21st Century Snake Oil Sales: FTC Regulation of OTC Drug Marketing

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Snake Oil Origins

- Late 19th & early 20th century traveling medicine shows
- Unregulated sale of cure-alls and panaceas such as Swamp Root, Microbe Killer, and Lydia Pinkham’s tonic
- “secret” ingredients included alcohol, opium, cocaine or morphine

Cold Curing/Preventing Mouthwash?

Nestle Boost Kid Essentials Prevents Colds?

- Unsubstantiated claims that Kid Essentials contains probiotics that reduce or prevent colds & flu
- FTC settled case in 2011, Nestle agreed to stop making claims without adequate substantiation, such as two well-designed human clinical studies

Acai Berry – magic berry from the rain forest?

- Weight loss?
- Prevents colon cancer?
- Claims made using fake news sites
- FTC got TRO & seeks permanent injunction in federal court against 10 websites, and against importer

Activia – Can Yogurt prevent colds?

- “probiotic” yogurt products
- Boosts immune system & relieves temporary digestive irregularity
- FTC settlement in 2010 requires caveat that it takes 3 servings per day
- Company agreed to stop claiming yogurt can help people avoid catching colds or flu

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Pom Wonderful – achieve immortality?

- Cheat death? Prevents or treats heart disease, prostate cancer and erectile dysfunction?
- FTC filed administrative complaint Sept. 2010
- FTC says scientific studies relied on by company were not adequate to substantiate claims

Federal Regulation of Food & Drugs

- Pure Food & Drug Act (1906) and Federal Food, Drug & cosmetic Act of 1938 required ingredient labeling and pre-testing of drugs for safety & efficacy
- Federal Trade Commission Act (1914, amended in 1938) prohibits unfair or deceptive trade practices and prohibits the dissemination of any false advertisement likely to induce the purchase of food or drugs

FDA/FTC Share Jurisdiction Over Food & Drugs

- FTC oversees over-the-counter drug and dietary supplement advertising
- FDA oversees prescription drug advertising, and also drug labeling and testing
- FTC & FDA coordinate their efforts, FTC accords substantial weight to FDA scientific determinations

FTC Advertising Substantiation Doctrine

- Ad substantiation doctrine developed in 1970’s, in response to Ralph Nader petition
- Based on theory that all ads imply that the advertiser has a reasonable basis for their claims, and if they don’t, it’s deceptive

FTC AD SUBSTANTIATION 1984 Policy

<table>
<thead>
<tr>
<th>Type of Claim</th>
<th>Substantiation Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most Claims</td>
<td>Reasonable basis</td>
</tr>
<tr>
<td>Limited Claims</td>
<td>Substantiation specified in advertisement</td>
</tr>
<tr>
<td>“Puffing”</td>
<td>No substantiation</td>
</tr>
<tr>
<td>“Establishment” claims for OTC drugs</td>
<td>Two well-controlled clinical studies</td>
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</tbody>
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Sterling Drug v. FTC, 9th Cir. 1984

- Claim of superior efficacy for Bayer aspirin made through images in ads
- Claim that efficacy is scientifically established for OTC drug requires two well-controlled clinical studies
Helsinki Formula case – FTC v. Pantron I, 9th Cir. 1994

- Placebo effect for hair loss product was not sufficient ad substantiation
- “to foist unsubstantiated claims on an unsuspecting public in the hope that consumers would believe the ads and the claims would be self-fulfilling.”

Q-Ray Ionized Bracelet – FTC v. QT, Inc. (7th Cir. 2008)

- 2008 7th Cir. Case held “placebo” effect cannot substantiate false claims
- “Since the placebo effect can be obtained from sugar pills, charging $200 for a device that is represented as a miracle cure but works no better than a dummy pill is a form of fraud.”
- FTC prevailed and Co. required to disgorge $16 million for consumer restitution

Dietary Supplements and the Effect of DSHEA

- Dietary Supplement Health & Education Act of 1994
- Created separate class of products known as “dietary supplements” which do not need FDA pre-marketing approval
- Dietary supplements often make “drug-like” claims and such claims still need to be substantiated

FTC Response to Dietary Supplements

- Advertising Guide for Dietary Supplement Industry
- Gives specific examples of needed substantiation for various types of claims
- FTC has required either FDA pre-approval of disease prevention or cure claims, or two well controlled clinical studies when a dietary supplement makes a specific disease prevention claim. E.g., Nestle, Iovate cases

FTC Corrective Advertising

- Established in 1977 Warner-Lambert case involving false claims that Listerine mouthwash prevents colds or sore throats or lessens their severity
- Corrective ad needed to correct lingering false beliefs created by ad