



# Public Policy Issues Surrounding Personal Genome Services

SACGHS Meeting  
July 8, 2008

Kathy Hudson  
Genetics and Public Policy Center  
Johns Hopkins University

# Evolution of DTC Genetic Testing

Focus on Health-Related DTC Genetic Tests



Fetal Gender



Inherited



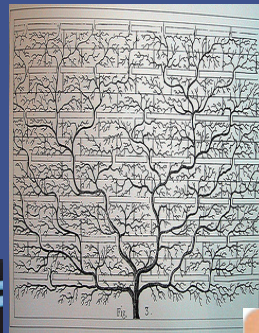
Pharma



Complex Disorders



Paternity



Ancestry



Nutrition



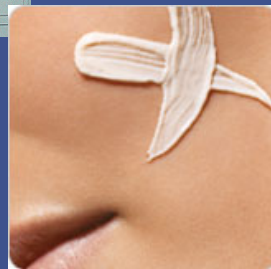
Athletic perf.



Complex Conditions



Infidelity



Skin care



Recreational



Infertility



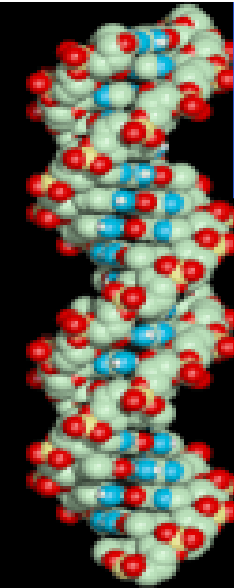
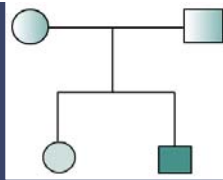


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# Breakthrough Genetic Profiling

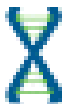


**Gene - Testing Now Available**

 **Navigenics**

**GENETICS IS ABOUT TO GET PERSONAL**

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# New Paradigm in Genetics?

Frank and Ernest





## Old Precepts of Genetic Medicine

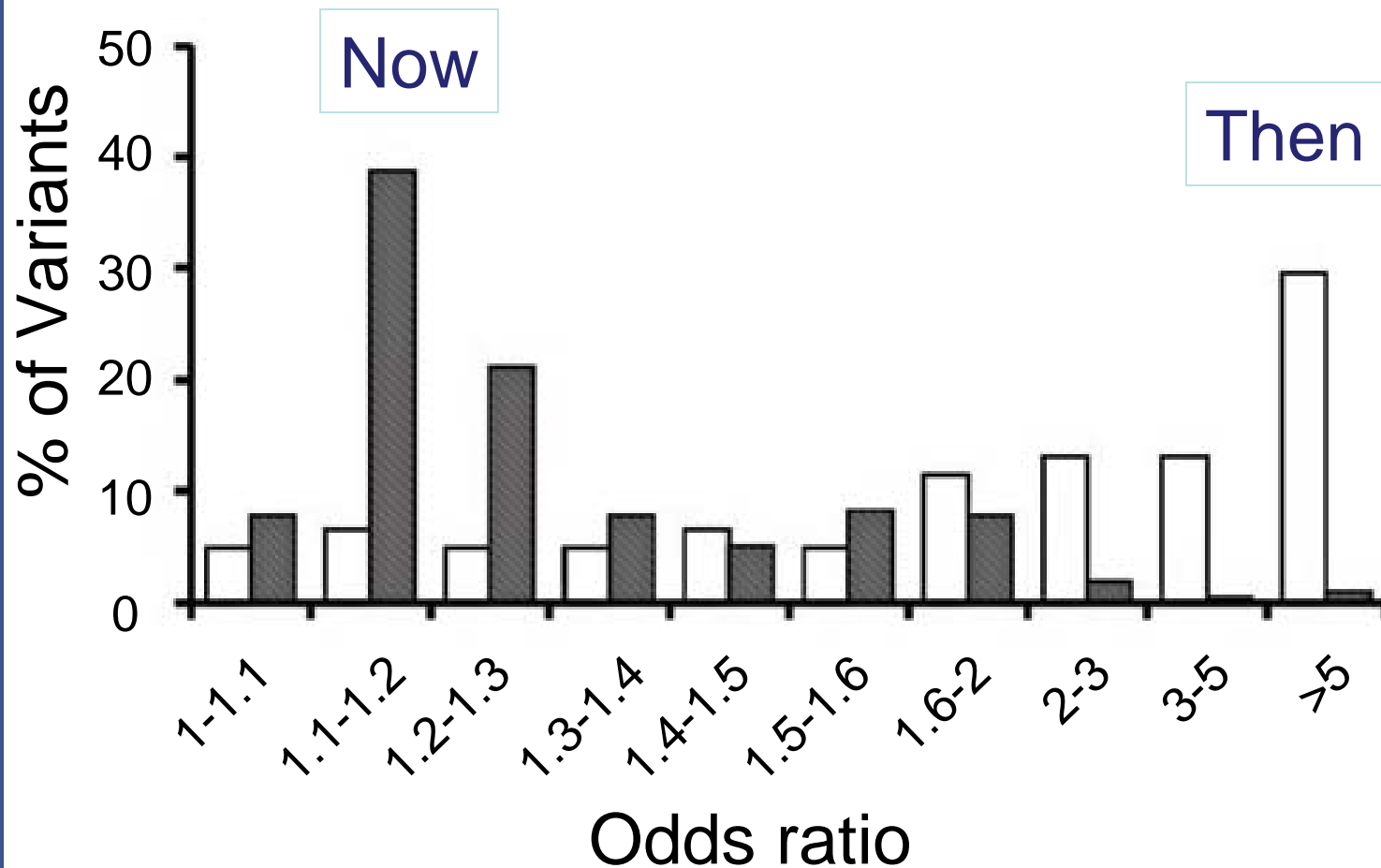
1. Requirement for pre and post-test genetic counseling
2. No genetic test can be offered or interpreted without a trained health care professional
3. Genetic tests for “non actionable” conditions are the highest risk – information as toxic
4. Genetic information is special

# Old Precepts of Genetic Medicine

1. Requirement for pre and post-test genetic counseling
  - Too many genes, not enough genetic counselors
  - We can't afford it
  - Model based on reproductive genetic testing and Huntington may no longer work (e.g. PGx for OTC drugs or disease associations with tiny odds ratios)



□ Rare    ■ Common



## Old Precepts of Genetic Medicine

2. No genetic test can be offered or interpreted without a trained health care professional
  - Not all genetic tests are created equal.
  - Not viable with high consumer interest?
  - Not consistent with some State laws

## Old Precepts of Genetic Medicine

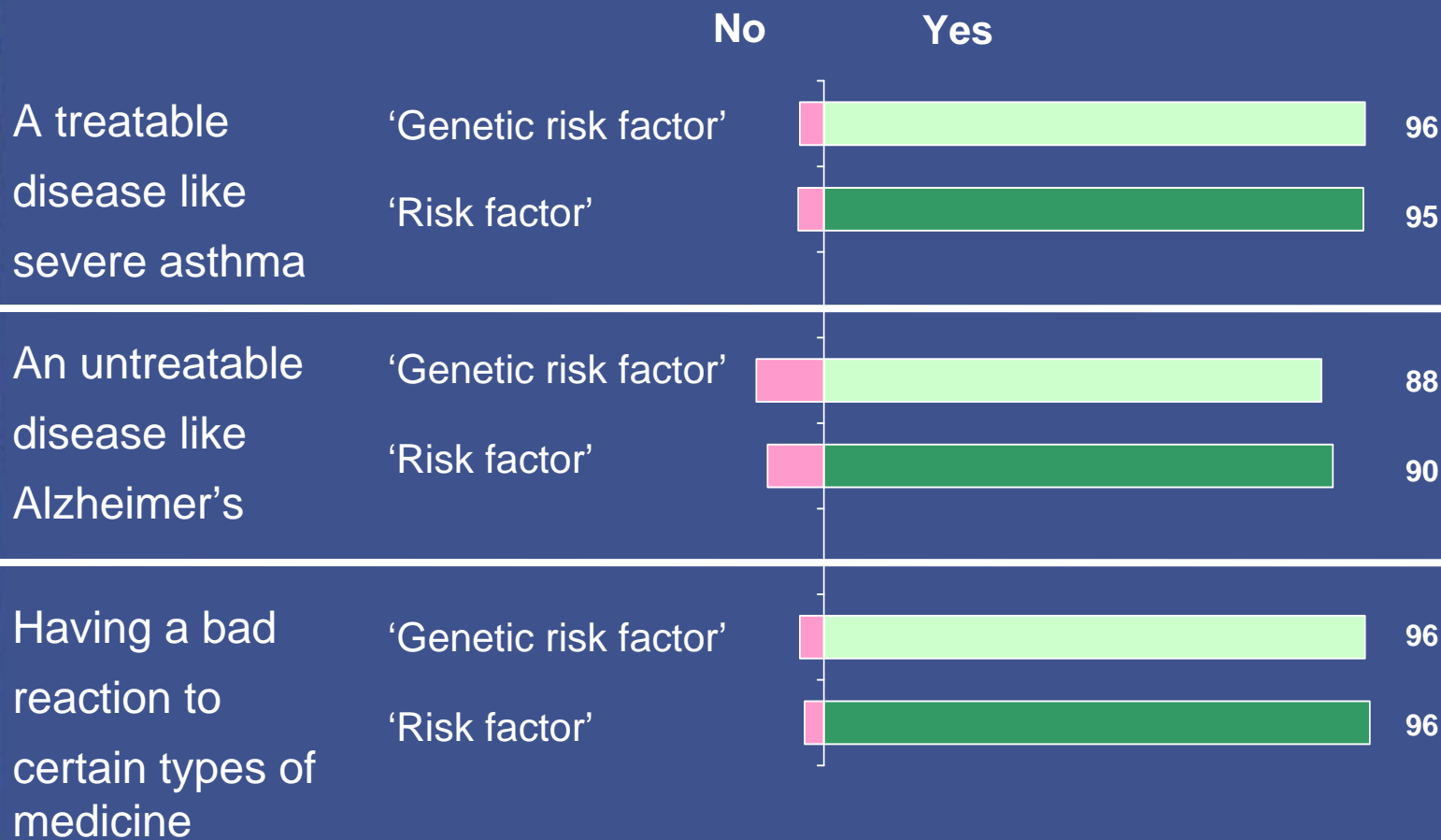
3. Genetic tests for “non actionable” conditions are the highest risk – information as ‘toxic’
  - Alzheimer risk does not result in suicide, heightened anxiety, etc.
  - Validity of tests used in making significant medical management decisions of utmost importance



# Old Precepts of Genetic Medicine

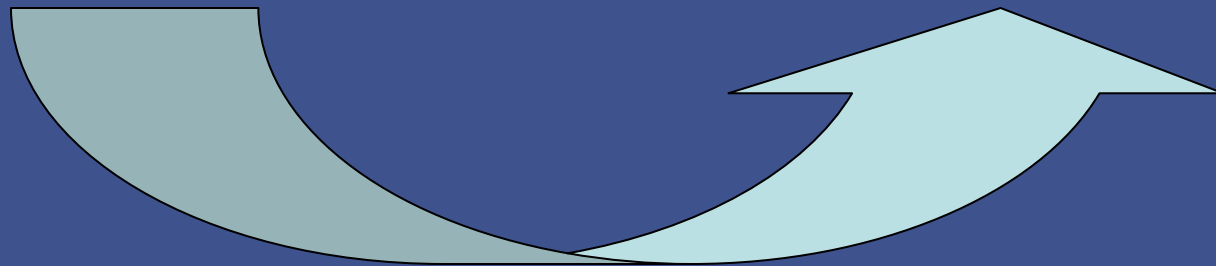
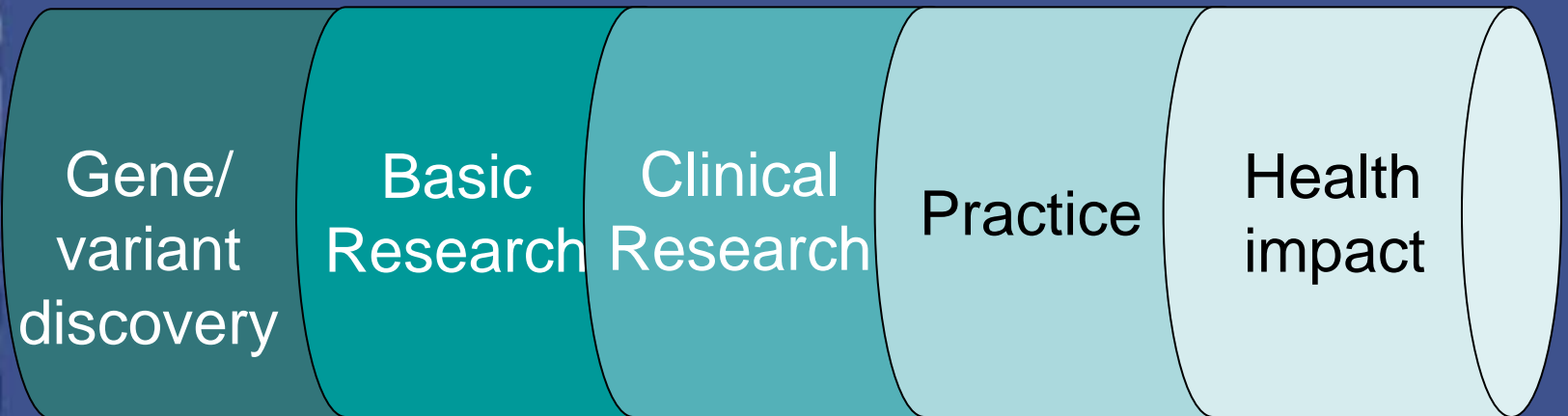
## 4. Genetic information is special

# Would you want to know if researchers found that you [have a genetic risk factor for/ were at increased risk for]



GPPC 2008, n=4,659

## The Old Way



## The New Way



# Creative Destruction???

Joseph Schumpeter (1883-1950)

Transformation through radical innovation and entrepreneurship.

“process of industrial mutation that incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one.”

# What should our response be?

1. Get your genome done.
2. Start your own company.
3. Ignore them. “They are just a nuisance.”
4. Insult them.
5. Support needed policies changes.

# Promise of Personalized Medicine and Direct-to-Consumer Genetic Testing

- Source of information for consumers
- Direct access
- Personal control
- Opportunity for entrepreneurs

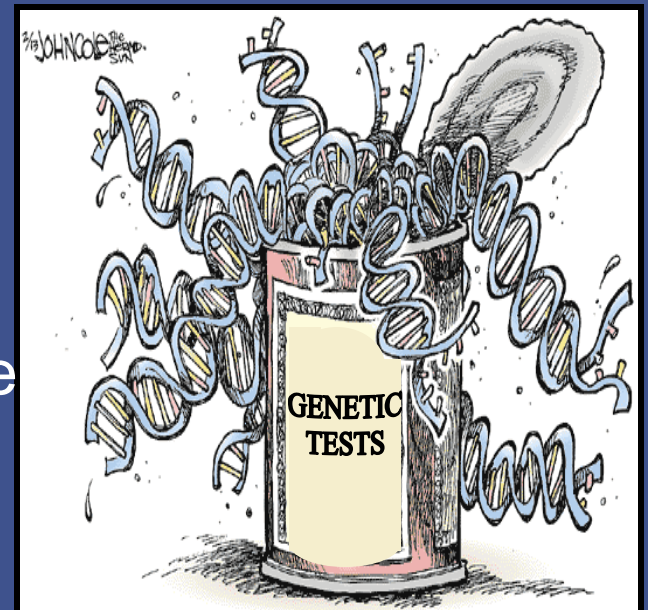




# Concerns About DTC Marketing

- Consumers can't understand genetic information; it is complicated.
- Consumers vulnerable to exaggerated claims.
- Consumers may get tested without adequately considering consequences to themselves and family
- Consumers may forego standard treatments or make dietary or lifestyle changes without proven benefit
- Consumers may seek and receive unneeded and costly care

Need empirical data



# Concerns About DTC Marketing

- Companies may not adequately protect privacy of genetic information
- The tests that are offered may not be valid
- The laboratories that perform the tests may not be competent
- Test claims unsupported by evidence
- Inadequate protections for research participants
- No legal barrier to surreptitious use of another's genetic information

# Current Oversight of Genetic Testing



A fractured oversight system, with many cracks, that endangers the public's health

# Problems with Federal Oversight of Genetic Testing (LDTs)

- No PT requirement
- No review of clinical validity (except IVDMIAAs, maybe....)
- No HHS authority over false claims
- No FTC enforcement action
- “Two path” system to market disincentive to seek FDA review; lack of regulatory “level playing field”



# Problems with Federal Oversight of Genetic Testing (LDTs)

- Lack of clarity on who is authorized or should be authorized to order and interpret tests
- Limited applicability of HIPAA
- Not subject to common rule for protection of research participants

# The Role of Professional and Industry Guidelines

More rapid and flexible than government

Have appropriate scientific expertise

May have conflict of interest

No enforcement capability

# ASHG Statement on DTC

1. Not all genetic tests are created equal
2. Appropriate that some tests be offered DTC (diagnostic equivalent of “over the counter” medicines)
3. Safety first!

# ACMG Statement on DTC

April 7, 2008

- A knowledgeable professional should be involved in the process of ordering and interpreting a genetic test.
- The consumer should be fully informed regarding what the test can and cannot say about his or her health.
- The scientific evidence on which a test is based should be clearly stated.
- The clinical laboratory must be accredited by CLIA, the state and/or other applicable accrediting agencies.
- Privacy concerns must be addressed.



# AMA Resolution on DTC

## D-480.987 Direct-to-Consumer Genetic Testing

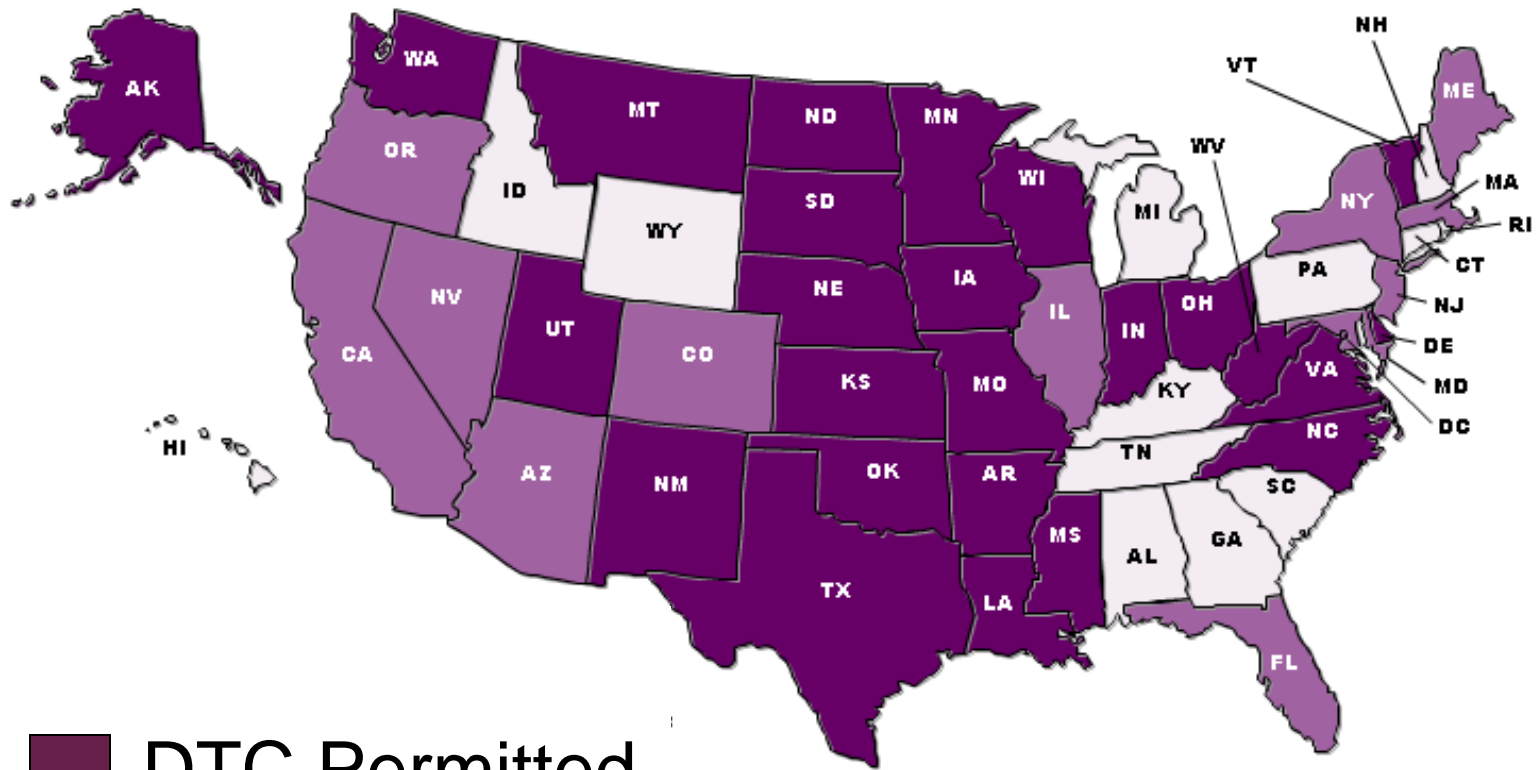
Our AMA: (1) recommends that states restrict the performance of clinical and laboratory **genetic** testing to individuals under the personal supervision of a qualified health care professional; and




(2) will work with all appropriate other organizations to discourage direct-to-consumer **genetic** testing. (Res. 502, A-04)

# The Role of States

- States administer CLIA
- States can impose higher standards (e.g., NY) and can require state-specific certification (e.g. CA)
- States determine who is “authorized person” to order and receive results of laboratory tests

# State DTC Testing Statutes and Regulations



-  DTC Permitted
-  Limited
-  DTC Not Permitted

Source: Genetics and Public Policy Center, <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>



■ DTC Permitted

Many state laws do not address the issue of who may order/receive results of laboratory tests.

■ DTC Not Permitted

Georgia: Tests must be ordered and reported as directed by a “licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations.”





## ■ DTC Not Permitted

California: “Any person conducting or operating a clinical laboratory may accept assignments for tests only from and make reports only to persons licensed under the provisions of law relating to the healing arts or their representatives.” Exceptions provided for limited tests (e.g., glucose, pregnancy).

In the absence of federal leadership, the states have stepped in.

# San Jose Mercury News

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MER

The Dallas Morning News

Genetic-t  
FEDER/

By Steve Johnson

Until California's recent  
consumer genetic testing

# The New York Times

T

## Gene Testing Questioned by Regula

June 26, 2008

Califor

By Todd Wallack

California regulators warned  
including Knome Inc. in Caml  
products in California unless  
and testing laws.

The California Department of Public Health warned the  
companies that they must obtain a clinical laboratory licens  
before conducting medical tests for Californians. In additio  
agency said the companies cannot offer laboratory tests d  
to California consumers without a doctor's order.

"Knome is in violation of California law," the agency warn  
"Genetic tests are not exempt" from rules requiring a  
physician's approval, it said.

Knome is one of more than a dozen companies that have  
offered to analyze an individual's DNA for markers related

Regulators are cracking down on companies that sell gene  
directly to consumers, threatening to crimp the growth of o  
hottest sectors of the biotechnology industry.

but be of little help in preventing illness

By Barb Berggoetz

Saliva swabbed from your cheek or spat into a  
vial can reveal your risk of Alzheimer's disease,  
diabetes and myriad other conditions, or pinpoint  
your body's nutritional weak spots.

Would you want to know?

she'll find out if she's at risk for 12 cor  
weaknesses, such as joint inflammati  
antioxidant levels or heart problems.

"It's not saying this is going to happen  
saying this is one of your body's area  
want to pay attention to," McClure-Sm

# Policy Options

- Buyer beware
- Demand transparency: information as the antidote
- Require third party review of accuracy and safety
- Take action against false claims
- Create a category of OTC LDTs
- Expand HIPAA
- Expand common rule



# The Pew Charitable Trusts

