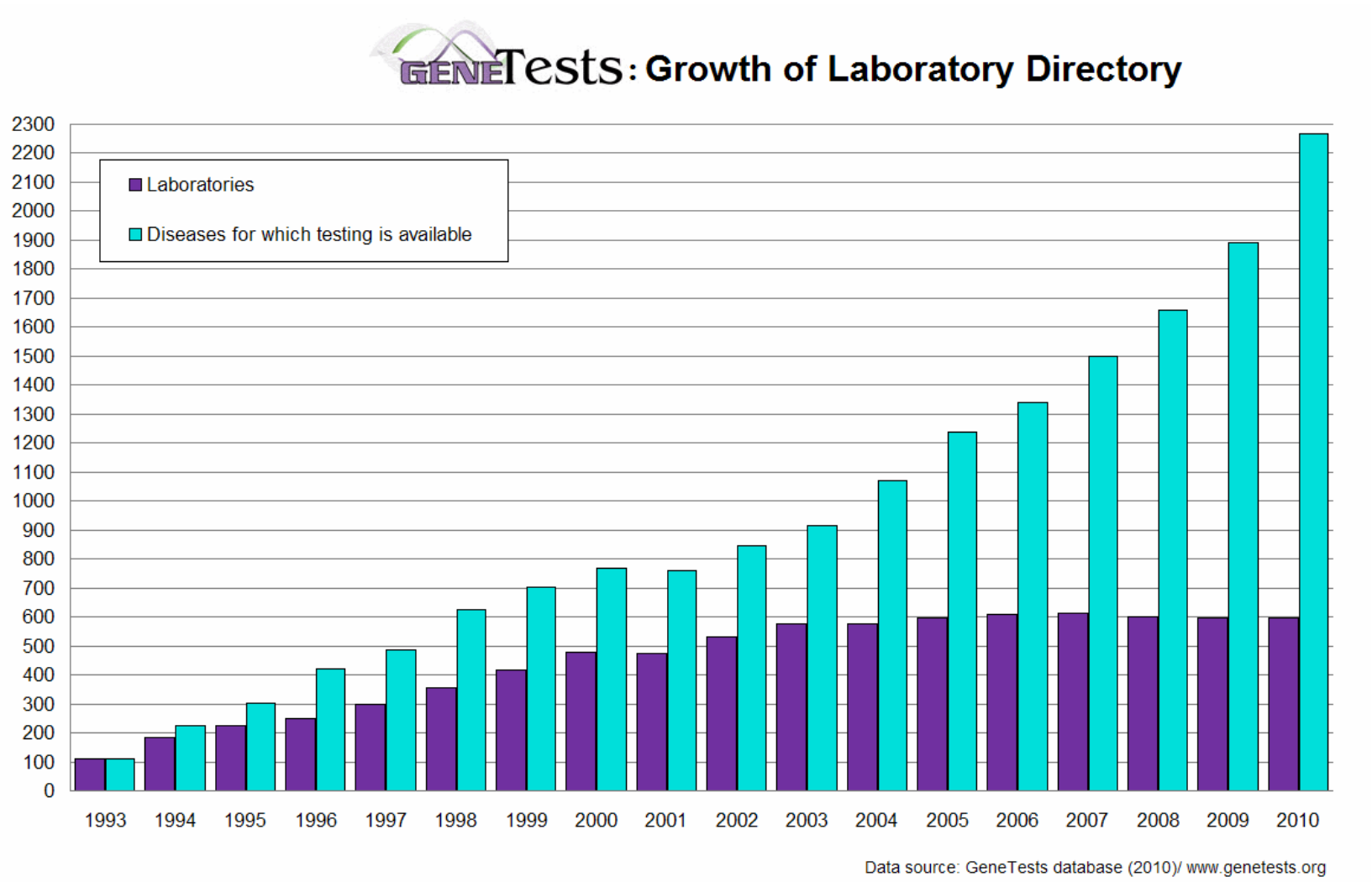
Regulating Direct-to-Consumer Genetic Testing: H.R. 5440's Failure to Get Noticed And How the FDA Might Resolve the Issue

Genetic Testing



Tests sold direct-to-consumer: Good or Bad?

- genetic testing more available
- results may trigger consumer to improve lifestyle

- not enough evidence for some test claims
- False positive result may lead to excessive screening
- False negative may prevent further screening

Current Oversight

- FDA has authority to regulate all medical devices, but no provisions specific to genetic tests
- FDA regulates kits, not lab developed tests (a.k.a. “home-brew”)
- As a result, most DTC genetic tests are unregulated

Should the industry be regulated?

YES:

- Protect consumers from false claims, ineffective tests
- Currently, unfair advantage for home-brew tests

NO:

- Tests just give you information, not diagnosis
- Oversight will stifle innovation

Legislative Attempts to Improve Oversight

- Laboratory Test Improvement Act of 2007 (strict)
- Genomics and Personalized Medicine Act ("soft")
  - Introduced by Senator Obama in '06, '07
  - Introduced by Representative Patrick Kennedy in '08, '10
- None were reported by committee

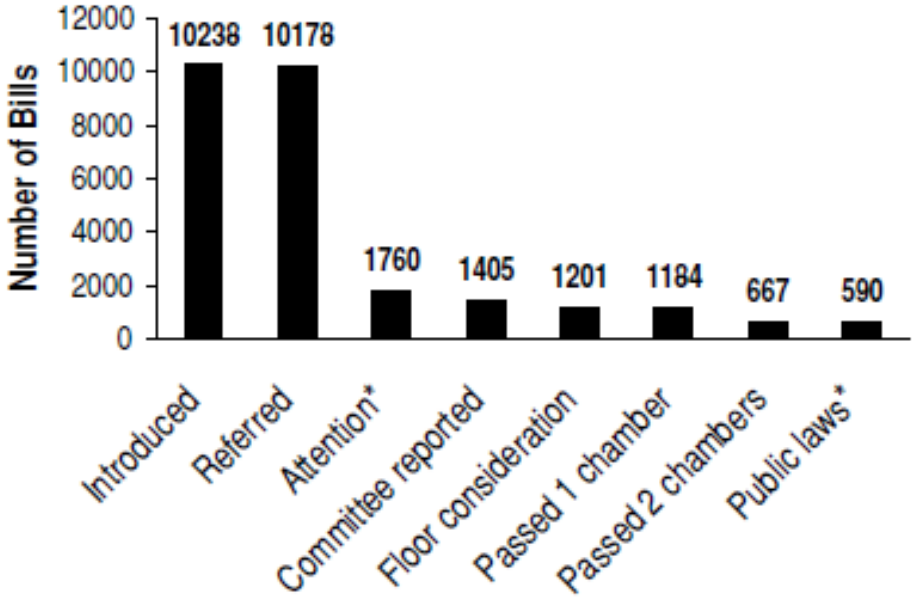
The Genomics and Personalized Medicine Act of 2010 (H.R. 5440)

- Provision addresses DTC genetic testing:
  - By requiring the CDC, FDA, and FTC to analyze the public health impact of the industry and make recommendations to protect consumers from harm.

- Introduced May 27, 2010 by Rep. Kennedy & Eshoo
- Referred to House Committee on Energy and Commerce
- Never reported → died at conclusion of Congress

Importance of Pre-Floor Process & Success Factors

FIGURE 1 Winnowing of Bills, 102nd Congress



Source: Congressional Research Service except for categories demarcated with a "*," which were compiled by the author from archival sources.

Success Factors:

- Publicity/Urgency around issue
- Influence of Sponsor
- Co-sponsorship

Krutz, Glen S. 2005. *Journal of Political Science* 49(2): 313–326.

Plenty of media attention on DTC genetic testing

- "Direct-to-Consumer genetic test kits coming soon to a drug store near you" (*Los Angeles Times*. May 11, 2010)
- "Pathway Genomics to Offer Retail Genetic Testing Kits At Walgreens" (*BusinessWire*. May 11, 2010.)
- "Walgreens won't sell over-the-counter genetic test after FDA raises questions." (*Washington Post*. May 13, 2010.)
- "F.D.A. Faults Companies on Unapproved Genetic Tests." (*The New York Times*. June 11, 2010)

Why did H.R. 5440 fail to move forward?

- Lack of urgency
  - DTC genetic testing an issue, not a crisis
  - Media attention ≠ public demand for oversight
  - FDA activity, so issue already being addressed
  - H.R. 5440 overarching goal is to incentivize personalized medicine- not pressing issue
- Lack of influential sponsor
- Lacked lots of diverse co-sponsors

FDA to Increase Oversight

- In a meeting on LDTs in July 2010, FDA concluded that it should implement its regulatory authority over LDTs
- FDA is currently proceeding on drafting guidance for DTC genetic testing.
- "probably not going to be able to take one approach to all the types of tests that the companies want to offer… it depends on the disease and the type of test."

Peterson, Molly. 2011. Home Gene Test Kits May Need Doctor Review, U.S. Rules, FDA Official Says. *Bloomberg*, March 9.

Principle Actors in Policy Debate: Opponents

- DTC genetic testing industry
  - Favor mild regulation… want stability and predictability
  - "overbroad regulation can chill genomic discoveries… driving innovation and investment to other countries."

Navigenics

23andMe

- Vanier, Vance. 2010. Testimony delivered before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, July 22.

Principle Actors in Policy Debate: Proponents

- Few DTC genetic testing companies
- FDA
  - Tests pose danger to consumers
  - Lack of regulation stifles innovation
  - Prefer to decide on regulation independently, without Congressional involvement

- Representatives Patrick Kennedy and Anna Eshoo
  - Want to incentivize personalized medicine and enhance regulation, but don't take firm position on level of oversight

Prospects for future legislation?

- Factors:
  - Regulatory environment: FDA decision on oversight
  - Fiscal environment: no appetite for “incentivizing personalized medicine” in current economic situation
  - Salience of issue to Congress
  - Does legislation align with one party’s ideology or does it appeal to both parties?
  - Which party is in the majority?

Questions? Comments?

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