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Pharmaceutical Advertising 2022

USA: Trends & Developments
Bryant Godfrey and August Horvath
Foley Hoag LLP

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Trends and Developments

Contributed by:

*Bryant Godfrey and August Horvath
Foley Hoag LLP see p.6*

Relevant Laws or Codes Governing Pharmaceutical Advertising in the USA

In the US, prescription drug advertising is primarily regulated by the US Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations, as well as through FDA guidance documents (see 21 USC § 352(n); 21 CFR § 202.1). Other federal and state government entities that enforce various false and/or deceptive advertising claims (pertaining to prescription drugs) include the US Federal Trade Commission (FTC) and individual state attorneys general. Pharmaceutical company product-related statements have also drawn enforcement scrutiny from the US Securities and Exchange Commission (SEC) where investors have somehow been misled.

Over-the-counter (OTC)/non-prescription drug advertising is primarily regulated by the FTC under 15 USC §§ 52–57, where false or deceptive OTC drug advertising (likely to induce the product's purchase) is unlawful and enforceable by the FTC. The National Advertising Division (NAD) of the Better Business Bureau (BBB), the advertising industry's self-regulatory body, independently reviews and monitors national advertising for accuracy and truthfulness, and offers a voluntary dispute resolution process for advertisers. Many challenges to OTC drug advertising are brought before the NAD for review and adjudication.

Pre-approval Product Communications

As a general matter, promotion of a prescription drug prior to FDA approval of that drug is not allowed (see 21 CFR § 312.7(a)). Over the last several years, the FDA has taken increased

interest in pharmaceutical company prescription drug product communications that cross over into promotional territory (as opposed to pure scientific discourse), issuing enforcement letters to a number of companies. The letters consistently highlight communications that tend to make conclusive statements or representations regarding the safety and efficacy of an investigational new drug (a drug being studied in clinical trials) where the safety and efficacy have not yet been established and the product lacks FDA approval. The FDA's focus on these types of communications has shown no signs of waning.

Product Safety

One area of pharmaceutical company advertising that consistently garners FDA scrutiny is communications involving product safety. Tracing back through decades of enforcement letters from the FDA's Office of Prescription Drug Promotion (OPDP) and its predecessor, the Division of Drug Marketing, Advertising and Communications (DDMAC), the Agency routinely objected to various promotional statements and tactics viewed as minimising or omitting important risk information. Embedded in the OPDP's mission is the aim to protect public health by helping ensure that prescription drug promotion is truthful, balanced and accurately communicated. Downplaying or completely omitting risk information from product advertising and promotion will continue to capture the OPDP's enforcement interest, as these misrepresentations work to throw off balanced promotional presentations.

Over the years, prescription drug product safety communications have also caught the attention of the US Department of Justice (DOJ), particularly when false statements relating to product

safety were made in order to increase the sales of prescription drugs.

Federal Trade Commission

The Federal Trade Commission (FTC) is the primary federal government agency enforcing unfair and deceptive trade practices, including false advertising. The FTC's primary authority stems from the FTC Act, 15 USC §§ 41–58, as to which the Commission has exclusive enforcement authority. The FTC shares primary responsibility with the FDA in the agencies' concurrent jurisdiction over pharmaceutical advertising, marketing and promotion, according to a memorandum of understanding pursuant to which the FDA regulates all aspects of prescription drugs and the mandated labelling of all other FDA-regulated products, while the FTC has primary responsibility over "the truth or falsity of all advertising (other than label[ing]) of foods, [non-prescription] drugs, devices, and cosmetics". The two agencies advise each other on matters within the other's turf; the FTC defers to the FDA's judgment where the subject matter of OTC drug advertising mirrors FDA-regulated labelling, for example, whereas the FTC has advised the FDA on potential deception in direct-to-consumer advertising of prescription drugs. The FTC actively enforces what it deems unfair or deceptive practices in the advertising of OTC drugs, devices and cosmetics, including such things as the efficacy of analgesics. The FTC, sometimes jointly with the FDA, also enforces disease prevention or treatment claims by foods, dietary supplements and other products that the agencies contend render these products unapproved or misbranded drugs or medical devices.

Social Media Marketing and Influencers

Given that we are predominantly living in a digital age, it is no surprise that pharmaceutical company advertising and promotion has increasingly explored digital delivery methods. Through the use of various social media platforms, com-

panies are finding new and innovative ways to deliver tailored messaging to consumers as well as healthcare professionals. Although these platforms may present new ways of delivering content, the rubric of FDA rules and policies governing prescription advertising has not really changed that much – as evidenced from OPDP enforcement letters implicating various social media platforms. At the end of the day, prescription drug advertising must be truthful, non-misleading, and balanced, no matter the medium.

The FDA has also continued taking interest in influencer advertising – where pharmaceutical companies use various celebrities and/or influencers to market to their large social media following. Influencer marketing of prescription drugs is overseen by the FDA, while that for non-prescription drugs and other products is overseen by the FTC. Sometimes the agencies act jointly, as they did in a late 2021 series of letters to companies and influencers promoting the nicotine-containing liquids used in vaping devices. These letters and other actions by the FDA and FTC stress the dual requirements associated with influencer marketing: (1) the advertising must be truthful, non-misleading and contain all disclosures that would be required in any other advertising; and (2) any material connection between the influencer and the advertiser must be disclosed, as the FTC considers the failure to disclose such connections to be a distinct deceptive practice.

Competitor Activities

Over the last several years, the FDA has taken a pretty inactive stance on competitor superiority claims. Remarks made in 2018 by the FDA's former director of the Center for Drug Evaluation and Research (CDER), Dr Janet Woodcock, at a discussion hosted by the Alliance for a Stronger FDA, signalled that the Agency was more inclined to let competitors "duke it out" when it came to

disputes not involving threats to human health or safety. Although under different leadership, not much has changed at CDER on this topic. In 2021, the FDA issued no-enforcement letters to pharmaceutical companies for unsubstantiated or misleading comparative claims, and 2022 will most likely continue to see the same level of inaction. Pharmaceutical companies wishing to stop competitors from making inaccurate or misleading product comparative claims should expect to continue seeking redress under the false/misleading advertising provisions of the Lanham Act and/or submitting complaints to the FTC and individual state attorneys general. Competitors may also lodge a self-regulatory challenge before the National Advertising Division (NAD), although participation in this forum is voluntary, and compliance with the NAD's decision is not legally enforceable.

Since FTC and state attorneys general are not always responsive to competitor complaints that primarily affect the commercial positions of the parties rather than consumer welfare, the federal Lanham Act litigation may be the only effective option to shut down a competitor's offending marketing claims. Such litigation has drawbacks, however:

- the complaining plaintiff carries the burden to prove the advertiser's claims false, whereas a regulator could require the advertiser to substantiate them;
- Lanham Act litigation permits counterclaims against the original plaintiff for any of its own allegedly false advertising that the sued party can dig up; and
- like any federal litigation, the process can be lengthy, invasive and expensive.

Off-Label Promotion

Although not at a level seen in the early to mid-2000s, OPDP has not stopped issuing enforcement letters for off-label promotion. The wording

and the charges, however, do differ as they are carefully crafted to focus more on misbranding, as opposed to vilifying speech. For example, recent letters cite off-label communications as providing evidence of a new, intended use for which the products' labelling did not provide adequate information for use, rendering the products misbranded. The last couple of letters honed in on sales representatives' oral statements and emailed communications. In an effort to continue asserting its presence in this space, continued but measured FDA enforcement against off-label promotion should be expected going forward.

Investor Lawsuits/SEC Scrutiny

Investor lawsuits against pharmaceutical companies for misleading statements made in public-required and investor-related disclosures are becoming more and more commonplace. Often, these statements also appear in company-issued press releases, which have the potential to be viewed as promotional – depending on what is stated and how it is stated. When crafting press releases concerning product performance, potential, or a candidate product's likelihood of FDA filing success, not only should pharmaceutical companies be aware of the various FDA promotional requirements that apply, but companies should also think about SEC implications. Many investor lawsuits allege that the company at issue made misleading statements about its product's safety or efficacy that turned out to be not as rosy as depicted, or somehow actually resulted in a negative FDA action, usually somehow causing injury to investors due to a decrease in stock prices.

Consistent with Labelling Communications

As the FDA has expressed an increased interest in real-world evidence (ie, clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data – which is data relating

to patient health status and/or the delivery of healthcare routinely collected from a variety of sources), many pharmaceutical companies have started incorporating or, at least, considering how and whether to include information in advertising and promotional materials that is supported by real-world evidence. Often, the information supported by the real-world evidence is not included in FDA-approved labelling for the product at issue. As companies continue to navigate this new area of information, the FDA's guidance for the industry, "Medical Product Communications That Are Consistent With the FDA-Required Labelling – Questions and Answers", in combination with lessons learned from various enforcement letters citing the use of real-world evidence, will continue to be of interest to companies.

Healthcare Fraud and Abuse Considerations

In recent years, pharmaceutical company speakers' programmes (a practice where pharmaceutical companies pay healthcare practitioners (HCPs), who often prescribe the companies' products, to promote these products to other

HCPs) and speaker training meetings have faced intense government scrutiny where the allegations have been that these events induced HCPs to prescribe prescription drug products in violation of the Anti-Kickback Statute (AKS) and False Claims Act (FCA). These programmes tend to be the highest-risk marketing practice in the pharmaceutical industry and most likely will retain that designation for some time going forward.

Conclusion

Navigating US rules and policies governing pharmaceutical advertising requires focused attention on several sources of oversight – both official and unofficial – each with unique requirements. Violations of official government-imposed requirements can land companies into significant trouble. However, industry self-regulatory activities are unlikely to yield the same level of enforcement consequences. Nonetheless, one thing is for sure – care should be taken to avoid false, misleading and/or deceptive promotional claims and practices, as these tend to be at the heart of many challenges to pharmaceutical product advertising.

USA TRENDS AND DEVELOPMENTS

Contributed by: Bryant Godfrey and August Horvath, Foley Hoag LLP

Foley Hoag LLP is a nationally recognised, full-service life sciences practice that draws on the talents of a wide variety of professionals – many of whom have had previous careers as scientists, medical doctors and high-ranking government officials – to advise clients across the industry ranging from start-ups to Fortune Future 50 companies. The firm's advertising and marketing legal team provides a broad range of regulatory, advisory and disputes-oriented representation around the promotion of goods and

services, and brings considerable experience to all the legal issues affecting a business's ability to promote its offerings. From offices in Boston, New York, Paris and Washington, DC, the team helps clients achieve their business goals while minimising risk, as they navigate the complex waters associated with the development, approval, commercialisation, reimbursement and coverage of innovative medical products and services.

AUTHORS



Bryant Godfrey is a partner at Foley Hoag who provides strategic regulatory advice to pharmaceutical, medical device and biotech companies, helping them to navigate challenges

relating to the development, manufacturing, approval and promotion of drugs, biologics, medical devices, and combination products. Having spent nearly a decade at the US Food and Drug Administration in senior regulatory and policy roles, including as the head lawyer of the FDA's Office of Prescription Drug Promotion, his experience encompasses a wide range of issues relating to advertising and promotion, scientific exchange, investigations of off-label marketing, product jurisdiction, medical product development and approval/clearance, labelling, and post-marketing commitments and requirements, among others.



August Horvath is a partner at Foley Hoag who counsels clients on how to substantiate and defend marketing claims they wish to make for their products and services, helps

them challenge false and disparaging advertising by competitors, and assists in managing relationships with competitors, customers and suppliers, without running foul of antitrust laws. He represents clients in federal and state enforcement actions and in litigation against competitors and consumer classes. August's hands-on experience in survey research and statistical analysis gives him exceptional insight into developing substantiation protocols, and designing and assessing research into the implied meaning of advertising claims.

Foley Hoag LLP

1717 K Street NW
Washington, DC
20006
USA

Tel: +1 202 223 1200
Fax: +1 202 785 6887
Email: contact@foleyhoag.com
Web: www.foleyhoag.com

