Online Direct-to-Consumer Genetic Testing

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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.
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
  - 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