

Medicine: Now It's Personal

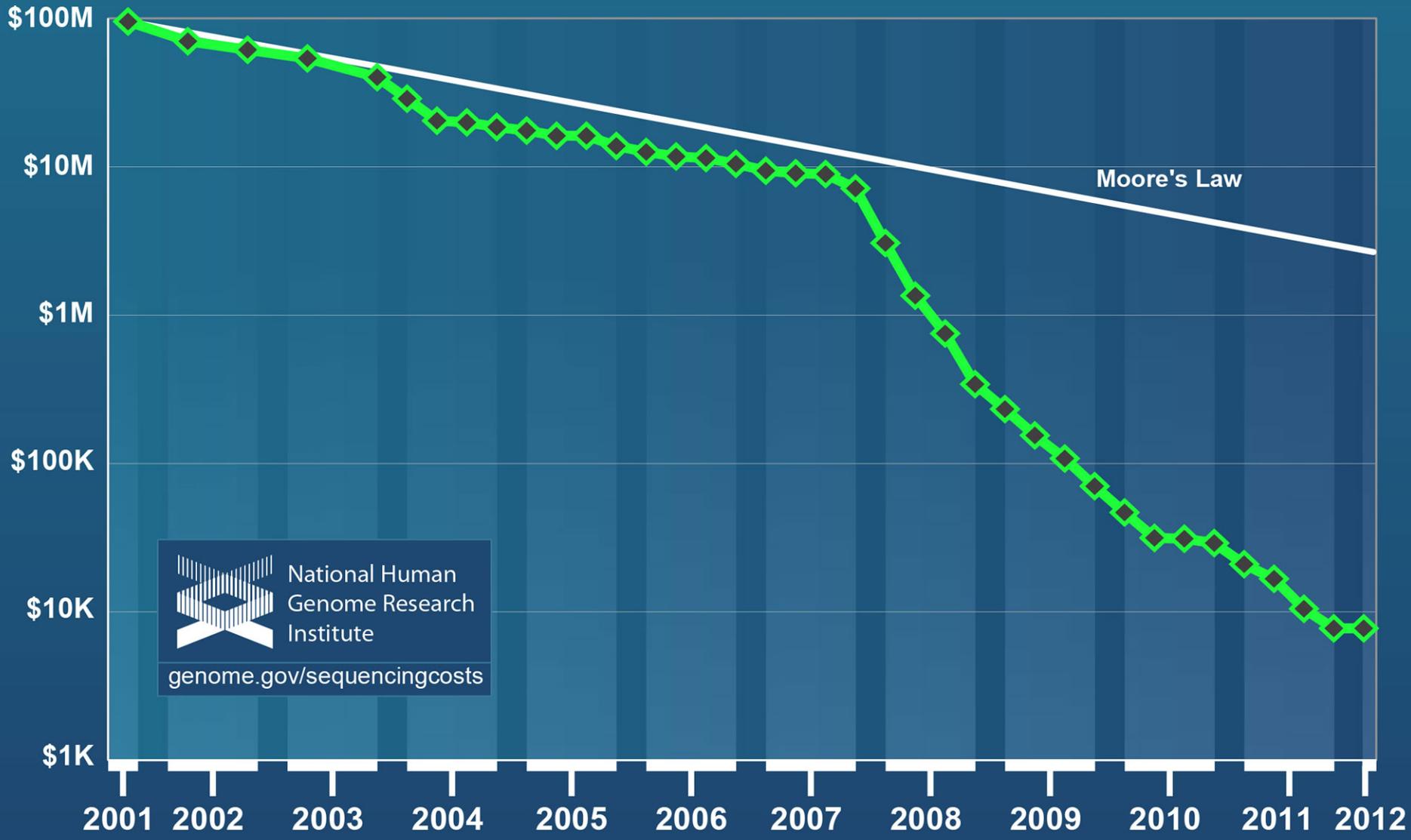


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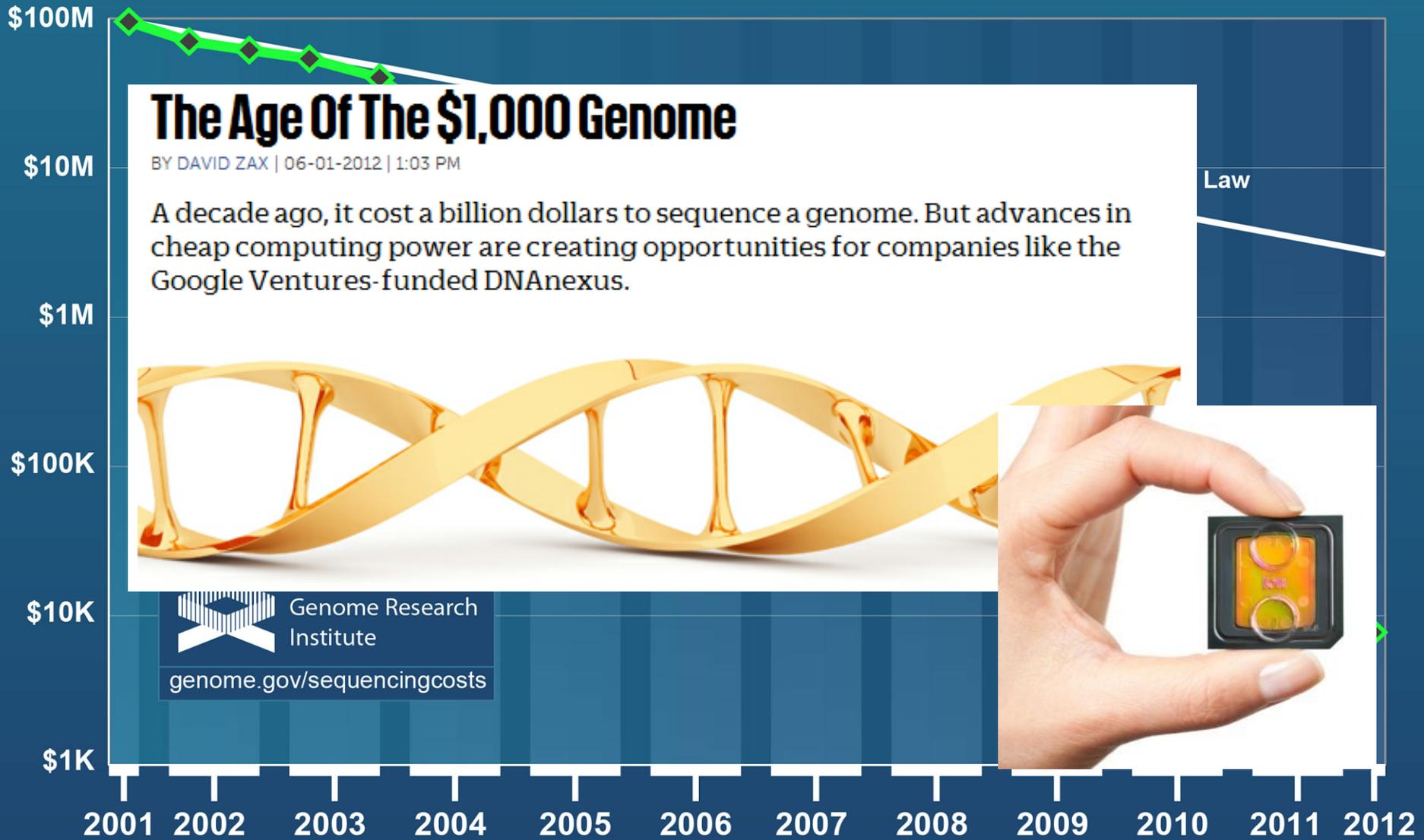
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Cost per Genome



 National Human
Genome Research
Institute
genome.gov/sequencingcosts

Cost per Genome



The Promises of Personalized Medicine

NATURE | CORRESPONDENCE

Biologics: Personalized drugs should cut care costs

Nafees N. Malik

Nature
Publish **Cost of Gene Sequencing Falls, Raising Hopes for Medical Advances**

By JOHN MARKOFF

Published: November 16, 2010, 9:50 AM | 4 Comments

Drug Companies Pursue Personalized Medicine Approach

By ANDREW POLLACK

Direct-to-Consumer Genetic Testing

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March 30, 2012, 3:38 PM

When Medicine Really Gets Personal: The DIY Clinical Trial

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Legislation and Federal Efforts

- **National Center for Advancing Translation Sciences (NCATS) at National Institutes of Health (NIH)**
 - Established by NIH in 2012
 - “catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.”
- **H.R. 3497: MODDERN Cures Act of 2011**
 - Helps to speed access to and delivery of novel tests and treatments
- **FDA User Fee Act**
 - Creates expedited approval process for “breakthrough therapies” developed using biomarkers



Guiding Questions

- What reforms are needed for direct-to-consumer genetic tests?
- How do we better ensure the protection & privacy of genetic data and other personal health information obtained from research and clinical practice?
- Do we need stronger regulations to prevent discrimination or stigmatization?
- How can we ensure effective public education about promises & limitations of personalized medicine?

Inconsistent Results, Inaccurate Claims

- GAO 2010 Report: *Direct-To-Consumer Genetic Tests*
 - Purchased tests from 4 companies; compared results for 15 common diseases; 5 undercover customers
 - One 48 year old male: below-average, average, and above-average risk for prostate cancer and hypertension
 - 10 egregious examples of deceptive marketing, including using DNA to create personalized supplement to cure diseases

Just Say No to DTC Testing



- EASAC and FEAM report
 - *“all kinds of genetic testing require an appropriate and relevant level of professional advice. On the whole, DTC GT has little clinical value at present and, on occasion, has potential to be harmful. We would not wish to encourage EU citizens to use DTC GT at present.”*

Further Issues for the Public

- Genetic determinism
- Personal information vs family information
- Autonomy vs. knowledge
- Behavior change?
- Electronic health records
 - collection and sharing of health data
 - Privacy
- Discrimination and stigmatization
 - Limits of GINA

Public Understanding

- 2010 study in *Public Health Genomics*
 - Majority never heard of “genomic medicine” and unfamiliar with “personalized medicine”
 - Expressed concerns about lack of affordability; unanticipated physical harm; mistrust of the government & researchers; playing God/disturbing the natural order; lack of regulations; privacy; discrimination; and moral dilemmas about genetic engineering
 - Unsure about whether they would change health behaviors with more information
 - Expressed strong interest in learning more about genetic testing and personalized medicine

Hah, et al. “A Community's Awareness and Perceptions of Genomic Medicine.” *Public Health Genomics*. 2010; 13(2):63-71.

Key Focus Group Findings

- **Familiarity**: “Cracking Your Genetic Code” significantly increased familiarity with biotechnology and bioethics. After viewing the program, two-thirds of the general population sample and three-fourths of the PBS viewer sample were familiar with biotechnology and bioethics. Furthermore, viewing closed the gap in familiarity between bioethics and biotechnology. Prior to viewing, familiarity with biotechnology was significantly higher than that for bioethics.
- **Attitudes towards having and raising children**: There was a significant increase among the general population and PBS viewers on one item—that people should only be allowed to use genetics to select traits in embryos that prevent life-threatening conditions.
- **Attitudes towards living as an adult**: Several significant increases in agreement on privacy issues, such as genetic testing is personal, not a family decision; genetic test results should be confidential; and the concern that employers and insurance companies could make decisions based on genetic test results.
- **Attitudes towards end of life decisions**: No significant changes across both samples. The general population decreased on wanting to know if they had Alzheimer’s and the PBS viewers increased on not wanting to burden family about risk of deadly disease, and on the notion that knowledge of future health reduces current quality of life.

Recommendations

- Increase regulation and oversight of DTC genetic tests by FDA to require medical consultation for all tests and improve effectiveness and clinical utility studies to reduce discrepancies.
- Create new protections for genetic information to ensure that patients are informed every time that their health data is shared with a third party, including other clinicians.
- Expand public education efforts around genetic information to dispel misconceptions (including genetic determinism) and better inform them about the complexities of interpreting and understanding genetic information.



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