DuaneMorris

FDA Regulation of Promotion & Advertising

Part 7: FTC Regulation

ComplianceOnline Seminar
November 6-7, 2014

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Who Has Jurisdiction …

- **Prescription Drugs and Biologics**
  - Labeling -- FDA
  - Advertising – FDA
- **Restricted Devices**
  - Labeling -- FDA
  - Advertising – FDA
- **OTC Drugs**
  - Labeling -- FDA
  - Advertising – Federal Trade Commission

Who Has Jurisdiction …

- **"Unrestricted Devices"**
  - Labeling -- FDA
  - Advertising – Federal Trade Commission
- **Dietary Supplements**
  - Labeling -- FDA
  - Advertising – Federal Trade Commission
- **Cosmetics**
  - Labeling -- FDA
  - Advertising – Federal Trade Commission

Jurisdiction – Snapshot View

Who Has Jurisdiction				
	Rx Drugs and Biologics	**OTC Drugs**	**Restricted Devices**	**"Unrestricted Devices"**
Labeling	FDA	FDA	FDA	FDA
Advertising	FDA	FTC	FDA	FTC
Internet**	FDA	FDA & FTC	FDA	FDA & FTC

** Internet – see next slide

FTC Legal Authority

- **Key FTC standards on advertising**
  - **Substantiation** – "competent and reliable scientific evidence"
    - but what that is – often two well-controlled clinical studies
  - **Deception** – ad is deceptive if a contains a representation or omission of fact that is likely to mislead a consumer and the rep. or omission is material to a consumer's purchasing decision.
- **Federal Trade Commission Act (FTCA) – does not define advertising, but does "false advertising:**
  - as "an advertisement, other than labeling, which is misleading in a material respect" 15 U.S.C. §55(a)(1)

FTC …

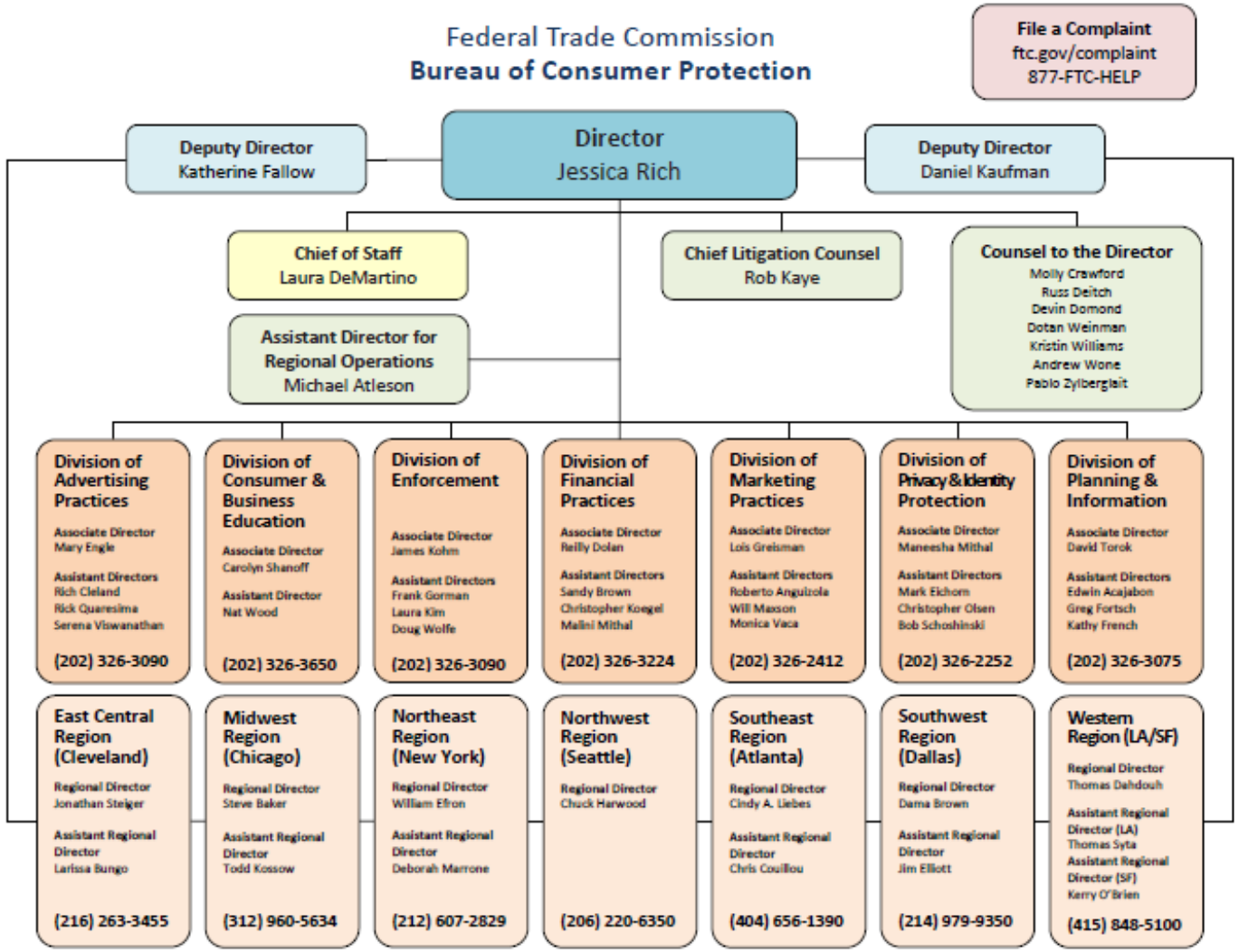
- **Criteria for When an ad is False"**
  - "… there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement ***fails to reveal facts material*** in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual"

FTCA – "Carve Out" for Drug Ads

- **"No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug" -- 15 U.S.C. §55(a)(1)**

FTC

- **Who at FTC? [see org chart on next page]**
  - Bureau of Consumer Protection
    - Division of Advertising Practices
- **Actions – typically handled privately; case-by-case basis**
  - most common result – Consent Decree
  - Other remedies
    - TRO's or injunction
    - Criminal prosecution if advertised use was injurious
    - Several instances – FTC has insisted that a violative health claim be corrected by securing FDA approval


Federal Trade Commission
Bureau of Consumer Protection
File a Complaint
ftc.gov/complaint
877-FTC-HELP
Director
Jessica Rich
Deputy Director
Katherine Fallow
Deputy Director
Daniel Kaufman
Chief of Staff
Laura DeMartino
Chief Litigation Counsel
Rob Kaye
Counsel to the Director
Molly Crawford
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Southeast Region (Atlanta)
Regional Director
Cindy A. Liebes
Assistant Regional Director
Chris Couillou
(404) 656-1390
Southwest Region (Dallas)
Regional Director
Dama Brown
Assistant Regional Director
Jim Elliott
(214) 979-9350
Western Region (LA/SF)
Regional Director
Thomas Dahdouh
Assistant Regional Director (LA)
Thomas Syta
Assistant Regional Director (SF)
Kerry O'Brien
(415) 848-5100

FTC

- **General principles on whether to take a case:**
  - The amount of consumer injury caused by the advertising.
    - Among the questions asked in this regard are whether or not the product itself is a fraud.
    - if case involves ineffective products, according to scientific data.
  - The potential risk to the user's health.
  - Whether or not the claims involved are the type that consumers can evaluate for themselves.
  - Whether or not other legal avenues (e.g., Lanham Act) can be pursued or self-regulating groups (NAD) can address the issues
  - Whether or not the case will help clarify an important legal question.

Endorsement Regulations

- **Endorsements – must be bona fide and honest**
- **If ad represents endorser as a user, must be one**
  - FTC regulations – any depiction of a consumer should use a consumer; if not, have to say so in the ad
  - Expert endorsements – OK, but the expert must really have evaluated the product – document that
  - Celebrity endorsements – dependent on sponsor's good faith view that celebrity continues to maintain views in the ad
    - e.g., endorse Coke, but seen drinking Pepsi …

Endorsement Regulations …

- **Endorsements involving efficacy of drugs or devices shall not be done in a lay endorsement unless**
  - advertiser has adequate scientific substantiation for claim
  - claims are not inconsistent with any FDA determination about the drug or device
- **"Experiential" Endorsements –** i.e., I got this great result with Drug X – unless that is a typical result for which you have adequate substantiation, advertiser must clearly and conspicuously disclose the generally accepted performance of the product

FTC and OTC Drugs

- **No specific regulations on OTC drug ads**
- **Warnings – generally, those needed to prevent ad from being deceptive (case by case)**
- **Anacin case (1981)**
  - FTC ordered Anacin to stop saying that "Anacin contained the pain reliever most recommended by doctors" without disclosing the ingredient
    - ingredient – was aspirin
    - FTC – because you never said that in the ads; was deceptive
  - FTC also ordered them to not make any comparative claims (safety or efficacy) without two well-controlled clinical studies

FTC and OTC Drugs …

- **Aspercreme® (1984)**
  - FTC –
    - ads implied product contained aspirin, which it did not
    - also misrepresented level of data that company had to support its claims
  - ALJ – backed FTC – standard, again, was two WCCT

POM Wonderful

- **Jan. 16, 2014 – FTC, by 5-0 vote,** upheld decision by ALJ that POM marketers deceptively advertised products and lacked support that their products could treat, prevent or reduce the risk of heart disease, prostate cancer, and erectile dysfunction, and that the products were clinically proven to work
  - Future claims have to be supported by two randomized, well-controlled human clinical studies
  - FTC -- deceptive – to make an objective claim without a reasonable basis for it

End of Part 7: FTC Regulation