

# Marketing of Genetic Tests: *The Role of the FTC*



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*The views expressed by Mr. Daynard are his and do not represent those of the Commission or individual Commissioners*



# Overview

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- Jurisdiction
- Advertising Principles
- FTC & Privacy
- Project Cure.All--HIV Home Test Kits
- Industry/Consumer Education

# FTC Jurisdiction

## Federal Trade Commission Act

- Unfair or deceptive acts or practices prohibited (15 U.S.C. 45(a))
- False advertisements for foods, drugs, devices, and services prohibited (15 U.S.C. 52)
- Includes ad claims by marketers of genetic tests, including “off-label” uses

## Definitions

**Deceptive:** a representation, omission, or practice is *deceptive* if (1) it is likely to mislead consumers acting reasonably under the circumstances; and (2) it is material; that is, likely to affect consumers' conduct or decisions with respect to the product at issue.

## Definitions

**Unfair:** a practice is unfair if the injury to consumers it causes or is likely to cause (1) is substantial; (2) is not outweighed by countervailing benefits to consumers or to competition; and (3) is not reasonably avoidable by consumers themselves.

## FTC-FDA Liaison\_Agreement

- Since 1954, agencies have operated under a formal agreement which provides that:
  - FTC has primary jurisdiction for the advertising of devices (among other products);
  - FDA has primary jurisdiction for the labeling of devices
    - Can have dual jurisdiction – e.g., ads for unapproved home test kits

# Ad Claims vs. Practice of Medicine

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- True and substantiated health claims are an important part of the FTC mission
- Injury to consumers can be serious should they use the wrong product/service or forego other treatment
- We do not regulate how doctors use or prescribe drugs/devices/services in treating patients or other choice of therapy issues.

# Basic Advertising Principles

- **Tell the truth: don't mislead consumers about the benefits or safety of your product by what you say expressly or by what your ad implies**
- **Tell all the truth: don't omit information that is needed to keep what you say from being deceptive**
- **Make sure it is the truth: do have adequate support for any objective claim (express or implied) before you run the ad**





## Claims/Ad Meaning

- Advertisers are responsible for express and reasonably implied claims
- Net impression of ad is important
  - **text, product name, visual images**
- Disclose qualifying information if necessary to prevent deception
- Disclosures must be clear and conspicuous



# Substantiation

- **Must have support for claims before disseminating ad**
- **Standard is flexible**
  - depends on claim: how presented, how qualified
  - ensures consumer access to information about emerging science/service
  - ensures that information is accurate
- **Standard is rigorous: “Competent and Reliable Scientific Evidence”**
  - consult with experts in wide variety of fields

## Consumer Testimonials/ Expert Endorsements



- Unsubstantiated claims can not be made indirectly through testimonials
- Testimonial = representative experience
  - if not, must disclose the typical experience, or that consumers should not expect to achieve those results
  - “results may vary” is inadequate disclosure



## Third Party Literature

- FTC does not regulate the content or accuracy of books, articles, or non-commercial literature
- FTC does prohibit the deceptive use of such materials in advertising
  - **FTC has jurisdiction if the primary purpose of using the literature is to propose a commercial transaction**

# FTC's Online Privacy Initiative

- Public Workshops since 1995
- Surveys of commercial Websites
- Annual reports to Congress since 1998
- Law enforcement actions
- Education of consumers and businesses

# Privacy & Genetic Testing

- 93% of consumers opposed the use of an individual's genetic information for research without prior consent

- Gallup Survey, August, 2000

# Privacy: Section 5 Law Enforcement Actions (e.g.)

- Geocities
  - Settled charges Web site misrepresented purposes for which it was collecting PII from children and adults
- Liberty Financial Companies, Inc.
  - Challenged allegedly false representations on “Young Investors” site that information collected from children in an online survey would be maintained anonymously

# Online Pharmacy: Privacy

- **FTC v. Rennert, et al., No. CV-S-00-0861 JBR (D. Nev. filed July 6, 2000)**
- **Represented to consumers that the information customers provided would be encrypted and that defendants use an SSL secure connection when transmitting this information over the Internet –**
- **Represented that they would use personal information only for medical consultations and billing for prescriptions and consultations –**



# Online Pharmacy: Privacy Order

- **Order prohibited these representations and required defendant to:**
  - **Establish and maintain reasonable procedures to protect the confidentiality, security and integrity of personal information collected from consumers;**
  - **Provide reasonable means by which a consumer may access and review personal information;**
  - **Provide reasonable means by which a consumer may modify inaccurate personal information or delete personal information**

# Pharmacy Order: Privacy Policy

- Clear and conspicuous disclosure of privacy policy covering
  - **Type of personal information obtained**
  - **Use of information and choices available to consumers**
  - **Means of access to information**
  - **Means to modify or delete information**
  - **Measures employed to ensure security**

# Eli Lilly settlement

- Eli Lilly Settles FTC Charges Concerning Security Breach
  - **unauthorized and unintentional disclosure of sensitive personal information collected from consumers through its Prozac.com and Lilly.com Web sites**
  - **Lilly to implement an information security program to protect consumers' privacy**

## Microsoft Settlement (2002)

- **Consequences can also be “potential” harm, rather than actual or realized harm**
- **“Passport” services had far less security than Microsoft represented**
- **consent order prohibits any misrepresentation of information practices in connection with Passport and other similar services. It also requires Microsoft to implement and maintain a comprehensive information security program. In addition, Microsoft must have its security program certified as meeting or exceeding the standards in the consent order by an independent professional every two years**

## Guess? (2003)

- False or misleading representations to consumers about the security of PII collected through Guess?'s online store
- Complaint alleged that Guess? misrepresented that PII it obtained from consumers through [www.guess.com](http://www.guess.com) was stored in an unreadable, encrypted format at all times
  - Representation false because a commonly known attack could and was used to gain access in clear readable text to sensitive personal information, including credit card numbers, that Guess obtained from consumers

# FTC Privacy Resources

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- [www.ftc.gov/privacy](http://www.ftc.gov/privacy)
- [www.ftc.gov/kidzprivacy](http://www.ftc.gov/kidzprivacy)
- [www.consumer.gov](http://www.consumer.gov)

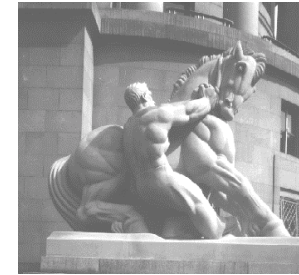
# HIV Home Tests

- E.g., **FTC v. Cyberlinx, Inc. and Jeffrey S. Stein** (Civ.Act.#CV-S-99-1564-PMP-LRL) (November 1999) (Nevada) (Stipulated Order)
- **Defendants falsely represented that their HIV home test kits accurately detected HIV**
- **Order bans defendants for life from marketing any HIV home test kits; defendants must pay back the money they received from the sale of their kits; and, if they sell other medical devices, they are required to post a \$500,000 bond.**

# Industry/Consumer Education

- Advertising Guidelines on [www.ftc.gov](http://www.ftc.gov)
  - Online: Rules of the Road
  - Dietary Supplements
- “Facts for Consumers”
  - Diet, Health & Fitness
  - “Home Use Tests for HIV Can Be Inaccurate”





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