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The New Regulatory Environment for Pharma Commercial Marketing

Governance, Not Overregulation, is the DTC Solution

By Zoë Dunn | February 4, 2025

No matter the regulatory uncertainty coming down the road as organizational changes at FDA are impacted by the new administration, compliant promotion for pharmaceutical products will continue to be a key priority as companies explore new digital technologies like modular content and GenAI for promotion. Now, more than ever, establishing clear marketing governance is pharma's path to efficient and effective development of compliant promotional communications. This means:

- Guidelines for priority channels, such as website, email, and digital media
- Documented Ways of Working for scaling across the organization
- Clear ownership of roles and responsibilities
- Simple yet effective replicable processes for bringing communications to market
- Preparing for a personalized, omnichannel approach to customer engagement

We don't know exactly what the future will bring to the focus of FDA and specifically the Office of Prescription Drug Promotion (OPDP), but there are some themes that have been floated, including banning direct-to-consumer (DTC) TV ads and more regulation over social media advertisements for the pharmaceutical industry.

These prospective regulatory actions would be a loss for public health. DTC advertising has been effective at bringing awareness of diseases to patients and bridging the gap between awareness and diagnosis, which is especially effective for conditions that can go undiagnosed or untreated such as high cholesterol, depression, and rare diseases.

Rather than imposing blanket bans or excessive restrictions, strengthening marketing governance is the most effective way to protect consumers.

The pharmaceutical industry has well-established internal review structures—Medical, Legal, and Regulatory (MLR) teams—that vet all promotional content to ensure compliance with FDA guidelines. Unlike independent content creators or telehealth companies operating in regulatory gray areas, pharmaceutical manufacturers submit their promotional materials for review and adhere to rigorous marketing governance processes that ensure transparency and accuracy. Moreover, companies proactively remove or correct misleading content they sponsor.

The FDA already has enforcement tools to address misleading promotions, as evidenced by its social media-related warning letters, which pharmaceutical companies use to further

inform and bolster their marketing governance systems as necessary. In recent years, there has been a decrease in the number of enforcement actions, suggesting that most pharmaceutical companies are acting responsibly.

Instead of diverting resources to rewriting social media guidance, policymakers should focus on public education initiatives that teach consumers how to critically assess online health information and on helping legitimate science sustain its foothold among misinformation online. Responsible advertising on social media by the pharmaceutical industry helps put verified fair and balanced scientific information into the hands of those who need it, who together with their healthcare professionals—the gatekeepers to these products—can make better treatment decisions.

The case for marketing governance is stronger now than it has been since DTC came into existence over 35 years ago. OPDP needs to maintain its role in helping the industry communicate the information consumers need to live better, healthier lives in a way that protects public health while providing access to validated, scientific information that reduces the noise of misinformation. It is important to support these efforts instead of weakening a system that already has built-in safeguards that have worked effectively for decades and were on a path to supporting innovation in human healthcare.

About the Author
Zoë Dunn has spent her career shaping how the life sciences industry looks at risk and marketing. She is the president and CEO of Hale Advisors, bringing to bear more than 20 years' experience in advertising and promotion governance strategy, as well as deep expertise in digital and omnichannel marketing and modular content readiness. Last year, Zoë penned the essential reference "Navigating the shift to omnichannel marketing" for *Regulatory Focus*, the peer-reviewed journal of RAPS, the Regulatory Affairs Professionals Society. She loves a good debate and can be contacted at zoe@haleadvisors.com.

About Hale Advisors
Hale Advisors is a consulting company focused on marketing governance for the life sciences. Hale has created the industry's best practice for managing advertising and promotion regulatory risk while creating organizational readiness for innovations such as omnichannel marketing, modular content, and GenAI. Founded in 2010, Hale has worked with 18 of the top 25 pharmaceutical companies. Twice named an *MM+M* "Best Place to Work," Hale Advisors is proud to be a WBENC-certified woman-owned business. Learn more at haleadvisors.com or follow along on LinkedIn.