

Genomics to Health: Opportunities for public engagement and public policy enhancements.

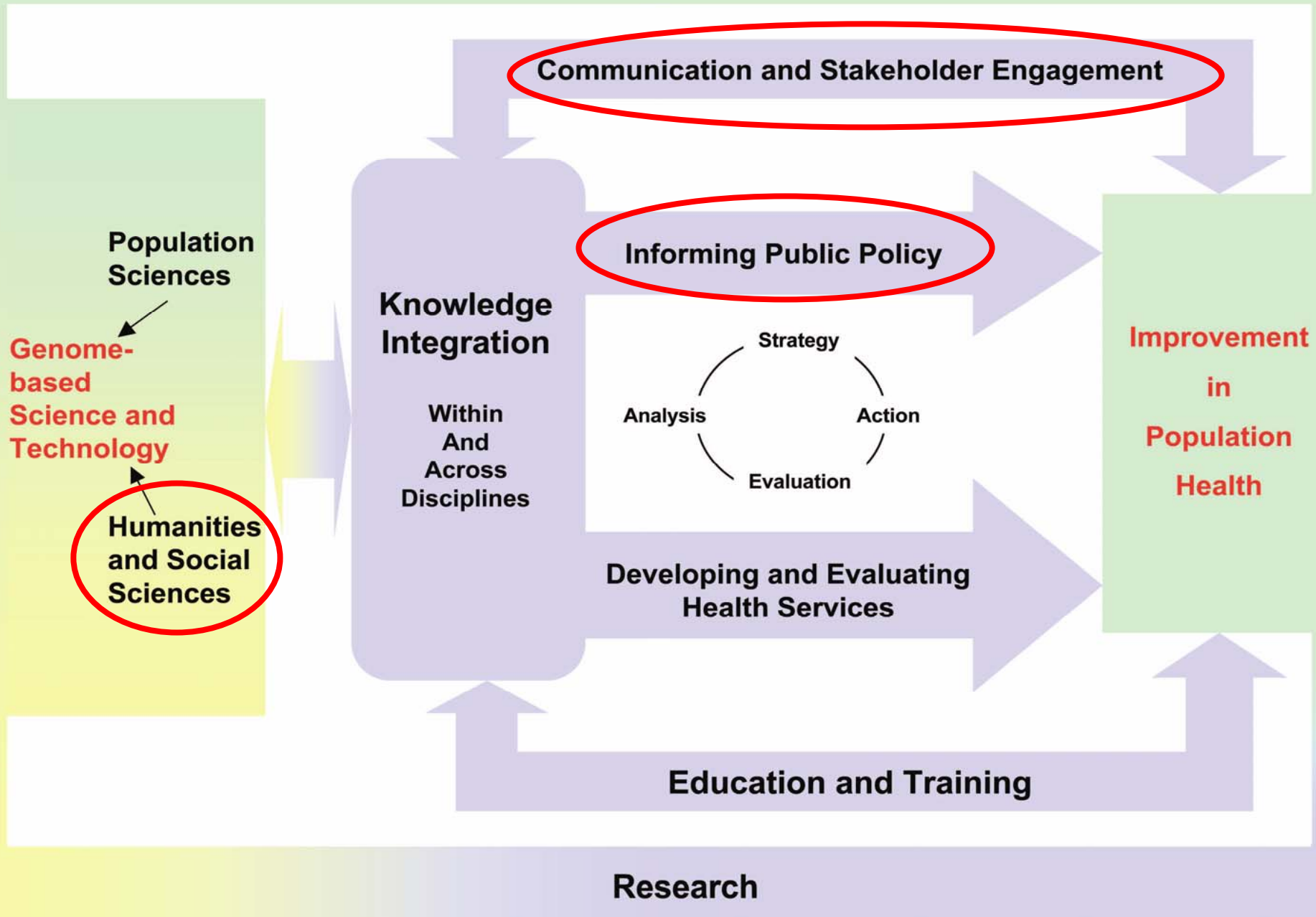
Kathy Hudson, Ph.D.
Genetics and Public Policy Center
Johns Hopkins University

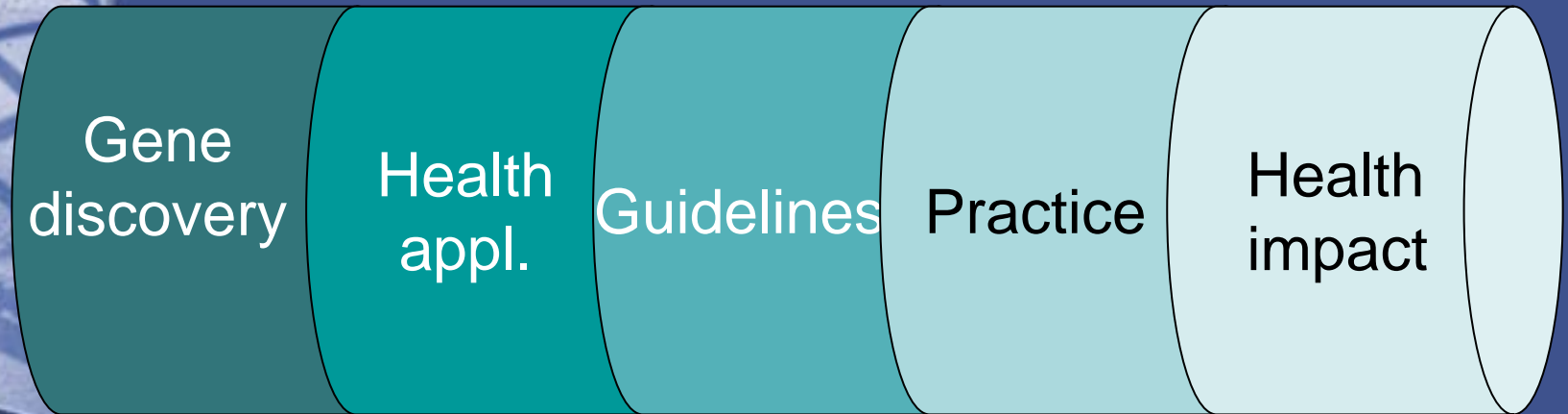
www.DNApolicy.org

Our Mission:

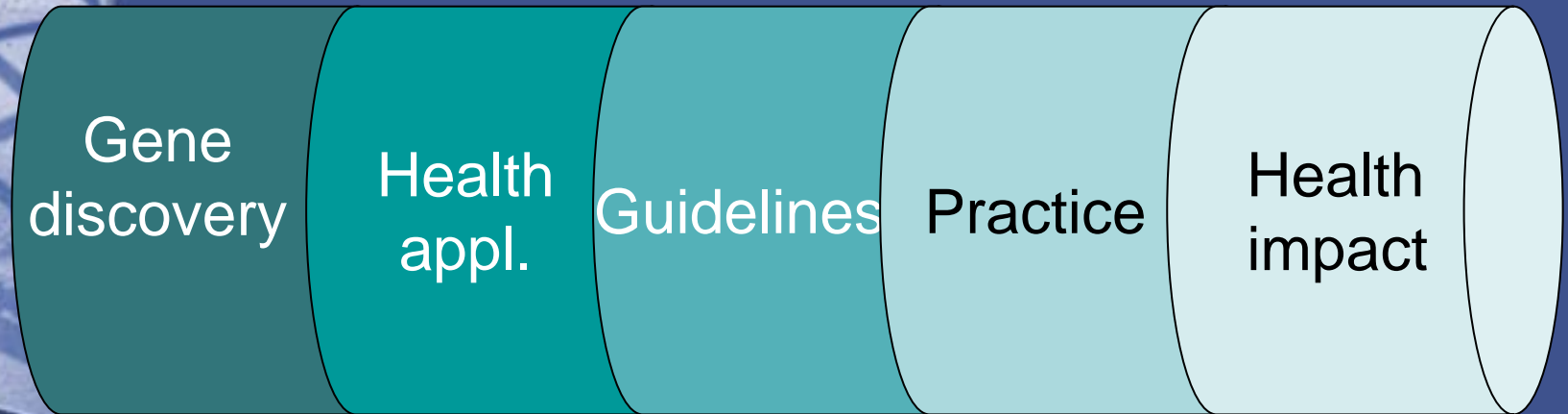
To create the environment and tools needed by key decision makers to carefully consider and respond to the challenges and opportunities raised by scientific advances in human genetics.

Society

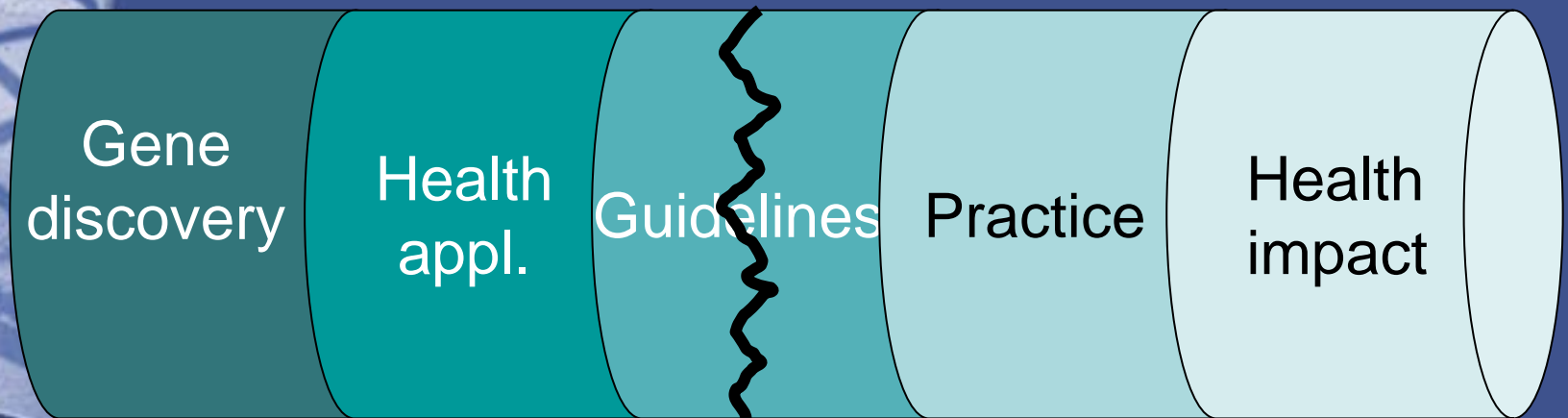




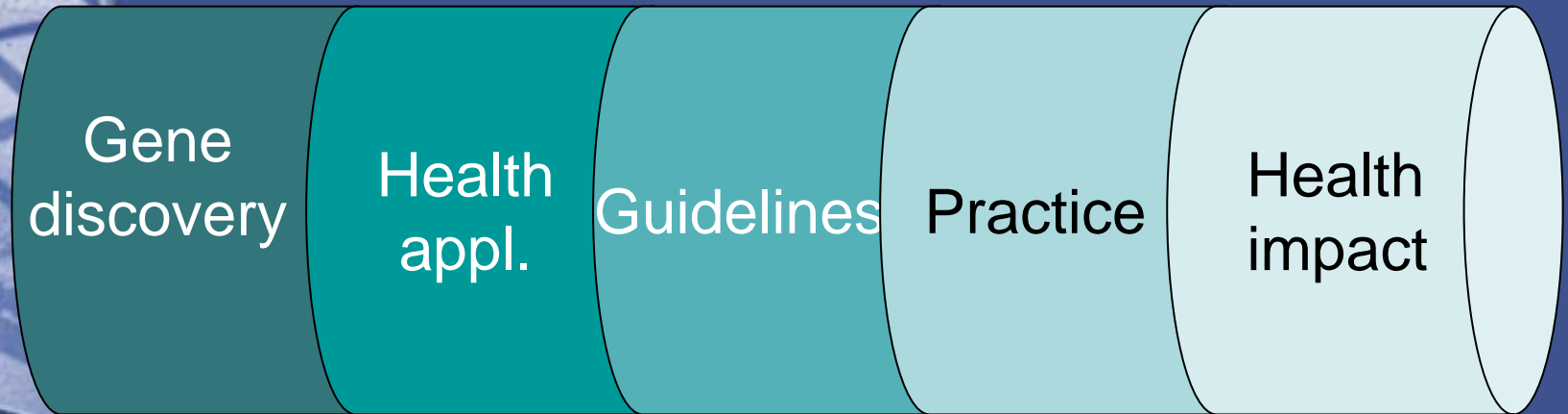
Robust and responsive research enterprise



Safe and effective tests and interventions



More effective guideline development,
dissemination and adoption



Safeguards for genetic information

Key Prerequisites for Genetic Medicine

1. Robust and responsive research enterprise
2. Safe and effective tests and interventions
3. Improved guidelines development and adoption
4. Safeguards for genetic information

Public confidence

Key Prerequisites for Genetic Medicine

1. Robust and responsive research enterprise

Public confidence

Why Is What the Public Knows & Thinks Important?

1. Better informed health decision making
2. Recruitment for research studies
3. Build S&T workforce
4. Better informed decisions and positions about S&T programs and policies
 - A. Garner support for S&T programs and policies
 - B. Diffuse opposition
5. Tailor public information, education, and engagement efforts
6. Meaningful input
7. Public accountability

Public Understanding of Science

- Information Deficit Model
 - Assumes direct correlation between increased knowledge and support
 - Assumes one way flow of knowledge from experts to the public
 - Driven communication of S&T since WWII
 - Public support for S&T has not changed as a result

Scientists' Thoughts on the Public

"...there has to be more education, because I don't think that [members of the public] really understand... a lot of the science that goes into building these technologies..."

Scientists' Thoughts on the Public

"The problem is that they don't understand a lot of the research. They don't have the knowledge to, you know, say what's important and what's not; where the dollars should go or shouldn't go. So... public education is important."

Scientists' Thoughts on the Public

“I don't think that the general uninformed public should have a say, because I think there's a danger. There tends to be a huge amount of information you need in order to understand. It sounds really paternalistic, but I think this process should not be influenced too much by just the plain general uninformed public...”

Simply trying to educate the public about specific science-based issues is not working... The centrality of science to modern life bestows an obligation on the scientific community to develop different and closer links with the general population. We need to move beyond what too often has been seen as a paternalistic stance. We need to engage the public in a more open and honest bidirectional dialogue about science and technology...

Science 14 February 2003

A Matter of Trust

PHYLIS: And sometimes there are scientists that say, you know what? If I can do this, I am going to make millions off it. I don't care.



A Matter of Trust

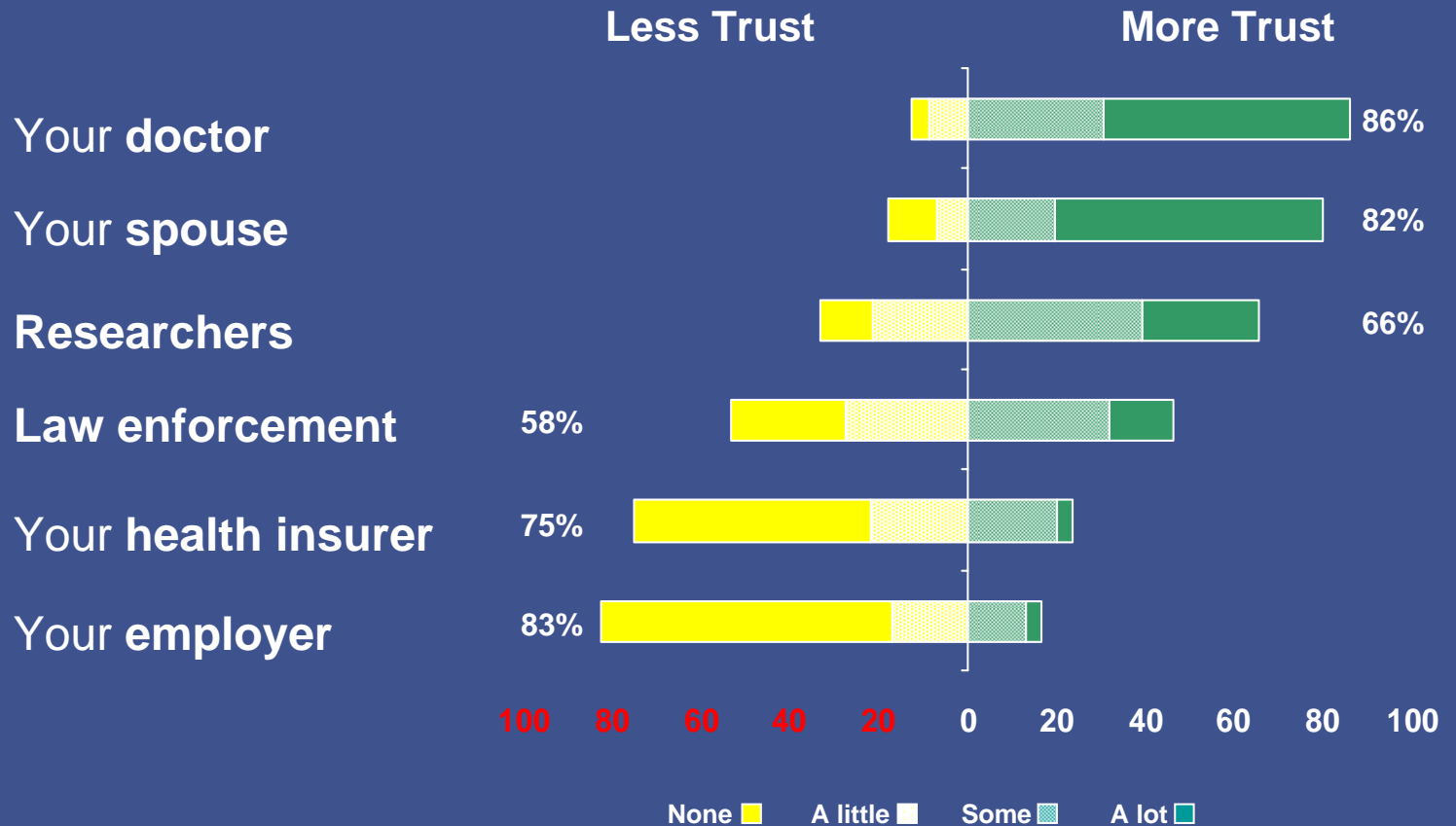
HAYDEE: Yes, but you know what? You are a reasonable person. We are responsible people here, but some of those scientists, because of the science and because of their warped minds, they will do something stupid like that, and you know they can, and they will.



Public Views About Science/Scientists

	Agree
A. Scientific research is essential for improving the quality of human lives	88%
B. Scientists are good people who work for the good of humanity.	76%
C. Scientists these days don't pay enough attention to the moral values of society.	50%
D. I trust scientists to put society's interests above their personal goals.	20%

How much do you trust each of the following to have access to your genetic test results?

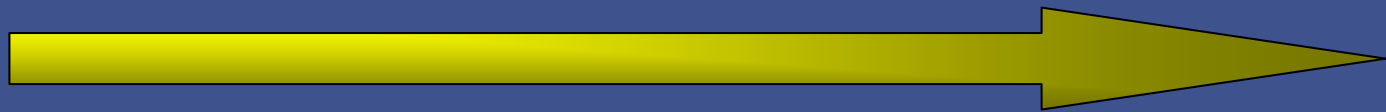


Genetics and Public Policy Center. <http://www.dnapolicy.org>. 2/27/07-3/4/07, N=1199 adults 18 years of age or older

- We have a problem with trust.
- Public engagement, once thought to be “just a good idea”, is now essential.

Levels of Engagement

- Inform
 - One way flow of information
 - Methodologies
 - Print or web materials
 - Media outlets
 - Lectures



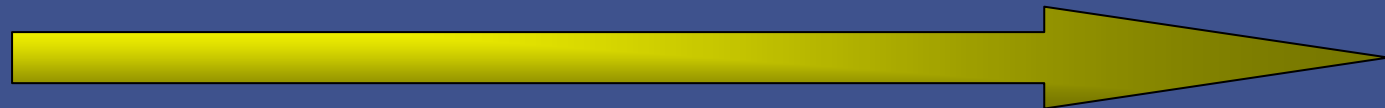
Inform

Levels of Engagement

- Consult
 - Obtain feedback from public
 - Methodologies
 - Surveys
 - Focus groups
 - Workshops
 - Scenario development
 - Deliberative democracy
 - Consensus conferences

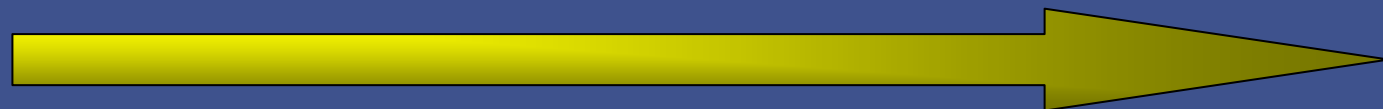
Inform

Consult



Levels of Engagement

- Collaborate
 - Public involved in issue identification, framing, prioritization and agenda setting
- Empower
 - Citizen juries or balloting



Inform

Consult

Collaborate

Empower

STUDY PARTICIPATION



NIH



Pilot Public Consultation Project

- 16 Focus Groups
- 50 Interviews
- 5 Town halls
 - Portland
 - Phoenix
 - Jackson
 - Kansas City
 - Philadelphia
- Survey of 5,000



Key Prerequisites for Genetic Medicine

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2. Safe and effective tests and interventions

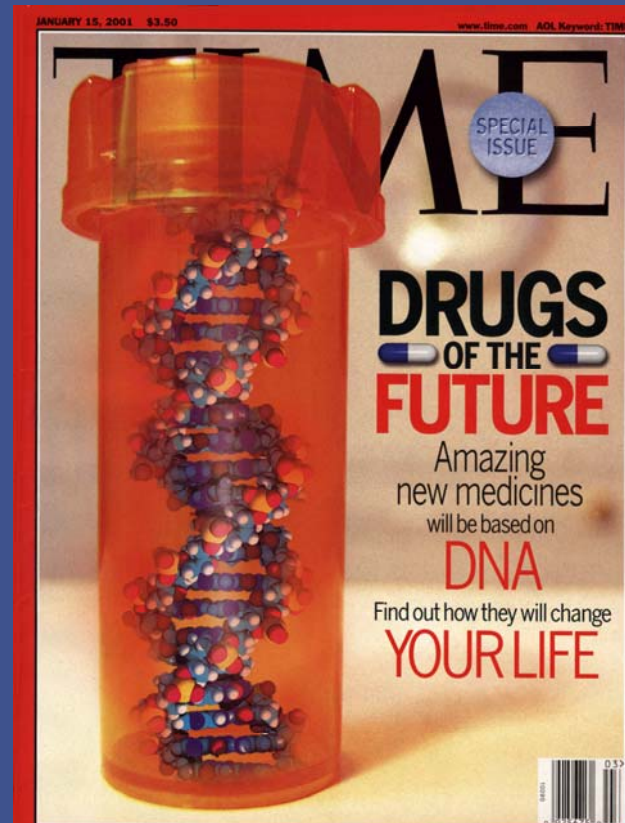
Public confidence

Clinical Genetic Tests To...

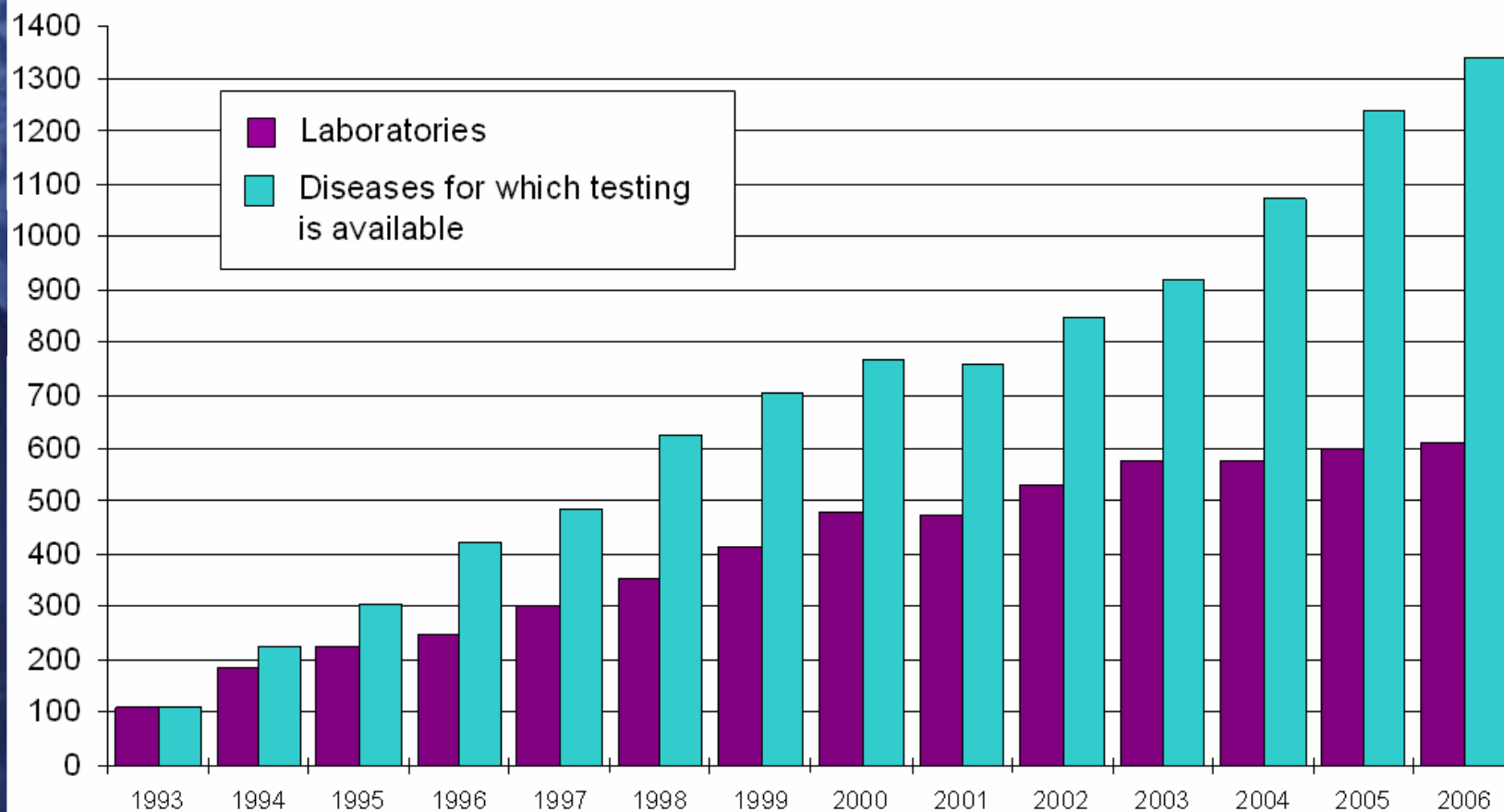
- Diagnose disease
 - e.g. Cystic Fibrosis, sickle cell disease
- Use in reproductive decision-making
- Determine prognosis
 - e.g. tumor profiling to determine recurrence risk for breast cancer
- Predict risk for future disease in asymptomatic individuals
 - e.g. Huntington disease, hereditary cancer

Clinical Genetic Tests To...

- Select optimal treatments
 - e.g. Herceptin treatment in Her2/neu positive breast cancer
- Identify risk for adverse drug reactions
 - e.g. CYP450 testing



Growth of Genetic Testing



Data source: GeneTests database (2006) / www.genetests.org

TSUNAMI SCIENCE: ONE YEAR AFTER THE WAVE THAT ROCKED THE WORLD

SCIENTIFIC AMERICAN

Alternatives to
Toxic Tests
on Animals

JANUARY 2006
WWW.SCIAM.COM

Know Your DNA

Inexpensive gene readers will soon
unlock the secrets in your
personal double helix

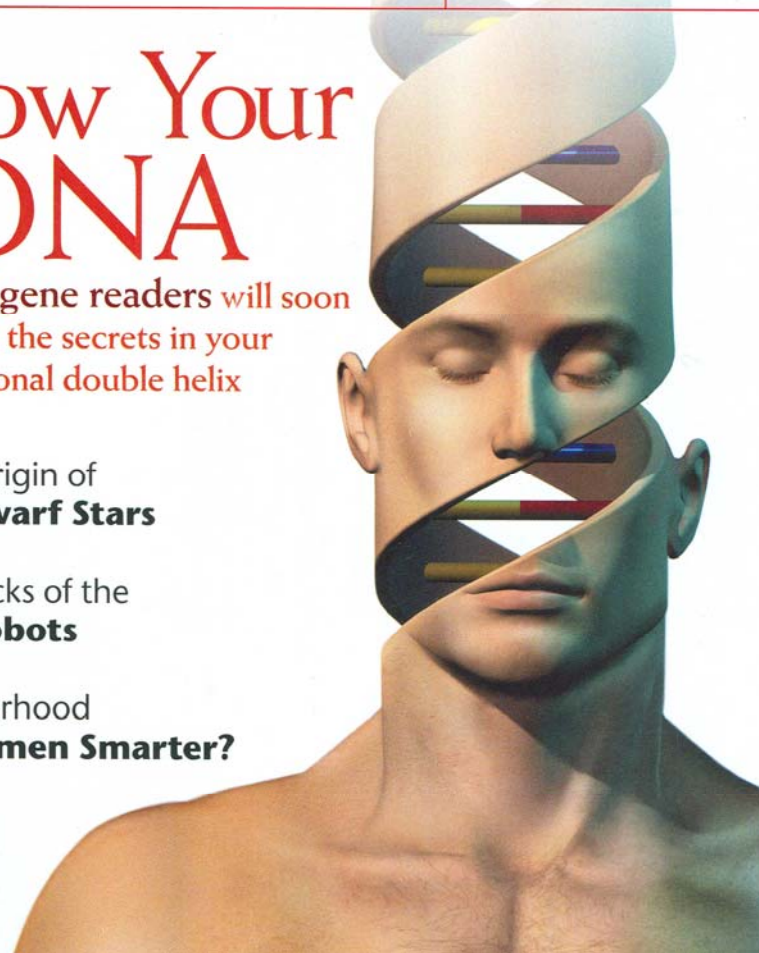
The Hazy Origin of
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Reading the Book of Jim

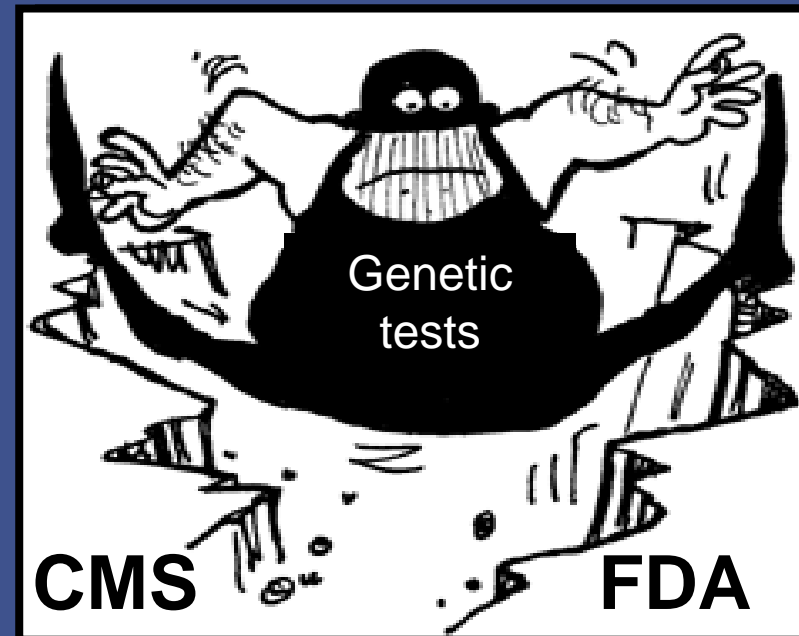
The co-discoverer of the double helix is making his DNA public, pioneering the 'personal genome.'

By Sharon Begley
Newsweek

June 4, 2007 issue - It would be a mistake to think that reaching the age of 79 has mellowed James Watson. Fifty-four years after he discovered, with Francis Crick, the structure of DNA, and 45 years after sharing the Nobel Prize for it, he delights in provocation just as much as when he made his reputation as the bad boy of molecular biology, bulldozing colleagues and competitors (and



- Genetic tests have great potential to improve health.
- Quality genetic testing depends on quality oversight.
- Oversight of genetic testing is grossly inadequate.



Oversight of Genetic Testing

The Two Path Problem



Non-FDA
reviewed lab
developed test.

FDA
approved test
“kit”

The Two Path Problem



- Adverse economic consequences
- Absence of public access to information
- Disparities in quality
- Risk to public health

Regulation of Clinical Laboratories in the United States

- Clinical laboratories are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- Law directs government to issue standards to “assure consistent performance by laboratories ... of valid and reliable laboratory examinations”
- Standards must address:
 - quality assurance/quality control
 - record keeping
 - facilities and equipment
 - personnel
 - proficiency testing (*)

Regulation of Clinical Laboratories in the United States

- Proficiency testing (PT)
 - “a method of externally validating the level of a laboratory’s performance”
 - Congress stated that PT “should be the central element in determining a laboratory’s competence, as it provides a measure of actual performance on laboratory test procedures rather than only gauging the potential for accurate outcomes.”

Regulation of Clinical Laboratories in the United States

- HHS has not issued standards for genetic testing laboratories and does not require PT for genetic testing labs.
- Our survey found that 35% of genetic testing labs do not do PT for some or all of tests they offer.
- Our survey found that the greater the use of PT, the lower the number of test errors.
- 73% of genetic testing lab directors support creation of new standards.

GPPC Clinical Laboratory Oversight Policy Objective:

CMS issues a proposed rule for genetic testing laboratory requirements and creates a specialty area and proficiency testing standards for genetic testing under CLIA

January 9, 2006 response to GPPC letter (from Thomas Hamilton):

“We intend to publish a Notice of Proposed Rule Making for genetic testing as quickly as is feasible. We are currently working with staff at the Centers for Disease Control and Prevention to this end, and we expect to publish in the coming months.”

recommendations of a federal advisory committee regarding the development of a genetic testing specialty. In issuing the Notice of Intent, the CDC noted that, along with its potential for improving health and preventing disease, genetic testing “can also do great harm if errors occur” in test selection, test performance, test interpretation, and clinical application of test results. The Notice further noted that false positive and false negative results “can be especially troublesome when the test is being used to predict future risk of disease in an individual without any current symptoms of disease.” The Notice cited reports documenting problems in the pre-analytic, analytic, and post-analytic phases of clinical testing.



**And then there was the abrupt
and inexplicable about-face!**

September 26, 2006
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Petition for Rulemaking

Dear Administrator McClellan:

This Petition is submitted by the Genetics and Public Policy Center, Public Citizen's Health Research Group, and Genetic Alliance pursuant to section 553(e) of the Administrative Procedure Act. Petitioners request that the Centers for Medicare and Medicaid Services (CMS) implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by creating a genetic testing specialty and establishing standards for proficiency testing. Petitioners believe this action is required under CLIA. Even if CLIA does not require this action, however, CMS has the authority to create a genetic testing specialty and should do so. Petitioners believe that creating such a specialty is critical to ensuring the quality of genetic testing in the United States and that the failure to do so poses a risk to public health.

Direct-To-Consumer Testing Catalyst for Policy Change?

CLICK HERE
Purchase Online

Learn about genetic testing for hereditary breast and ovarian cancer.

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GenesLink™
GENETIC BIOSCIENCES FOR IMPROVING THE QUALITY OF LIFE

GENOVATIONS™
Predictive Genomics for Personalized Medicine
Custom Fit for Life!

Discover How Your Genes can hold the Secret to your Well-Being

Breakthrough Genetic Profiling

Gene - Testing Now Available

early
BabyGenderMentor
THE MOST ACCURATE DNA GENDER TEST

An Amazing Opportunity

LAB21
100% CUSTOM SKIN CARE
100% 100% 100%

GENOVATIONS

Your skin is as unique as your DNA.


improve mental health and child depression - Microsoft Internet Explorer

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IMAGENE™


GENETIC TESTING FOR THE MILLENNIUM

Introducing a ground breaking addiction treatment tool.

Are you compulsive? Have you ever wondered why you crave certain things and/or act in an irrational manner? Would you like to know if you have the genetic predisposition to abuse drugs and alcohol? Are you concerned about your children's future? Does your child have the genetic trait that leads to disruptive and addictive personalities? DNA testing can help you understand and manage a child's behavior before it gets out of control.

Imagene will test a panel of dopaminergic related Reward Deficiency Syndrome(RDS) genes. This will allow you to know if there is a genetic predisposition towards any of the associated addictions. The Reward product line is then available to treat the genetic predisposition towards RDS.

Imagene is an at home genetic testing kit that is simple to use. Here are the actual



[CLICK HERE TO ORDER IMAGENE](#)

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Baby Gender Mentor Home DNA Gender Testing Kit - Microsoft Internet Explorer

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Baby Gender Mentor™ Home DNA Gender Testing Kit

Boy or Girl? Now You Can Know Even *Before* You Show



As featured on ABC's World News Tonight, CNN, NBC's Today show -- watch the TODAY show segment now, and other major news and media outlets! Offered Exclusively Online From PregnancyStore.com! Are you pregnant and want to know if you're having a boy or girl? [Not pregnant yet but know that you want to know the sex of your baby when you are pregnant?](#)

It's estimated that about 50-70% of parents-to-be want to know if they're having a baby boy or girl. Knowing the gender of your unborn baby helps prepare for your baby's birth: you can decorate the nursery, choose your baby's name, and make gender-specific purchases during your pregnancy.

"We are excited to tell you we are having a baby boy!!! My wife and I could not be more happy! Thanks to you and all the great people on your team for rushing our order through so quickly... the suspense was killing us!" Robert & Ann T.



If you want to know the gender of your unborn baby, forget old wives tales like the Chinese lunar calendar chart, the Wedding Ring Spin, needle on a string test, or how you're carrying your baby. **Now there's a scientific, non-invasive way to predict your baby's gender – with 99.9% accuracy. [Are you having twins?](#)** Now you can find out what you're having as early as five weeks after conception!!

With a few drops of your maternal blood you can find out your baby's sex AS EARLY AS FIVE WEEKS after conception with the NEW Baby Gender Mentor Home DNA Gender Testing Kit.

"Wow! That's all I can say about this test. It came very quickly in the mail. Was easy to understand and perform. I had my results within less than 48 hours. And my husband and I were tickled to learn we will be having our first baby girl!! Our two sons are delighted about their baby sister! I wouldn't hesitate to tell women to take this test. Thank you so much for making this kit available to pregnant women everywhere!" -- Paul & Kimberly H.

How Does the Baby Gender Mentor Home DNA Gender Testing Kit Work?

This technology has been in trial for 14 years -- and works! Baby Gender Mentor Home DNA Gender Test employs cutting-edge, patent-pending technology to attain the **earliest gender detection with unprecedented sensitivity and unsurpassed accuracy.** The technique traces the amount of Y

Done Internet

https://www.dnadirect.com/jsp/tests/frameworkQuestionnaire.jsp?questionnaire_step_number=step2& - Microsoft Internet ...

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Fertility Issues

[Fertility Issues Questionnaire](#)

- Questionnaire
- Results**
- Begin Order

Need more information?

Use our decision tools and step-by-step information to help you decide whether to test. (PDF 184K)

You answered that you and your partner have been trying to get pregnant for several months and that you have had a positive pregnancy test at some time in your reproductive history. If you have experienced 2 or more pregnancy losses (miscarriages, fetal death or stillbirth) the following tests are appropriate for you to consider at this time: **chromosome analysis and factor V testing.**

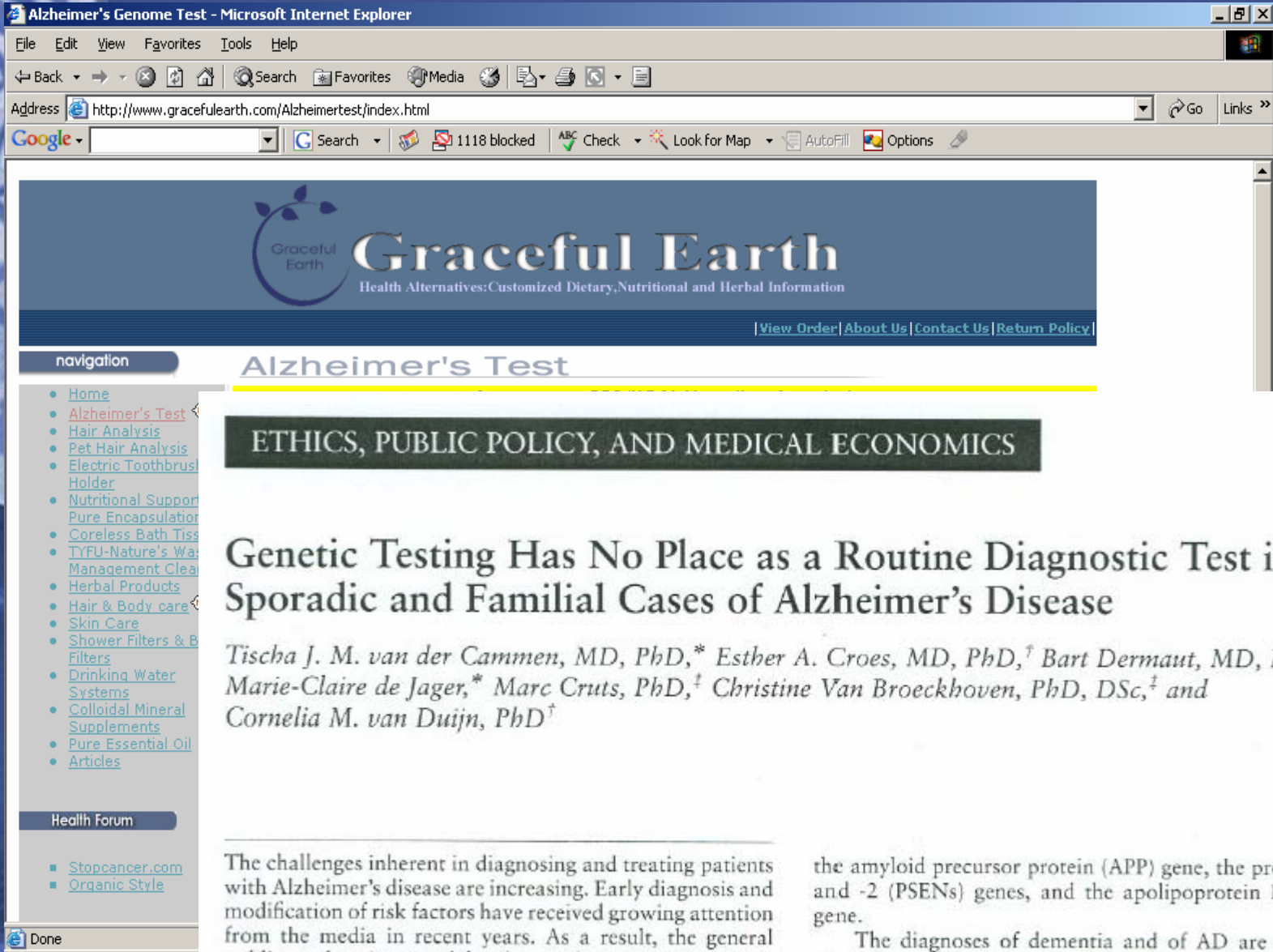
Chromosome analysis looks at the number and structure of your chromosomes. People who have extra, missing, or rearranged chromosomes (or parts of chromosomes) may experience reproductive difficulties.

Factor V testing identifies a common genetic variation that increases the likelihood of blood clots. Women with recurrent miscarriage may experience pregnancy loss due to blood clot formation in the developing placenta.

Call for a Free, Personalized Consultation: Our board-certified genetic experts can discuss your medical and family history and help you make an informed choice

Done Local intranet 4:39 PM

Start D. M. P. a. N. M. M. M. M. P. H. C. D. h.



Alzheimer's Test

ETHICS, PUBLIC POLICY, AND MEDICAL ECONOMICS

Genetic Testing Has No Place as a Routine Diagnostic Test in Sporadic and Familial Cases of Alzheimer's Disease

Tischa J. M. van der Cammen, MD, PhD, Esther A. Croes, MD, PhD,† Bart Dermaut, MD, PhD,‡ Marie-Claire de Jager,* Marc Cruts, PhD,‡ Christine Van Broeckhoven, PhD, DSc,‡ and Cornelia M. van Duijn, PhD‡*

The challenges inherent in diagnosing and treating patients with Alzheimer's disease are increasing. Early diagnosis and modification of risk factors have received growing attention from the media in recent years. As a result, the general public, and patients and family members, are increasingly better informed about the disease, its genetic background, and the possibilities for treatment. The physician is often faced with questions about hereditary patterns within the family and with requests to perform genetic testing. Cl

the amyloid precursor protein (APP) gene, the presenilin-1 and -2 (PSENs) genes, and the apolipoprotein E (ApoE) gene.

The diagnoses of dementia and of AD are made on clinical grounds following international criteria.¹⁻³ The clinical value of genetically screening patients with a diagnosis of dementia is an issue of debate.^{4,5} When considering sporadic dementia patients, it is generally agreed that

DTC as Catalyst

GAO Investigation and Report

Senate Hearing, Special Committee on Aging,
“At Home DNA Tests: Marketing Scam or
Medical Breakthrough”

Federal Trade Commission releases consumer
advisory

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

Register
For The Course
1-877-710-HELP
Federal Trade Commission



Key Prerequisites for Genetic Medicine

1. Robust and responsive research enterprise
2. Safe and effective tests and interventions
3. Guidelines development, dissemination, adoption

Public confidence

Tools for Health Care Providers

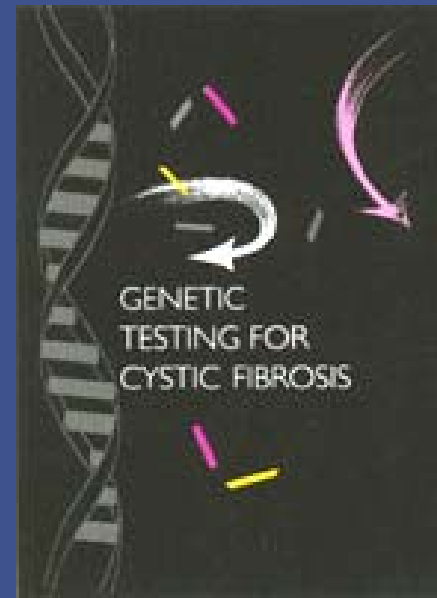
- Only a handful of genetic testing guidelines are available to guide laboratory practice and clinical decision making
- Need to increase evidence base of tests (e.g. EGAPP project funded by CDC)
- Health care professional organizations need resources to develop evidence-based guidelines and educational materials
- Need new and improved methods of dissemination and adoption

NIH Consensus Panel April 14-16, 1997

Recommendations

CF genetic testing should be offered to

- 1) adults with a positive family history
- 2) to partners of people with CF
- 3) to couples planning a pregnancy
- 4) to couples seeking prenatal testing.



Ob-Gyns Offering Large-Scale Cystic Fibrosis Screening

Represents First Major Clinical Change from the Human Genome Project

Washington, DC -- The nation's obstetrician-gynecologists have initiated one of the first clinical changes in the US arising from discoveries of the human genome project.

ACOG now recommends that ob-gyns make DNA screening for cystic fibrosis available to all couples seeking preconception or prenatal care -- not just those with a personal or family history of carrying the CF gene, as previously recommended.

ACOG News Release
December 12, 2001

Cystic Fibrosis
Carrier Testing:
The Decision Is Yours



**Laboratory Standards and Guidelines
for Population-based
Cystic Fibrosis Carrier Screening**

*Wayne W. Grody, MD, PhD¹, Garry R. Cutting, MD²,
Katherine W. Klinger, PhD³, Carolyn Sue Richards,
PhD⁴, Michael S. Watson, PhD⁵, and Robert J.
Desnick, PhD, MD⁶ (Subcommittee on Cystic Fibrosis
Screening, Accreditation of Genetic Services
Committee, ACMG)*

Genetics in Medicine

March/April 2001 (and later updated)

ObGyns asked about CF screening in 2004 (n=547):

Practices that did not coincide with guidelines:

- 66% offered CF screening to all pregnant patients
- Another 25% did not select all the recommended criteria for screening
- 17% did not offer CF screening to non-pregnant patients
- 60% were concerned about their ability to interpret or deal with a positive screening test

-- MA Morgan et al. 2004, *Genetics in Medicine*, 6:450-455
Practice patterns of obstetrician-gynecologists regarding preconception and prenatal screening for cystic fibrosis

U.S. genetic testing laboratory directors who performed CF carrier screening in 2006 (n=81):

Only 10% used the recommended 23-mutation panel (median=32)

72% correctly performed 5T test only as a reflex

17% performed 5T test on all samples

6% never performed 5T

7% adhered to both guidelines

26% adhered to neither

-- Genetics and Public Policy Center.
Submitted to Genetics IN Medicine, June 2007.

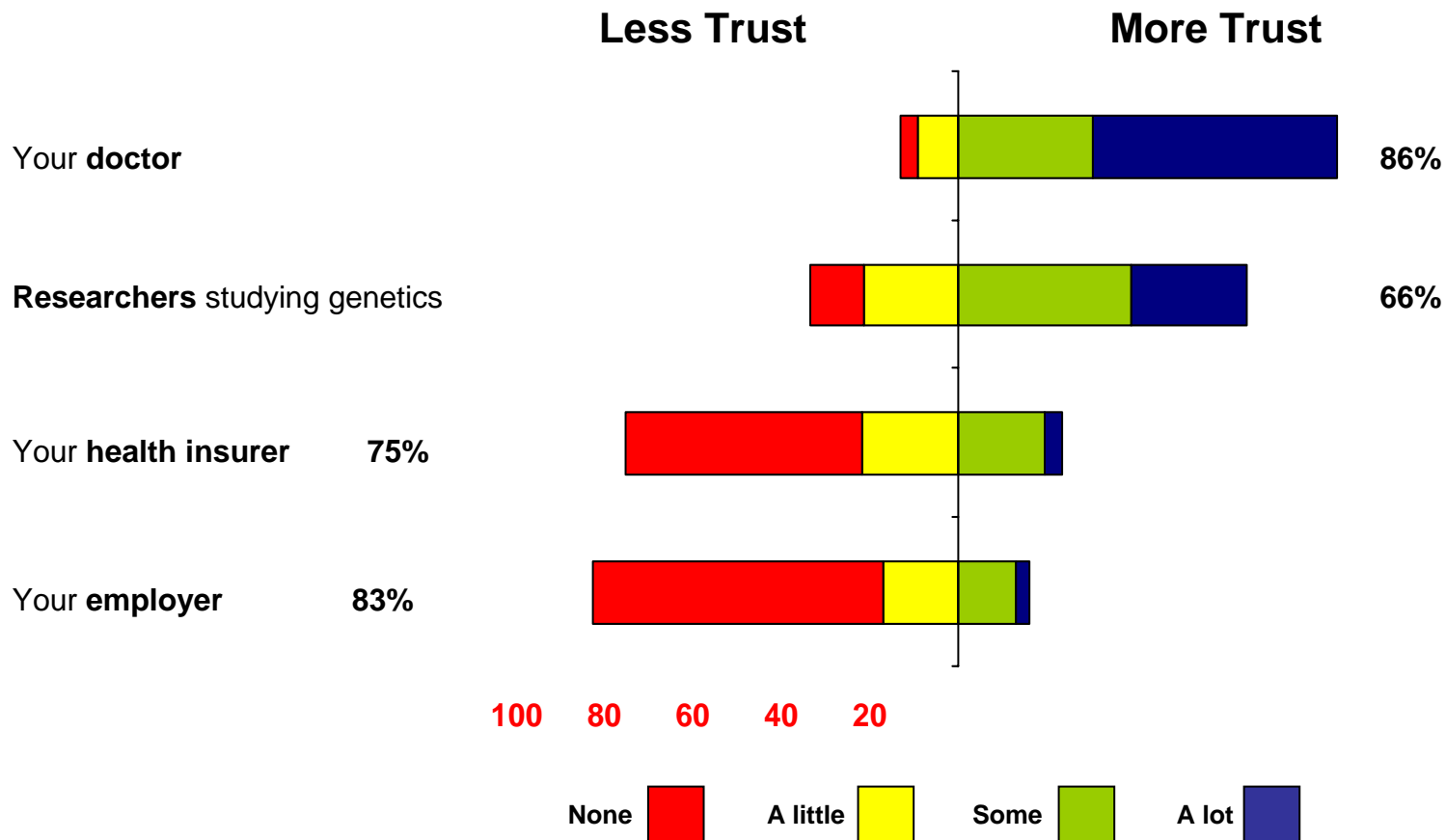
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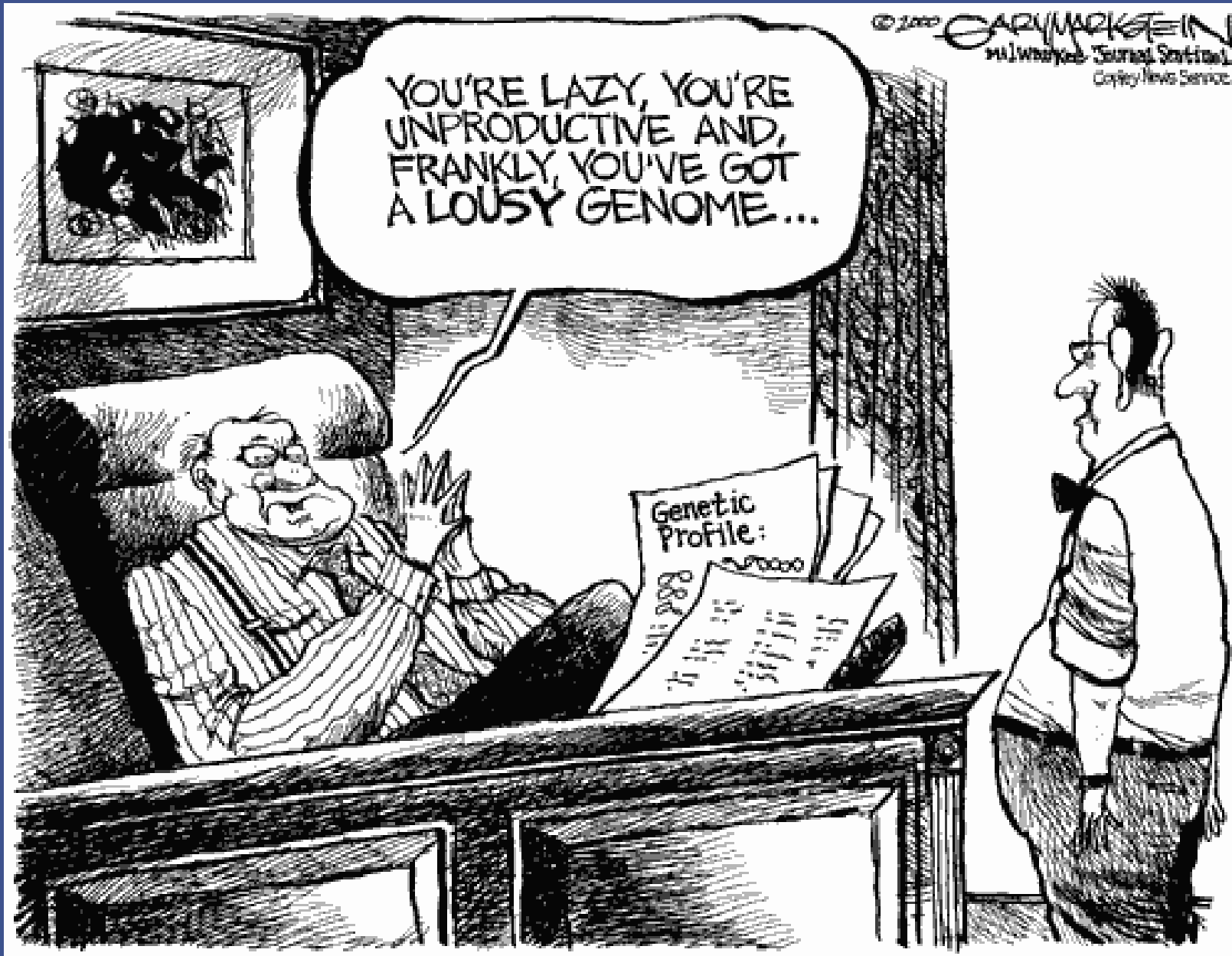
How much do you trust each of the following to have access to your genetic test results?



Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- Group health plans may not establish eligibility, enrollment, continuation or premium requirements based on health status-related factors.
- Factors include medical conditions, claims experience, receipt of health care, medical history, genetic information, evidence of insurability, disability

© 2000 **CARL MACKSTEIN**
Milwaukee Journal Sentinel
Copley News Service



Americans with Disabilities Act

Provides protections against discrimination to those with:

- 1) a physical or mental impairment that substantially limits one or more of the major life activities of such individual;
- 2) a record of such an impairment; or
- 3) being regarded as having such an impairment.

Clinton Signs Executive Order Banning Genetic Discrimination in the Federal Workplace



“By signing this executive order, my goal is to set an example and pose a challenge for every employer in America, because I believe no employer should ever review your genetic records along with your resume.”

February 8, 2000

The Genetic Information Nondiscrimination Act

Prohibits group and individual health insurers from using genetic information in setting eligibility or premium or contribution amounts.

Prohibits health insurers from requesting or requiring that a person undergo a genetic test.

Prohibits employers from using genetic information in making employment decisions such as hiring, firing, job assignments, and promotions.

Prohibits employers from requesting, requiring, or purchasing genetic information about an employee or family member.

Status Report

Introduced in 1995

Passed Senate in 2003

Passed Senate in 2005

Blocked in House by Employer Groups

2006 Election

Passed House April 25, 2007

Senate passage expected

Bush has said he will sign





Department of Defense Personnel Policy

- Provides medical coverage for enlisted men/women
- Provides medical & disability benefits for retired service men/woman



Department of Defense Personnel Policy

- Served in the Marines for 14 years
- Diagnosed with renal cell carcinoma & cerebellar nodules
- Diagnosed with von Hippel-Lindau disease
- Requested medical discharge



DOD Instruction 1332.38

E3.P4.5.2.2.1. Presumption. Any injury or disease discovered after a service member enters active duty -- with the exception of congenital and hereditary conditions -- is presumed to have been incurred in the line of duty;

Biomedical Biobanks

- How safe are your samples?
- Hacking, sloppiness, codebreaking, public access to genotypes
- Direct law enforcement access?





Today all 50 states participate-with variations
50 enter convicted sex offenders
40 enter convicted felons
38 enter qualifying misdemeanors
11 enter arrestees
(Alaska, Arizona, California, Kansas,
Louisiana, Minnesota , New Mexico,
North Dakota, Tennessee, Texas, and
Virginia)



Forensic index

DNA profiles from crime scene evidence
(Includes intimate partners of victims)

>160,000 DNA profiles

Offender index

DNA profiles of offenders of certain
specified crimes

4 million DNA profiles

STUDY PARTICIPATION



NIH



Biomedical Biobanks

Certificates of Confidentiality

- Issued by the Secretary to biomedical, behavioral, clinical, or other researchers to protect the privacy of research subjects by withholding their names or other identifying characteristics. [PHS Act, Section 301 (d)]
- Researchers with a CoC cannot be compelled in any civil, criminal, administrative, legislative or other proceeding to identify research subjects.
- CoCs available for all research projects, and federal funding is not required.

A Better Way?

No officer or employee of the Federal Government, and no recipient of assistance...shall use or reveal any research or statistical information furnished under this title by any person and identifiable to any specific private person for any purpose other than the purpose for which it was obtained in accordance with this title. Such information and copies thereof shall be immune from legal process, and shall not, without the consent of the person furnishing such information, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceedings.

(USC §3789g and 28 CFR Part 22)

NIJ

- Obligatory
- Covers all employees and funded researchers
- Prohibits voluntary disclosure by researcher
- Protects against compelled disclosure

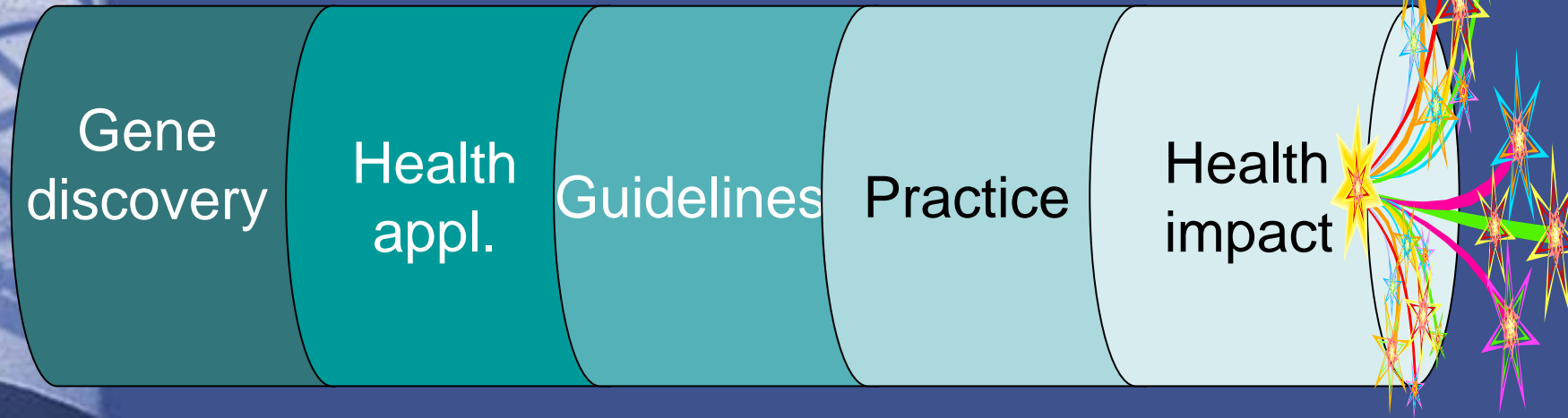
NIH

- Must be requested
- Available irrespective of funding source
- Protects against compelled disclosure

Key Prerequisites for Genetic Medicine

1. Robust and responsive research enterprise
2. Safe and effective tests and interventions
3. Improved guidelines development and adoption
4. Safeguards for genetic information

Public confidence



Gene
discovery

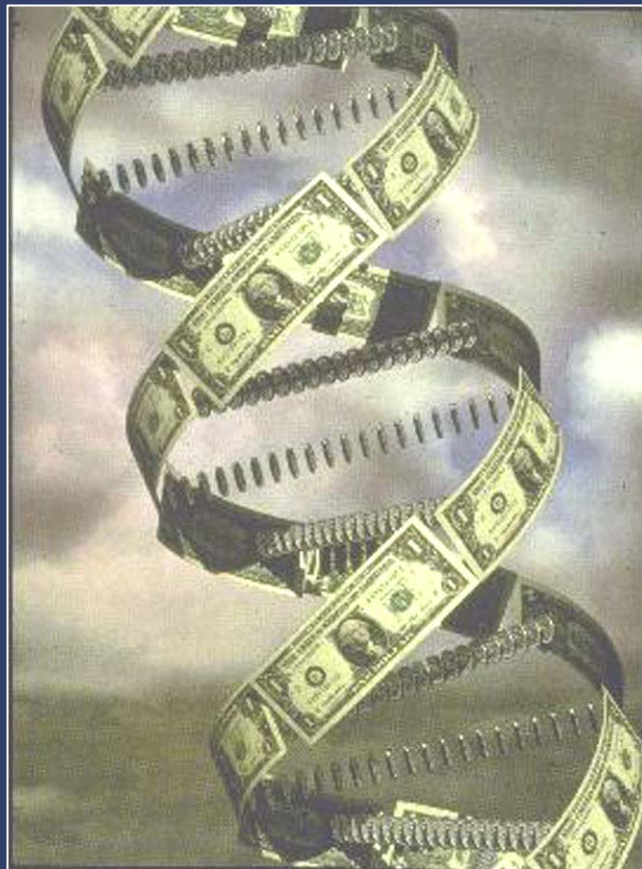
Health
appl.

Guidelines

Practice

Health
impact

Thanks to the
Pew Charitable Trusts
and NHGRI.





www.DNAPolicy.org