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FDA Tightens Direct-to-Consumer Pharmaceutical Advertising in the US

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On September 9, 2025, the US Food and Drug Administration (FDA) launched one of its most aggressive and comprehensive enforcement initiatives in decades, targeting deceptive pharmaceutical advertising practices across television, digital platforms, and social media.

The FDA's shift toward greater transparency and proactive enforcement marks a turning point in US pharmaceutical regulation. For Canadian regulators, marketers, and policymakers, this development raises questions about the adequacy of domestic oversight, particularly as cross-border exposure increases, and evolving advertising formats test the limits of Canada's current regulatory framework.

FDA Enforcement Shift

The FDA's concerns are that pharmaceutical advertising frequently places disproportionate emphasis on therapeutic benefits while minimizing or obscuring safety information. Patients are often exposed to promotional content that highlights efficacy while relegating serious risks to fine print or omitting them altogether, not meeting the "fair balance" that advertising standards require. This imbalance compromises informed decision-making and fails to provide patients with a comprehensive and transparent understanding of both the benefits and potential harms associated with the medication.

In response, the FDA has shifted from a reactive, complaint-driven approach to enforcement to proactive, comprehensive enforcement across all media platforms. On September 9, 2025, the agency delivered over 100 cease-and-desist letters and issued thousands of warning letters to companies demanding immediate compliance with existing regulations.[1] The FDA has also announced its intention to conduct rulemaking to eliminate the "adequate provision" loophole, which previously allowed companies to satisfy risk disclosure requirements by providing a major-risk statement in advertisements and directing viewers to external sources for complete prescribing information.[2] Under current FDA guidance, this approach has been considered sufficient to meet disclosure obligations. The proposed reforms would require key safety disclosures, such as boxed warnings and contraindications, to appear directly within the advertisement.[3] This change is intended to ensure that risks and benefits are presented with equal prominence and clarity.

Recognizing the rapid growth of pharmaceutical advertising on digital platforms, the FDA is deploying artificial intelligence tools to monitor online activity. The agency now intends to monitor all forms of social

media promotion, such as influencer partnerships, sponsored content, algorithm-driven ads, and telehealth promotions that blur the distinction between educational messaging and promotional content.[4] This expanded oversight is specifically intended to close digital loopholes and ensure that all promotional communications meet FDA standards for accuracy and transparency.

The FDA's focus on digital enforcement and promotional transparency is likely to reshape consumer expectations for pharmaceutical advertising. This shift may prompt Canadian stakeholders and regulators to reassess how domestic advertising standards are interpreted and applied in practice, and whether current oversight mechanisms are sufficient to address the influence of increasingly visible US campaigns.

Enforcement in the US and Canada

Pharmaceutical advertising rules in the US and Canada differ significantly in both scope and enforcement. In the US, the FDA permits direct-to-consumer (DTC) advertising of prescription drugs, provided that such messaging includes a "fair balance" of benefits and risks.[5] Conversely, in Canada, the *Food and Drugs Act*[6] prohibits product-claim DTC advertising, and permits only "reminder" ads, which may include a drug's name but not its use, or "help-seeking" ads, which describe a condition without referencing a specific product.[7]

Each country's respective enforcement mechanisms highlight this divergence in regulation. The FDA does not require preclearance of ads before they air and has traditionally relied on post-publication review.[8] Its recent enforcement shift marks a move toward real-time oversight and stricter standards.

As it stands, Health Canada's enforcement remains largely reactive, often intervening in response to complaints or identified safety concerns. While proactive measures do exist, such as issuing guidance and monitoring high-risk areas, the system relies heavily on voluntary preclearance and post-publication review.[9] While companies may voluntarily submit materials to the Pharmaceutical Advertising Advisory Board (PAAB) or Advertising Standards Canada (ASC) for review, preclearance is not mandatory.[10] Advertising content is assessed based on promotional intent, which is in turn determined using contextual factors such as sponsorship, message delivery, and audience targeting.[11]

Implications for Canadian Pharmaceutical Advertising

Although product-claim DTC advertising is prohibited in Canada, Canadian audiences are regularly exposed to US pharmaceutical campaigns through television, streaming platforms, and algorithm-driven social media platforms. This exposure is longstanding, but the FDA's proposed reforms have the potential to intensify its impact.

This shift in expectations could influence prescribing behaviour in ways that may not always align with Canada's regulatory intent or clinical best practices. For example, patients may request specific drugs they have seen advertised, and physicians have discretion to oblige, even if the drugs are newer, more costly, or not the most clinically appropriate option.[12] The recent surge in demand for GLP-1 drugs (the popular weight-loss medication) illustrates this trend – although product-claim advertising is prohibited in Canada, reminder ads and social media engagement have driven brand recognition and off-label interest.[13]

Canadian pharmaceutical companies and marketers should be mindful of US enforcement trends and how the evolving tone of US pharmaceutical advertising may shape consumer expectations in Canada. As cross-border exposure increases, domestic campaigns may face closer scrutiny, especially where reminder ads or influencer content risk blurring the line between education and promotion. Voluntary preclearance through PAAB or ASC remains a practical safeguard, particularly for initiatives involving digital platforms or public-facing messaging.

Conclusions

In light of the FDA's recent changes, it would be prudent for Canadian companies operating in the pharmaceutical space to (i) monitor US enforcement trends, (ii) prepare for the potential of closer scrutiny of ads and influencer content, and (iii) consider submitting their pharmaceutical advertisements for voluntary preclearance through PAAB or ASC, particularly for digital campaigns and public-facing messaging.

The Cassels team regularly advises pharmaceutical companies, marketers, and industry stakeholders on drug advertising in Canada. For more information on how these developments may impact your business, or for guidance on advertising compliance, digital campaigns, or regulatory risk management, please contact any member of our Regulatory Group.

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