

Public Policy Issues Surrounding Personal Genome Services

SACGHS Meeting
July 8, 2008

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Genetics and Public Policy Center
Johns Hopkins University

Evolution of DTC Genetic Testing

Focus on Health-Related DTC Genetic Tests



Fetal Gender



Inherited



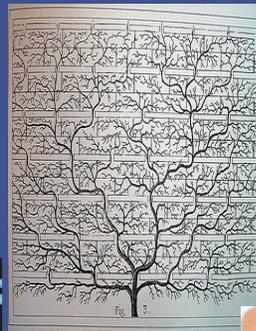
Pharma



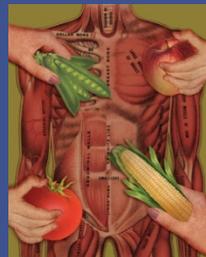
Complex Disorders



Paternity



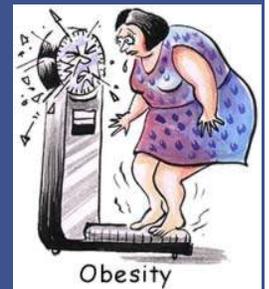
Ancestry



Nutrition



Athletic perf.



Complex Conditions



Infidelity



Skin care



Recreational



Infertility



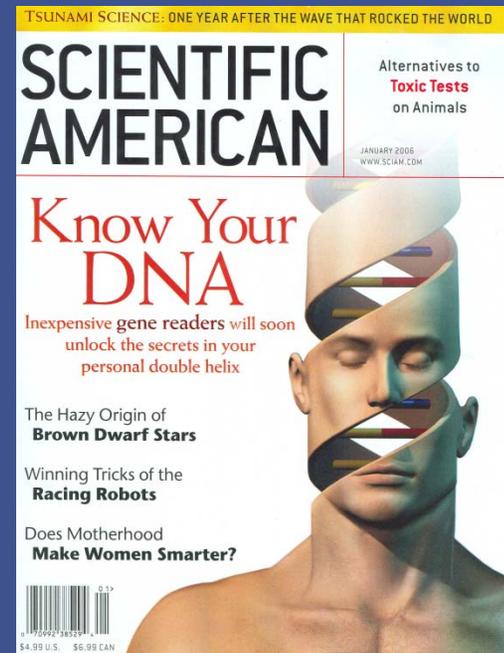
Newsweek Technology & Science

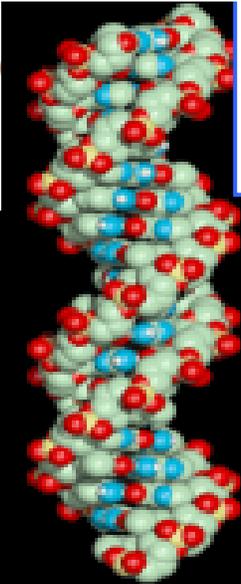
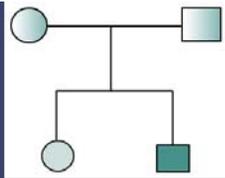
Reading the Book of Jim

The co-discoverer of the double helix is making his DNA public, pioneering the 'personal genome.'



Know thyself.





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Learn about genetic testing for hereditary breast and ovarian cancer.

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GENETICS IS ABOUT TO GET PERSONAL

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New Paradigm in Genetics?

Frank and Ernest



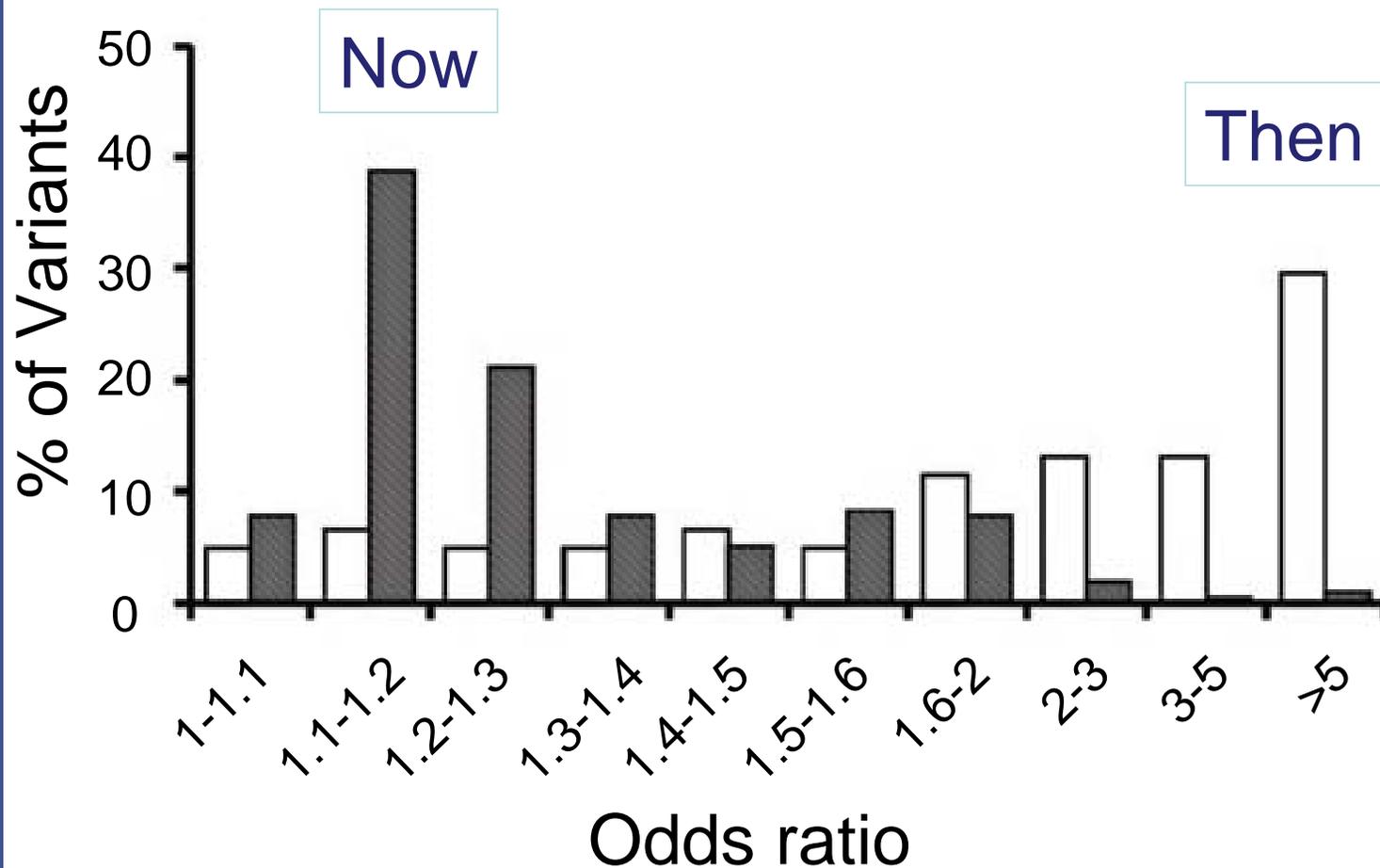
Old Precepts of Genetic Medicine

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

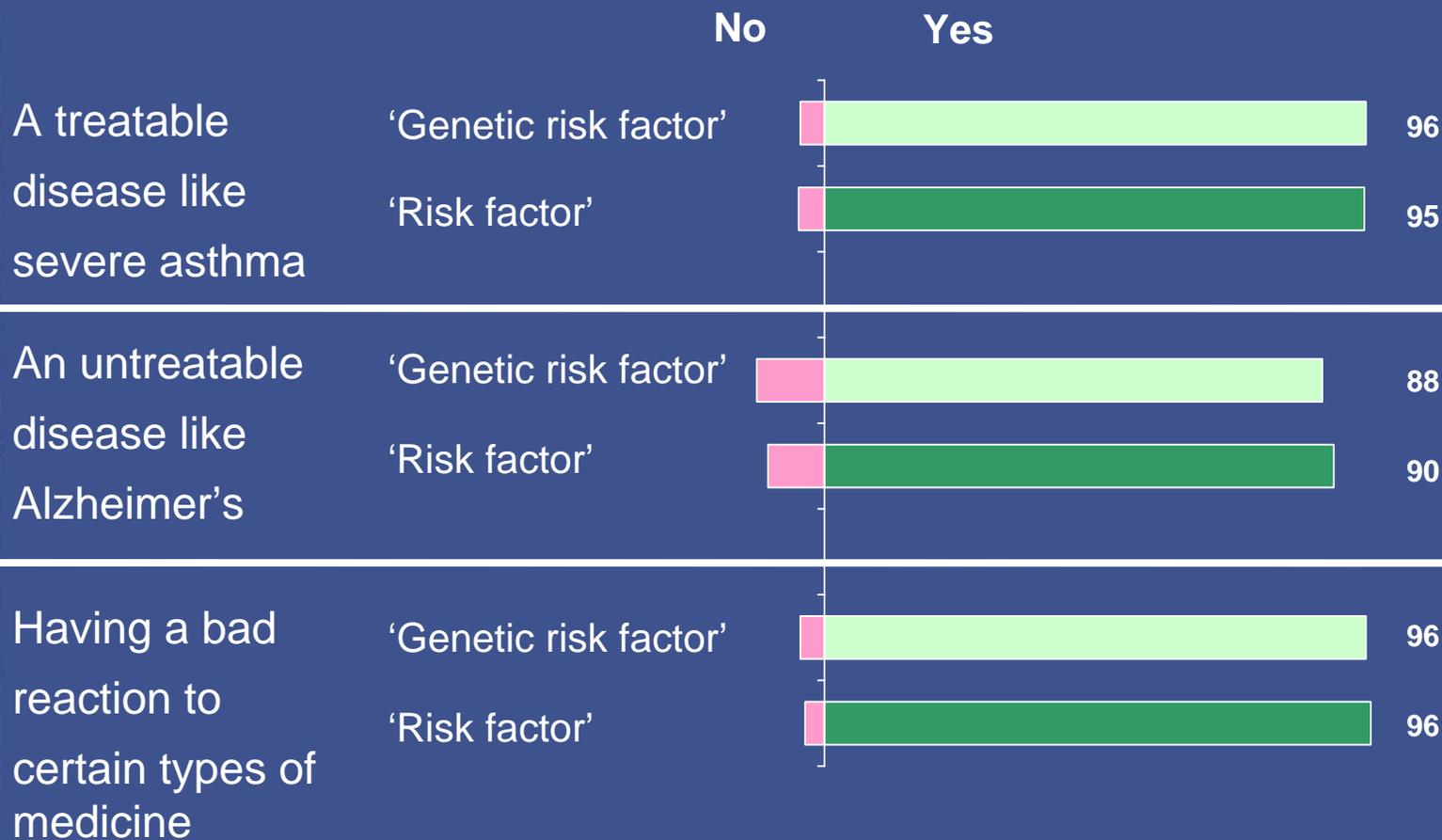
Old Precepts of Genetic Medicine

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

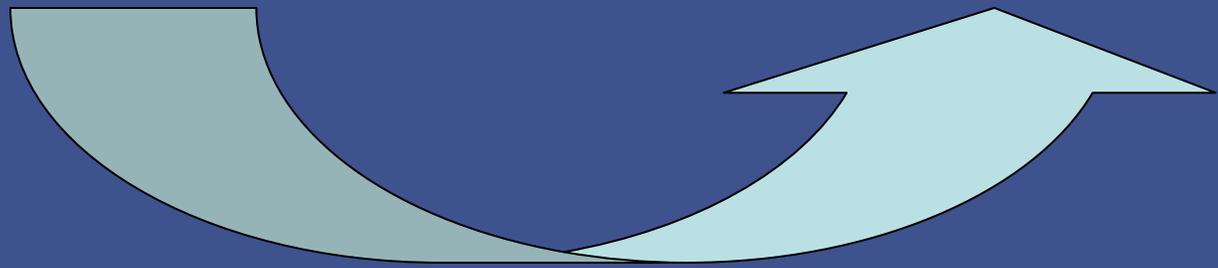
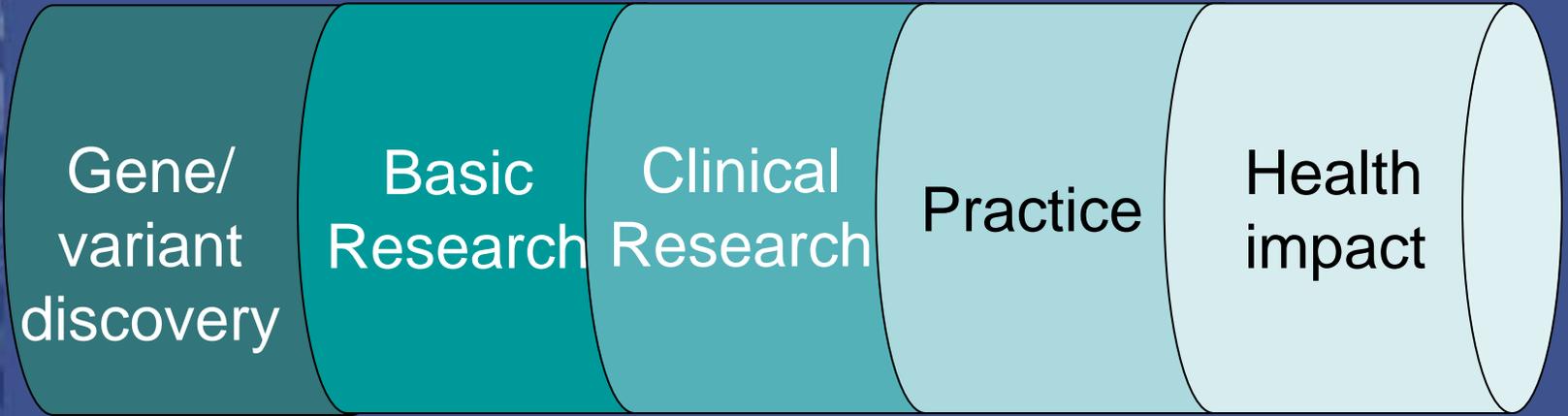
4. Genetic information is special

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

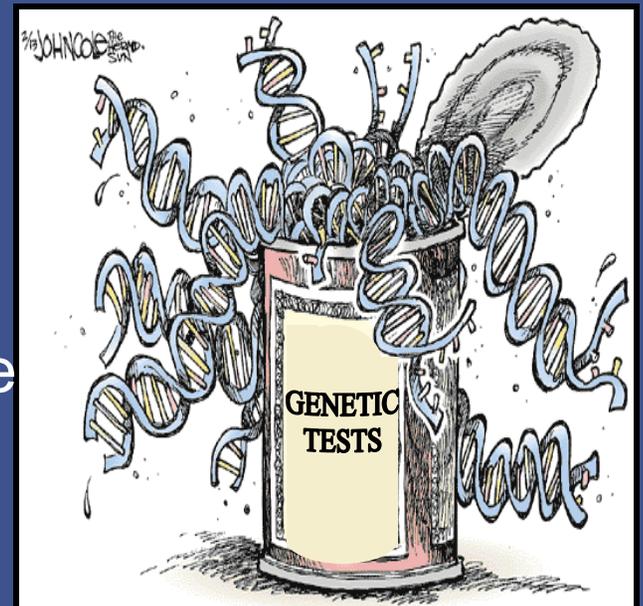
- Source of information for consumers
- Direct access
- Personal control
- Opportunity for entrepreneurs



Concerns About DTC Marketing

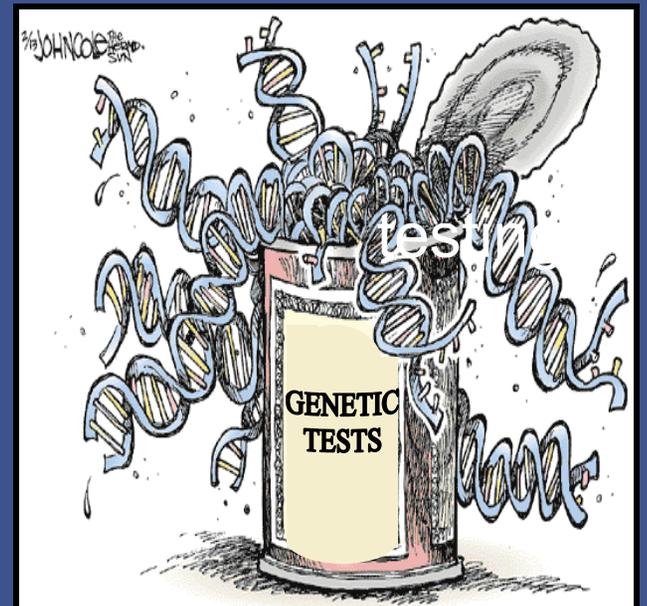
- Consumers can't understand genetic information; it is complicated.
- Consumers vulnerable to exaggerated claims.
- Consumers may get tested without adequately considering consequences to themselves and family
- Consumers may forego standard treatments or make dietary or lifestyle changes without proven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



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



■ 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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The Dallas Morning News

Genetic-t
FEDER/

By Steve Johnson

Until California's recent
consumer genetic testing

The New York Times

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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

