohibits false or misleading claims (FDA, 2015). In print media, a brief summary of risk information must be included, and broadcast advertisements must provide access to more detailed prescribing information.

The regulatory authority governing prescription drug promotion was significantly shaped by the Kefauver-Harris Drug Amendments of 1962, which strengthened consumer protection and transferred oversight of prescription drug advertising from the FTC to the FDA (Kravitz, 2000). These amendments reflected growing concern that therapeutic claims required scientific substantiation and regulatory scrutiny.

Despite these safeguards, federal law prohibits the FDA from requiring mandatory pre-approval of advertisements prior to dissemination (FDA, 2015). As a result, oversight is largely reactive. Enforcement relies on post hoc mechanisms such as untitled letters, notices of violation, injunctions, consent decrees, seizures, and referrals for criminal investigation (FDA, 2015; FDA, 2019). By the time corrective action occurs, advertisements may already have reached millions of viewers. This structure raises questions about whether reactive enforcement adequately addresses the speed, repetition, and scale of modern "Product Claim" campaigns, particularly in digital media environments.

3. Why 'Product Claim' Ads Differ

Proponents argue that DTCA promotes patient empowerment and facilitates communication between patients and healthcare providers (PhRMA, 2018; Cortina, 2020). Evidence suggests that DTCA exposure may increase care-seeking behaviors and awareness of treatment options, particularly among individuals

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who might otherwise delay consultation (Eisenberg et al., 2022). Help-seeking advertisements, in particular, have been associated with destigmatization of mental illness and greater recognition of underdiagnosed conditions (Cortina, 2020). Public campaigns that avoid naming specific drugs, such as those highlighting pseudobulbar affect, illustrate how awareness can be raised without direct brand promotion (Appleby, 2017). Reminder advertisements similarly reinforce familiarity with established medications without introducing new clinical claims (Riserbato, 2021).

However, "Product Claim" advertisements differ in both structure and behavioral impact. By directly linking a specific branded drug to symptom relief or quality-of-life improvement, they may shape patient expectations before clinical consultation. Critics argue that this framing can narrow perceived therapeutic options and encourage preference for newer, higher-cost medications even when lower-cost generics or non-pharmacologic interventions are appropriate (Shmerling, 2022; Behrman, 2005). If educational intent were primary, pharmaceutical manufacturers could instead support class-level informational campaigns rather than brand-specific promotion (Abel et al., 2006). The persuasive format of "Product Claim" advertising may therefore shift patient focus from condition management to product acquisition, subtly influencing decision-making dynamics during clinical encounters (Eisenberg et al., 2022).

4. Economic Impact and Market Forces

DTCA has been implicated in rising drug expenditures, particularly when advertising stimulates demand for newer, branded therapies (Shmerling, 2022; Lamartina, 2022). GAO reports document substantial spending on DTCA campaigns (GAO, 2021), reflecting the commercial importance of consumer-facing promotion. Advertising expenditures are sustained partly by shareholder expectations for revenue growth and market expansion (Katz, 2016).

However, marketing data complicate assumptions that DTCA alone drives cost escalation. Between 1997 and 2016, DTCA spending increased from $2.1 billion to $9.6 billion, yet marketing directed toward healthcare professionals accounted for a substantially larger share of total promotional spending, increasing from $15.6 billion to $20.3 billion during the same period (Schwartz & Woloshin, 2019). These findings suggest that DTCA functions within a broader ecosystem of pharmaceutical promotion.

Even so, "Product Claim" advertisements may uniquely shape consumer demand at the population level. When patients request specific branded medications following advertisement exposure, prescribing patterns may shift toward higher-cost therapies. While such shifts do not automatically imply inappropriate prescribing, they may influence overall spending trends and formulary dynamics in ways that warrant closer evaluation.

5. Influence on Clinical Decision-Making

"Product Claim" advertisements may influence clinical encounters by prompting patients to request specific medications by name (Shmerling, 2022). When patient expectations are formed through repeated exposure to persuasive advertising, prescribers may face tension between maintaining evidence-based practice and responding to patient preferences. In oncology and other high-stakes specialties, such pressures may be particularly complex (Abel et al., 2006).

Critics have argued that DTCA has been used to "drive choice" rather than facilitate balanced understanding (Humphreys, 2009). This dynamic becomes more consequential when combined with other forms of pharmaceutical promotion. Industry payments and detailing practices have been associated with prescribing patterns favoring brand-name drugs (Hartung et al., 2018). The American Medical Association's call for a ban on prescription drug advertising reflected concerns about cost escalation and

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potential distortion of clinical judgment (AMA, 2015). Some academic medical centers have restricted detailing activities to reduce conflicts of interest (Larkin et al., 2017).

Although DTCA does not directly govern these professional interactions, "Product Claim" advertisements may amplify consumer demand that intersects with these broader promotional influences, reinforcing brand preference within clinical decision-making environments.

6. Risk/Safety Communication and Patient Behavior

Under FDA regulations, "Product Claim" advertisements must disclose risks alongside benefits to maintain fair balance (FDA, 2015). In theory, this requirement supports informed consumer awareness. In practice, however, the rapid presentation of side-effect information within emotionally positive advertisements may produce mixed behavioral responses.

Reports have documented instances in which patients discontinued medications after exposure to side-effect disclosures in advertisements (Polen et al., 2009). At the same time, concerns have been raised that risk information may be presented in ways that minimize perceived severity or overemphasize benefits (Shmerling, 2022). Furthermore, early and aggressive promotion of newly approved medications - before long-term safety profiles are fully established - has in some cases preceded post-market safety concerns and withdrawals (Gleeson & Menkes, 2018).

These patterns suggest a behavioral paradox: "Product Claim" advertisements may simultaneously increase initiation of therapy and contribute to premature discontinuation due to heightened concern about adverse effects. From a population health perspective, such dual effects warrant careful evaluation.

7. Digital Platforms and Global Context

Prescription drug promotion has increasingly shifted toward digital platforms, including social media, streaming services, and targeted online advertising (Sullivan et al., 2016). Digital dissemination allows for repeated exposure, algorithmic targeting, and integration with consumer search behavior, potentially expanding the reach and personalization of "Product Claim" campaigns. Celebrity endorsements and influencer marketing strategies may further enhance persuasive impact (Bluhm, 2018).

International reactions to U.S. pharmaceutical advertising underscore its distinctiveness. Following the widely viewed 2021 Oprah Winfrey interview, international audiences reportedly expressed surprise at the frequency of prescription drug advertisements during American broadcasts (Farzan, 2021). Although supporters frame DTCA as consistent with consumer autonomy and market-driven healthcare (Cortina, 2020), most other high-income nations - including capitalist economies - have elected to prohibit prescription drug advertising directed at consumers (AlShammari et al., 2020). Policy-oriented analysis - for example, comparing U.S. and Swiss regulatory approaches, has examined how DTCA operates within different enforcement frameworks and health-system sustainability contexts, revealing that institutional architecture shapes advertising's population-level effects (Umaru & Aremu, 2026). This divergence highlights the unique regulatory environment within which "Product Claim" advertising operates, and raises questions about whether U.S. safeguards adequately address the distinctive mechanisms through which these advertisements influence prescribing and spending patterns.

8. Conclusions

Debate surrounding DTCA has frequently treated prescription drug advertising as a uniform policy issue, obscuring important distinctions among regulatory categories. Evidence suggests that the effects of DTCA are not evenly distributed: while help-seeking and reminder advertisements may contribute to disease awareness and patient engagement, many of the most consequential concerns - including brand-

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driven demand, displacement of generics, prescribing pressure, and medication discontinuation - appear concentrated within the 'Product Claim' category.

Recognizing this distinction is not merely semantic; it has regulatory implications. 'Product Claim' advertisements uniquely combine persuasive branding with clinical claims, reaching mass audiences before enforcement mechanisms can address misleading content. A category-specific approach would allow policymakers to evaluate whether existing safeguards - such as fair balance requirements and post-market enforcement - are sufficient for advertisements that simultaneously promote branded products and frame treatment expectations at scale. If 'Product Claim' advertisements exert disproportionate influence on prescribing patterns, healthcare expenditures, and patient perceptions of risk and benefit, then regulatory refinement may require more targeted oversight mechanisms rather than broad reconsideration of DTCA as a whole.

The evolution of pharmaceutical promotion toward digital platforms intensifies these concerns. As algorithmic targeting and personalized advertising expand 'Product Claim' reach, the structural gap between promotional impact and regulatory response grows. Future inquiry should prioritize empirical assessment of how repeated 'Product Claim' exposure affects prescribing trends, medication adherence, and substitution of lower-cost alternatives. Clarifying these population-level effects would strengthen the evidence base for regulatory decision-making and help determine whether the U.S. approach to pharmaceutical advertising - exceptional among developed nations - adequately aligns commercial promotion with rational prescribing and public health objectives.

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