NELSON HARDIMAN

Cracking the Whip: The FTC's Clampdown on Healthcare Marketing

Regulatory Update

Cracking the Whip:

The FTC's Clampdown on Healthcare Marketing

The American reverence for entrepreneurial spirit and free enterprise is reflected in the profound influence of capitalism on our healthcare system. In contrast to many other advanced industrialized countries with state-run healthcare, the U.S. healthcare system is driven by a complex mix of <u>economic considerations</u> for providers, insurers, and pharmaceutical companies. The competitive nature of this system not only shapes healthcare delivery, but also profoundly affects the marketing and distribution of medical products.

Notably, the United States is unique among its peers in permitting direct-to-consumer pharmaceutical advertising—a practice strictly regulated in the European Union and other Western nations. Proponents argue that a healthy measure of regulatory latitude is crucial for spurring innovation, as evidenced by developments in telehealth, private addiction treatment centers, and direct-to-consumer genetic testing, along with an expansive market for dietary supplements. However, the advertising of healthcare products and services comes with significant risks. Poor medical choices can have devastating, irreversible consequences, and individuals with cognitive impairments or serious health conditions are particularly vulnerable to the persuasive power of overstated claims and assertive marketing strategies. With the waning of the pandemic's immediate dangers, federal regulators in the U.S. have moved from a stance of regulatory relaxation to one of <u>increased scrutiny</u>. This shift is manifested in a series of Federal Trade Commission (FTC) investigations and settlements aimed at curbing deceptive practices within the healthcare industry.

Too Much Puffery is Unhealthy

Historically, U.S. courts have permitted "puffed up" exaggerations in advertising, characterized as subjective claims that are unlikely to deceive a reasonable consumer. However, the FTC has begun to apply a different standard to healthcare. In March 2023, the FTC settled a lawsuit against Dr. Dalal A. Akoury and her company, AWAREmed, for misleading advertising claims in treatments for addiction, cancer, and neuro-degenerative diseases. Claims that the FTC deemed misleading, given the vulnerability of the targeted groups, included:

- "Most Effective Medical Clinic . . . Anywhere"
- "98% Improvement Rate Treating Just About... Anything"
- "Experience Rapid, Painless Detox and Recovery From ANY Addiction"
- "Attain work-ready functionality in only 3 days"

For these deceptive claims, the FTC utilized a general statute against deceptive marketing (15 U.S.C. § 52) and one, specifically for substance abuse treatment claims, the Opioid Addiction Recovery Fraud Prevention Act of 2018 (<u>Opioid Act</u>). The imposition of a \$100,000 fine, while modest, signaled the FTC's shifting prioritization to protecting vulnerable patients.

Dietary Supplements for Substance Abuse?

In mid-2023, the Federal Trade Commission took enforcement action against Rejuvika, a company marketing



<u>Sobrenix</u>, a liquid dietary supplement claimed to aid alcohol dependency. Sobrenix was promoted as reducing alcohol cravings and helping to detoxify the body, with assertions that "taken before drinking, Sobrenix's ingredients help you stop before you've had too much."

The FTC's action required Rejuvika to issue \$650,000 in refunds to consumers, marking a significant step given the typically light regulation of the dietary supplement industry. Companies in this sector, which often tout novel remedies, mitigate risk with a standard disclaimer: "The statements and claims made about this product have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." However, by leveraging the Opioid Act, the FTC signaled that it would not extend the same leniency to promotional materials for substance abuse products as it does for claims related to other remedies in the dietary supplements space.

Click-Wrap Disclaimers & Hidden Consents

In April 2024, the FTC's <u>\$7 million settlement</u> with behavioral telehealth provider Cerebral highlighted a stark breach of consumer trust through deceptive marketing and serious privacy violations. Cerebral, which offers online mental health services, used opaque "click-wrap" agreements to obscure critical terms. Consumers, often unknowingly, consented to the sharing of their personally identifiable information (PMI) with third-party platforms like LinkedIn, Snapchat, and TikTok. This practice not only violated promises of confidentiality but also exposed sensitive health data under the guise of dense, complex legal jargon.

The FTC also settled similar charges against <u>Monument</u>, another telehealth service specializing in alcohol addiction treatment. The company advertised "100% confidentiality" while burying the reality of personal data sharing deep within its <u>voluminous privacy policy</u>.

In both of these recent cases, the FTC relied upon the Opioid Addiction Recovery Fraud Prevention Act of 2018 (OARFPA) – a part of the federal omnibus 2018 SUPPORT legislation that received scant attention relative to other parts of that bill. The FTC's enforcement of OARFPA sends an unequivocal message: it will not tolerate healthcare providers who misuse and disclose sensitive data for promotional purposes. Keep an eye out for further FTC enforcement actions aimed at protecting vulnerable consumers from deceptive healthcare marketing practices.

Harry Nelson, Managing Partner, Nelson Hardiman

Yehuda Hausman, Law Clerk, Nelson Hardiman

Nelson Hardiman LLP

Healthcare Law for Tomorrow

Nelson Hardiman regularly advises clients on new healthcare law and compliance. We offer legal services to businesses at every point in the commercial stream of medicine, healthcare, and the life sciences.