



Online Direct-to-Consumer Genetic Testing

Sarah Botha
Division of Advertising Practices
Federal Trade Commission

**The opinions expressed are my own and do not represent
those of the FTC or individual Commissioners**



Regulation of DTC Genetic Testing in the U.S.

- Regulation of laboratories under CLIA
- Regulation of DTC genetic tests by FDA
- FTC's jurisdiction over DTC advertising of genetic tests
- FTC's method for evaluating promotional claims for health-related products



Clinical Laboratory Improvement Amendments of 1988

- In general, labs that process DTC genetic tests are subject to regulation by CMS under CLIA for compliance with general laboratory standards.
- Some DTC genetic tests (*e.g.*, fetal gender tests) may not fit within the definition of “laboratory” and may not require CLIA-certification.



FDA Regulation of DTC Genetic Tests

- Traditionally, FDA has exercised enforcement discretion with respect to LDTs
- May 10, 2010: Letter to Pathway Genomics
- June 10, 2010: Letters to 5 DTC genetic testing companies
- June 17, 2010: FDA issued a Federal Register notice announcing a public meeting to address FDA oversight of LDTs (75 Fed. Reg. 34463)



Advertising and the FTC

“The dissemination or the causing to be disseminated of any false advertisement . . . shall be an unfair or deceptive act or practice . . . under section 5 [of the FTC Act, 15 U.S.C. § 45].”

15 U.S.C. § 52(b)



Health Products and the FTC

“It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement . . . by any means . . . for the purpose of inducing . . . directly or indirectly, the purchase . . . of food, drugs, devices, services, or cosmetics.”

15 U.S.C. § 52(a)



FTC Legal Framework and Approach to Regulation

- Primarily a law enforcement agency
- No pre-market approval process
- No regulatory distinction between product categories



Advertiser's Responsibilities

- All objective claims must be substantiated *at the time they are made*
- Health- or safety-related claims must be substantiated with **competent and reliable scientific evidence** *at the time that the claims are made*



Policy Options under Consideration

- Control access to genetic tests for more serious conditions
 - FDA oversight process underway
 - Health Canada and other public health agencies could monitor and consult with FDA



Policy Options under Consideration

- Allocate resources to enforce existing consumer protection laws
 - Two FTC investigations of nutrigenetic testing companies closed in August 2009: Sciona, Inc. and Genelex Corporation
 - www.ftc.gov/os/closings/090814scionaclosingletter.pdf
 - www.ftc.gov/os/closings/090814genelexclosingletter.pdf
 - Difficulty in evaluating substantiation in area of emerging science



Policy Options under Consideration

- Enhance information availability
 - July 2006: FTC-FDA-CDC joint consumer fact sheet titled, “At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription”
 - Privacy and data security concerns: in the U.S., these companies generally fall outside of HIPAA protections



Policy Options under Consideration

- Wait and see
 - In cases of concrete fraudulent claims and egregious abuses, we would enforce now
 - Cancer cure Internet sweep
 - Eli Lilly consent order: data security breach
 - Non-compliance with privacy representations
 - For substantiation questions, we defer to FDA on the science



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Sarah Botha
sbotha@ftc.gov
202-326-2036

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Headlines

For Your Information: May 29, 2009
FTC Files Joint *Amicus* Brief in Matter of American Needle, Inc. v. National Football League; FTC Approves Final Consent Order in Matter of Whole Foods Market
The Federal Trade Commission has joined the U.S. Department of Justice in filing an *amicus* brief in the U.S. Supreme Court in the matter of *American Needle, Inc. v. National Football League, No. 08-661 (U.S. S. Ct.)*.

For Your Information: May 29, 2009
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FTC Provides Tips for Saving Money at the Gas Pump and Cooling Your Home

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