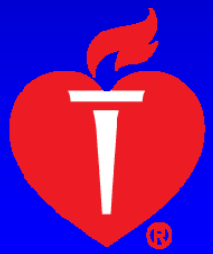


American Heart Association® | American Stroke Association®

Learn and Live®

American Heart Association. | American Stroke Association.
Learn and Live.

Oversight of Genetic Tests: a Congressional Perspective

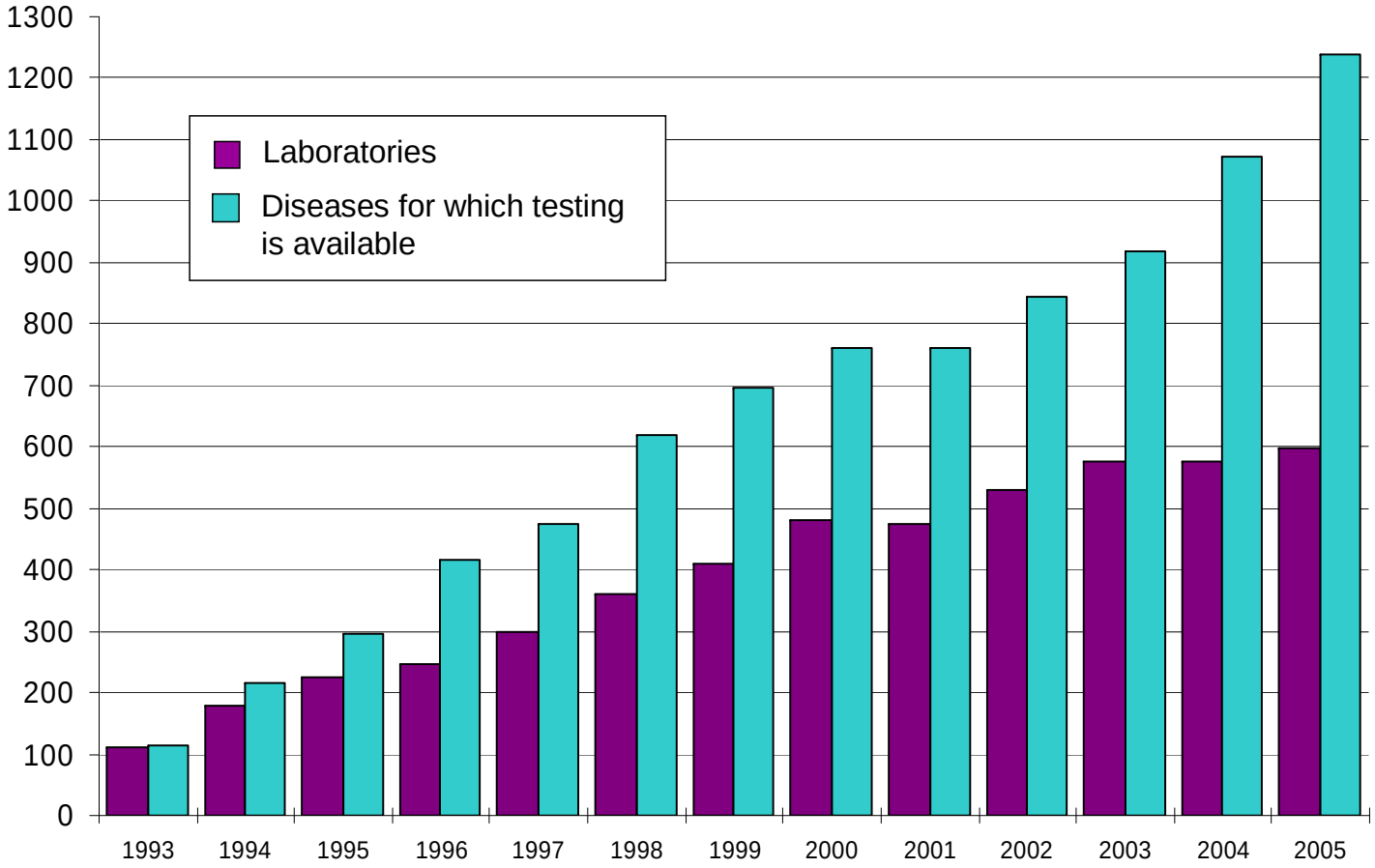
Derek Scholes,

Government Relations Manager,

American Heart Association

American Heart Association. | American Stroke Association.
Learn and Live.

GeneTests: Growth of Laboratory Directory



Data source: GeneTests database (2005) / www.genetests.org

American Heart Association. | American Stroke Association.
Learn and Live.

The landscape of tests

- Early genetic tests were for single gene disorders (e.g. cystic fibrosis.)
- Now, multi-gene tests for chronic disease are coming on the market (e.g. risk of heart disease, cancer, obesity)
- Also tests available for to aid disease treatment (e.g. dosage of the blood thinner coumadin)
- Also, ‘nutrigenomic’ tests, tests to predict gender, addictiveness to tobacco, and so on.
- Many tests now available direct to the consumer.

American Heart Association. | American Stroke Association.
Learn and Live.

Ongoing discussion on oversight of genetic tests

1997 Task Force on Genetic Testing

(National Institutes of Health/Department of Energy)

2000 Enhancing the Oversight of Genetic Tests

(Secretary's Advisory Committee on Genetic Tests)

2008 U.S. System of Oversight of Genetic Testing

(Secretary's Advisory Committee on Genetics, Health and Society)

American Heart Association. | American Stroke Association.
Learn and Live.

Terms of Art

Analytical validity – The extent to which a test is accurate and reliable.

Clinical validity – The degree to which a test result is medically meaningful.

Clinical utility – the extent to which the test can be used to improve health care.

Current Oversight of Genetic Tests

- Centers for Medicare and Medicaid Services
  - Regulate clinical labs.
  - Analytical validity

    proficiency testing for some tests

- Food and Drug Administration
  - Clinical validity of some tests
    - Testing kits (about a dozen on the market)
    - Multigene tests that involve an algorithm.

      ("In Vitro Diagnostic Multivariant Index Assays" - IVDMIA)

- Federal Trade Commission
  - False and misleading advertising

American Heart Association. | American Stroke Association.
Learn and Live.

Regulatory gaps

- Proficiency testing is not required, and analytical validity is not known, for all tests.
- Most tests are developed in laboratories and come to market without FDA review of clinical validity.
- Scientists and administration officials question the validity of many tests on the market.

2006 Senate Committee Hearing

Government investigation into ‘nutrigenomic’ genetic tests sold directly to consumers

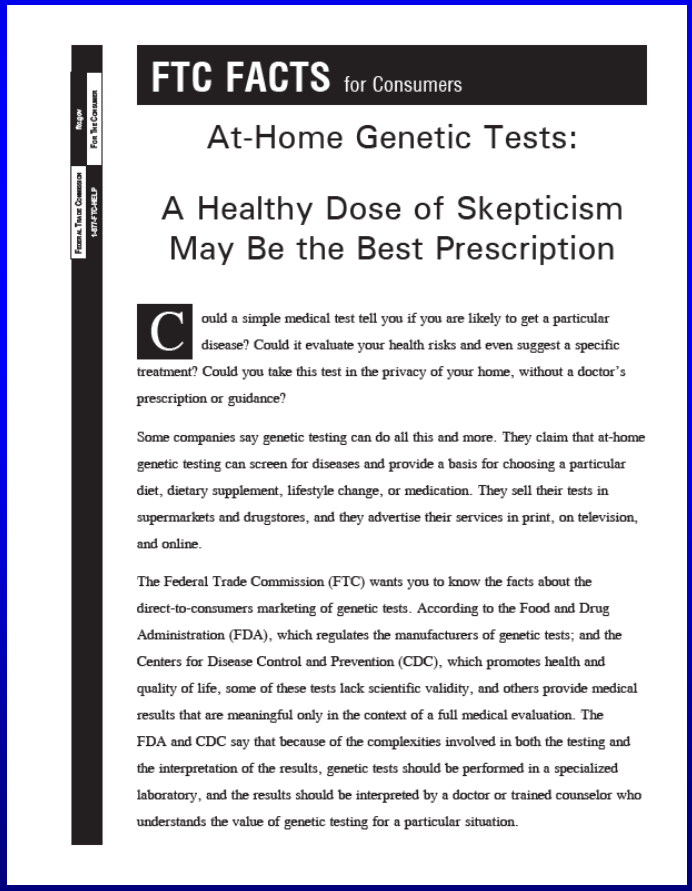
- **Identified several companies misleading and exploiting consumers by making unproven and meaningless predictions.**

'modern-day snake oil'
Senator Gordon Smith
Chair of Senate Special Committee on Aging

“genetic horoscope”
Thomas Hamilton
Director of Survey and Certification Group, CMS

American Heart Association. | American Stroke Association.
Learn and Live.

“Some of these tests lack scientific validity…Be wary of claims about the benefits these products supposedly offer.”



Federal Trade Commission
1-877-FTC-HELP

Bulk Rate
Postage & Fees Paid
Consumer

FTC FACTS for Consumers

At-Home Genetic Tests:

A Healthy Dose of Skepticism May Be the Best Prescription

Could a simple medical test tell you if you are likely to get a particular disease? Could it evaluate your health risks and even suggest a specific treatment? Could you take this test in the privacy of your home, without a doctor’s prescription or guidance?

Some companies say genetic testing can do all this and more. They claim that at-home genetic testing can screen for diseases and provide a basis for choosing a particular diet, dietary supplement, lifestyle change, or medication. They sell their tests in supermarkets and drugstores, and they advertise their services in print, on television, and online.

The Federal Trade Commission (FTC) wants you to know the facts about the direct-to-consumers marketing of genetic tests. According to the Food and Drug Administration (FDA), which regulates the manufacturers of genetic tests; and the Centers for Disease Control and Prevention (CDC), which promotes health and quality of life, some of these tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation. The FDA and CDC say that because of the complexities involved in both the testing and the interpretation of the results, genetic tests should be performed in a specialized laboratory, and the results should be interpreted by a doctor or trained counselor who understands the value of genetic testing for a particular situation.

American Heart Association. | American Stroke Association.
Learn and Live.

Challenges for Sen. Kennedy in legislating appropriate oversight

- There are several different types of tests.
  - Looking for a specific mutation.
  - Analysis of genetic sequence of many genes.
  - Detecting patterns of gene activity.
- Tests are being constantly updated to keep pace with the science.
- Some tests are only available through a physician's office; some are available direct to the consumer.
- Many tests are already available and being used.
- Overregulation may stifle innovation.

American Heart Association. | American Stroke Association.
Learn and Live.

Laboratory Test Improvement Act

Sens. Kennedy (D-MA) and Smith (R-OR)

- Establishes FDA oversight of all Laboratory Developed Tests related to health, categorizing them as medical devices.
- Mandatory submission of data:
  - Demonstrate analytical validity, clinical validity, intended use
- FDA Public registry of tests.
- Only tests sold directly to consumers (DTC) must undergo FDA review.
- FDA has the authority to require any test to go through regular review if they find submission data to be insufficient.
  - Only tests found to be without merit are removed from the market.
- Requires enhanced proficiency testing by CMS.

American Heart Association. | American Stroke Association.
Learn and Live.

Avoiding stifling innovation

- Upon enactment, only DTCs have to go through FDA review to remain on the market. All other tests remain on the market by default.
- New non-DTC tests can come to market without FDA review.
- The submission requirements for the registry are not onerous.
- If FDA requires a test (DTC or other) to go through review, the default procedure is of relatively low burden.
- No company need demonstrate clinical utility for their test before it comes to market.
- Enhanced reimbursement for FDA reviewed tests.
- Exemption from FDA lab inspections.

American Heart Association. | American Stroke Association.
Learn and Live.

Prospects for the Act

Very unlikely to pass this year.

- Has not moved through committee.
- Little time left
- Little support in Congress.
  - Only one cosponsor
  - No House companion bill
- Some opposition by industry.
- Patient advocacy groups not demanding it.

American Heart Association. | American Stroke Association.
Learn and Live.

Genomics and Personalized Medicine Act of 2007

Sens. Obama (D-IL) and Burr (R-NC)

- **Requires National Academies to provide recommendations for oversight.**
- **Requires Administration to determine which tests need review, and the manner of the review.**
- **Enhanced proficiency testing by CMS.**

American Heart Association. | American Stroke Association.
Learn and Live.

In the meantime…

2008 Secretary's Advisory Committee on Genetics Health and Society report recommends:

- **CMS expand proficiency testing**
- **FDA 'address all laboratory tests'**
- **Mandatory, publicly available, registry of all laboratory tests.**

American Heart Association. | American Stroke Association.
Learn and Live.

Derek Scholes
Government Relations Manager
American Heart Association
(00)-1-(202) 785-7927
derek.scholes@heart.org