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Revisiting Direct-to-Consumer and Pharmacy Advertising: 2024 Lessons from the Rise of Anti-Obesity Medicines

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Abstract

What is the message?

The emergence of the Direct-to-Consumer and Pharmacy (DTCA-DTCP) advertising model, particularly through anti-obesity medications like Lilly's Zepbound, highlights regulatory challenges and ethical concerns as pharmaceutical companies leverage social media and telehealth referral networks. Addressing the balance between patient safety, accurate information, and affordability in this new advertising paradigm requires updated guidelines, collaborative oversight, and independent research.

What is the evidence?

An analysis of recent literature, global macro-trends, federal regulations, and emerging pharmaceutical industry practices.

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Introduction

The landscape of prescription drug advertising in the United States has undergone a significant transformation, with direct-to-consumer advertisements (DTCA) becoming ubiquitous on American television. The trend began in 1983 with the first such ad, which was promptly taken down but gained momentum in 1997 when the U.S. Food and Drug Administration (FDA) relaxed its guidelines around DTCA.[1]

A New Model of Drug Sale

After four decades, the introduction of anti-obesity medicines (AOMs) and Lilly's 2024 direct-to-consumer pharmacy (DTCP) strategy with Zepbound, which offers medications directly to patients, is likely to reignite discussions on the welfare effects of drug advertising. There have been past instances of pharmaceutical companies selling medicines directly to consumers who already have prescriptions. But the launch of Lilly's DTCP service, LillyDirect, comprising direct-to-consumer along with a referral network of independent telehealth providers (including Form Health and 9amHealth) with prescribing powers, will likely give rise to a new category of DTCA-DTCP. Lilly Direct joins firms such as Hims & Hers who combine prescribing and product dispensing. We discuss the regulatory challenge of this emerging practice. While there have been discussions about direct-to-consumer drug company pharmacies,[2] we aim to emphasize how DTCA-DTCP is poised to play a potentially concerning role in this emerging model.

One of the most significant concerns arising from DTCA, especially for drugs with a mass appeal like AOMs such as Wegovy (semaglutide) by Novo Nordisk and Zepbound (tirzepatide) by Lilly, is the shift in patient behavior from relying on evidence-based medical discussions to seeking medications based on social media influences. Social media platforms, particularly TikTok, have become influential sources of information for patients. Doctors report instances where patients request specific medications, such as the "*skinny jab*"[3] or weight loss shots, based on what they have seen influencers or celebrities discuss online.

Control over Advertising

In the United States, the FDA exercises control over advertisements from the pharmaceutical industry, mandating the acknowledgment of drug risks and side effects (the major statement according to the FDA). However, advertisements by telehealth companies are not subject to FDA promotional rules since telehealth companies are not a regulated drug manufacturer.

The DTCA-DTCP model exists in a regulatory vacuum. The First Amendment limits the ability of government to control advertising (since it is deemed speech). While the FDA has power over DTCA by manufacturers,[4] it does not regulate the practice of medicine or physician prescribers. The Federal Trade Commission (FTC) has broad authority to ensure that claims in advertisements are truthful, are not deceptive or unfair, and are evidence-based.[5] Thus, telemedicine companies need to meet the FTC standard in DTCA, which importantly does not include the FDA requirements on presentation of risks in advertisements.

The FDA is collaborating with external partners, such as the FTC, to tackle apprehensions related to the marketing practices of telehealth companies concerning prescription drugs across diverse platforms, including social media and public billboards. Despite these policies, marketing campaigns by several of these telehealth providers have exploited this regulatory gray area, even mentioning brand names in simple pitches such as "*Wegovy to lose weight*" without the requirement to provide a fair balance of information. Many of these companies aim to reduce the stigma associated with obesity while also advocating for the use of anti-obesity medications, which may influence individuals to consider these treatments.

The phenomenon extends beyond traditional medical settings, with spas offering drugs like semaglutide often without adequate medical support. Some providers and telehealth companies offer '*compounded*' semaglutide, which carries some potential downsides, including the possibility of contamination. Weight loss clinics also promote unconventional additions to these drugs, contributing to the complexity and potential risks associated with their usage.

Internationally, regulatory bodies are becoming more active in combating unethical pharmaceutical advertising on social media. Instances in the United Kingdom demonstrate efforts to scrutinize and regulate misleading drug promotions, underscoring the global nature of the issue.[6] While the focus is on pricing and supply chain optimization to meet the increasing

demand for AOMs, it is more critical than ever to revisit the DTCA policies and create rules suited explicitly to this emerging category of DTCA-DTCP with a sponsor referral network of providers that lacks the usual prerequisite of a neutral physician prescription to get access to medicines.

A Long-Standing Debate

The impact of manufacturer DTCA on medicine uptake and prescribing practices has been a longstanding question with mixed evidence. A recent review on DTCA practices highlights how complicated it is to understand the impact of DTCA on health systems.[7]

The potential consequences of DTCA extend beyond legislative solutions. A pertinent worry is that these ads exacerbate the situation by fostering a culture of demand for lifestyle drugs such as Wegovy and Zepbound and higher-cost options, even when lower-cost alternatives are available. The concern surrounding misleading direct-to-consumer advertising extends to other medications, such as ketamine, which could potentially increase the risk of misuse. As the healthcare system grapples with issues of accessibility and affordability of AOMs, the role of DTCA-DTCP in shaping patient preferences and contributing to the overall cost burden cannot be ignored. DTCA-DTCP can influence coverage decisions by employers who are struggling to address the cost of this new explosion of interest in these expensive products.[8]

Suggested Changes

For manufacturer DTCA-DTCP, it is crucial to develop specific guidelines that align with pharmacovigilance and the FDA adverse events monitoring system. This entails fortifying regulatory frameworks to ensure that advertisements with such a mass appeal offer precise, comprehensive, and easily understandable information regarding medication benefits and potential side effects, which the new rule from FDA in November 2023 partly addresses,[9] pending widescale implementation. Addressing misconceptions about drug safety and the mixed evidence on these drugs, including the ‘boomerang effect’ for weight regain, requires balanced, evidence-based marketing. Furthermore, the inclusion of pricing information in these advertisements, with full transparency for discounted price eligibility with drug coupons and co-pay/co-insurance assistance, can inform individuals with crucial knowledge about the economic

implications of the medications being promoted.

Independent research and assessment are crucial components of a robust regulatory framework. Encouraging and funding independent randomized trials and retrospective matched-cohort studies can produce the unbiased information required to help assess the impact of the DTCA-DTCP model. These studies would use administrative claims databases on effectiveness, along with patient behaviors such as adherence and impact on quality of life, for individuals using medicines such as Zepbound through DTCP, compared to those individuals obtaining access through conventional provider prescription. This research could build on past studies from the 2000s on anti-depressants.[10]

Given the influence of social media and the rising demand for AOMs, it is crucial to monitor DTCA-DTCP ads on these platforms. Collaboration with social media companies is essential to curb misinformation. International cooperation, particularly with countries like New Zealand, the only other nation to allow DTCA, is vital for sharing best practices and strategies in regulating prescription medication ads globally.

The rise of DTCA-DTCP with the discovery and diffusion of AOMs amid the global increase in non-communicable diseases ,presents a nuanced and significant challenge for the healthcare industry. Eli Lilly aims to secure an early-mover advantage and create inelastic consumers to leverage pricing power as competition grows. But, from a regulatory perspective, are Lilly product advertisements statements of manufacturers or of independent telehealth providers? The answer to this question will guide our ability to understand how to regulate the messages received by consumers.

Balancing accurate information, patient safety, and healthcare affordability requires collaborative efforts from regulators, healthcare professionals, and pharmaceutical companies to ensure informed patient decisions.

Conflict of Interest

Dr. Ray has no conflicts of interest to disclose.

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