Advertising & Promotion for Medical Products Conference

October 16-17, 2018
Renaissance Downtown Hotel
999 Ninth Street, NW | Washington, DC 20001

Key Legal Background Materials

I. FEDERAL STATUTES[1]

a. Federal Food, Drug, and Cosmetic Act (FDCA)

§201(n)(21 U.S.C. §321(n)): A drug or device is deemed misbranded if the labeling or advertising fails to reveal material facts.

§502(a)(21 U.S.C. §352(a)): A drug or device is deemed misbranded if its labeling is false or misleading in any particular.

§502(f)(1)(21 U.S.C. §352(f)): Labeling for drugs and devices must include adequate directions for use.

§502(n)(21 U.S.C. §352(n)): Prescription drug advertising must include a "brief summary relating to side effects, contraindications, and effectiveness." No prior approval of advertisements required except "in extraordinary circumstances." Direct-to-consumer advertisements must contain information on reporting adverse events to FDA, and direct-to-consumer broadcast advertisements must contain a "major statement relating to side effects and contraindications . . . presented in a clear, conspicuous, and neutral manner."

§502(q)(21 U.S.C. §352(q)): Restricted device advertising must not be false or misleading in any particular.

§502(r)(21 U.S.C. §352(r)): Restricted device advertising must include a "brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications." No prior approval of advertisements required except in "extraordinary circumstances."

§503C (21 U.S.C. § 353c): Permits FDA to require the submission of any television advertisement for a drug not later than 45 days before dissemination of the advertisement.

b. Federal Trade Commission Act

15 U.S.C. §45(a) prohibits "unfair and deceptive acts and practices."

15 U.S.C. §45(n): An advertisement or trade practice is unfair if it causes or is likely to cause substantial consumer injury that is not reasonably avoidable by consumers themselves and that is not outweighed by countervailing benefits to consumers or competitors.

[1] Federal Statutes are laws enacted by the U.S. Congress that provide an agency with the authority to regulate.

15 U.S.C. §52-55 prohibits "false advertising [of FDA-regulated products] that is misleading in a material respect" and authorizes the FTC to file suit in federal court to enjoin violations.

c. Lanham Act

15 U.S.C. §1125(a) prohibits use of a false or misleading representation in commercial advertising or promotion that "misrepresents the nature, characteristics, qualities, or geographic origin of . . . goods, services, or commercial activities." Provides a right of action from a competitor likely to be damaged by false or misleading advertising.

II. CODE OF FEDERAL REGULATIONS[2]

21 CFR Part 201 (drug labeling)

21 CFR Part 202 (prescription drug advertising)

21 CFR 312.7 (prohibition on pre-approval promotion for investigational drugs; scientific exchange)

21 CFR Part 610 (biologic labeling)

21 CFR Part 801 (medical device labeling)

21 CFR 812.7 (prohibition on pre-approval promotion for investigational devices)

III. CASE LAW[3]

***Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002)*:** Supreme Court held that FDA could not prohibit the advertisement of compounded drugs. The Food and Drug Administration Modernization Act of 1997 (FDAMA) criminalized advertising of compounded drugs. While acknowledging the usefulness of the ban in "[p]reserving the effectiveness and integrity of the FDCA's new drug approval process," the Court held that FDA could not restrict this commercial speech. Citing the government's concurrent interest in ensuring access to necessary medical treatment, the Court held that FDA's prohibition "does not appear to directly further any asserted governmental objective."

***Sorrell v. IMS Health Inc.,* 564 U.S. 552 (2011)**: Supreme Court held that Vermont law restricting drug manufacturer's ability to use prescriber information for marketing purposes was unconstitutional. In its majority opinion, the Court rejected the state's argument that these restrictions advanced a substantial government interest and concluded that the statute placed an undue burden on commercial speech. The Court applied "heightened scrutiny" and concluded that "speech in aid of pharmaceutical marketing . . . is protected by the First Amendment."

***United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012)**: The Second Circuit vacated the criminal conviction of a pharmaceutical sales representative who promoted a narcolepsy drug for a range of off-label uses. The Court held that the First Amendment's protection of commercial speech supported the sales representative's ability to engage in truthful, non-misleading off-label promotion of an FDA-approved drug, stating that "the government cannot prosecute

---

[2] The Code of Federal Regulations is a compilation of administrative laws that federal agencies promulgate under authority of the governing statute.

[3] Case law is a body of court rulings that can have the force of law based on, and equal to, applicable statutes. In common law systems such as the United States, a court is bound by previous rulings based on facts similar to those the court is considering.

pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug." Although FDA declined to appeal and initially stated that the ruling would not affect its enforcement activity, many view this decision as a landmark case that opened the door to further legal challenges to the agency's strict regulation of manufacturer speech.

***Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015)**: Applying *Caronia*, the court held that truthful and non-misleading manufacturer communications, including proactive, promotional off-label statements, are protected by the First Amendment. The company and FDA consequently reached a settlement agreement stipulating, among other things, that certain off-label communications (*i.e.*, claims and accompanying disclosures) were truthful and non-misleading, and permitting Amarin to submit up to two proposed communications containing off-label use information to FDA per year for preclearance.

Pacira Pharmaceuticals, Inc. v. FDA,* No. 15-7055 (S.D.N.Y. 2015)*: Pacira filed a lawsuit against FDA alleging that the agency had violated Pacira's First and Fifth Amendment rights, as well as the Administrative Procedure Act, in issuing a warning letter that accused Pacira of engaging in off-label promotion. Pacira and FDA ultimately reached a settlement agreement in which FDA took the unprecedented step of withdrawing the warning letter and confirming that Pacira's promotional claims were on label. Additionally, to clarify ambiguities that gave rise to the warning letter, FDA agreed to approve significant revisions to the label.

***U.S. v. Vascular Solutions* 181 F.Supp.3d 342 (2016)**: The company and its CEO were acquitted of misbranding charges after the government alleged that the company had promoted its device off label. The jury instruction in the case stated that it is "not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device."

***POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014)**: Even if the product label complies with FDCA requirements, a private party can bring suit under the Lanham Act alleging unfair competition based on misleading advertising or labeling.

- ***Also see Church & Dwight Co. v. SPD Swiss Precision Diagnostics*, GmbH, 843 F.3d 48 (2d Cir. 2016)**, holding that plaintiff can bring a Lanham Act action against a medical device manufacturer.
- ***But see Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 64 (2d Cir. 2016)*** ("[R]epresentations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability.").

IV. GUIDANCE DOCUMENTS[4]

a. FDA Guidance Documents

Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers, Final Guidance (June 2018)
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537130.pdf

[4] Guidance documents, or Guides, represent the agency's current thinking, or recommendations, on a particular topic. Guidance documents by themselves do not establish legally enforceable responsibilities.

Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers, Final Guidance (June 2018)
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling, Final Guidance (December 2017)
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM375784.pdf

Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs, Draft Guidance (August 2015)
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf

Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices, Draft Guidance (June 2014)
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm400104.pdf

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, Draft Guidance (June 2014)
https://www.fda.gov/downloads/drugs/guidances/ucm401079.pdf

Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, Draft Guidance (June 2014)
https://www.fda.gov/downloads/drugs/guidances/ucm401087.pdf

Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices, Revised Draft Guidance (February 2014)
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, Draft Guidance (January 2014)
https://www.fda.gov/downloads/drugs/guidances/ucm381352.pdf

Direct-to-Consumer Television Advertisements -- FDAAA DTC Television Ad Pre-Dissemination Review Program, Draft Guidance (March 2012)
https://www.fda.gov/downloads/Drugs/.../Guidances/UCM295554.pdf

Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, Draft Guidance (December 2011)
https://www.fda.gov/downloads/drugs/guidances/ucm285145.pdf

Presenting Risk Information in Prescription Drug and Medical Device Promotion, Draft Guidance (May 2009)

https://www.fda.gov/downloads/drugs/guidances/ucm155480.pdf

Consumer-Directed Broadcast Advertisements, Final Guidance (August 1999)
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf

Consumer-Directed Broadcast Advertisements Questions and Answers, Final Guidance (August 1999)
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM122825.pdf

Industry-Supported Scientific and Educational Activities, Final Guidance (December 1997)
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf

b. FTC Guides

Guides Concerning the Use of Endorsements and Testimonials in Advertising (October 2009)
https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-publishes-final-guides-governing-endorsements-testimonials/091005revisedendorsementguides.pdf

The FTC's Endorsement Guides: What People are Asking (September 2017)
https://www.ftc.gov/tips-advice/business-center/guidance/ftcs-endorsement-guides-what-people-are-asking

FTC Reminds Influences and Brands to Clearly Disclose Relationship (April 2017)
https://www.ftc.gov/news-events/press-releases/2017/04/ftc-staff-reminds-influencers-brands-clearly-disclose