

Kathy L. Hudson, Ph.D.
Chief of Staff
Office of the Director
NIH



NATIONAL INSTITUTES OF HEALTH

NIH's Major Opportunities for Research and NIH

RESEARCH AGENDA

The promise of fundamental diagnosis, prevention, disease has never been

1 JANUARY 2010

Francis S. Collins

The mission of the National Institutes of Health (NIH) is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and to reduce the burden of illness and disability. The power of the molecular approach to health and disease has steadily gained momentum over the past several decades and is now poised to catalyze a revolution in medicine. The foundation of success in biomedical research has always been, and no doubt will continue to be, the creative insights of individual investigators. But increasingly the scientists are working in teams, accelerated by interdisciplinary approaches and empowered by open access to tools, databases, and technologies, so a careful balance is needed between investigator-initiated projects and large-scale community resource programs. For both individual and large-scale efforts, it is appropriate to identify areas of particular promise. Here are five such areas that are ripe for major advances that could reap substantial downstream benefits.

High-Throughput Technologies

In the past, most biomedical basic science projects required investigators to limit their scope to a single aspect of cell biology or physiology. The revolution now sweeping the field is the ability to be comprehensive—for example, to define all of the genes of the human or a model organism, all of the human proteins and their structures, all of the common variations in the genome, all of the major pathways for signal transduction in the cell, all of the patterns of gene expression in

Understand
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treatments
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diverse information about the genetic underpinnings of 20 major tumor types. This information will likely force a complete revision of diagnostic categories in cancer and will usher in an era where abnormal pathways in specific tumors will be matched with the known targets of existing therapies. Another example is the opportunity to understand how interactions between ourselves and the microbes that live on us and in us (the “microbiome”) can influence health and disease (2).

Translational Medicine

Critics have complained in the past that NIH is too slow to translate basic discoveries into new diagnostic and therapeutic advances in the clinic. Some of that criticism may have been deserved, but often the pathway from molecular insight to therapeutic benefit was just not

bring them to
Drug Admini

As one example, the Rare and Neglected Diseases Program will allow patients to be taken to NIH in an open-access model. NIH experts on the disease. Furthermore, as information about disease increases, many are being identified as distinct molecular subsets, and so the model will be even more widely applicable.

The first human protocol (for spinal cord injury) involving human embryonic stem cells (hESCs) was approved by the FDA in 2009, and the opening up of federal support for hESC research will bring many investigators into this field. The capability of transforming human skin fibroblasts and other cells into induced pluripotent stem

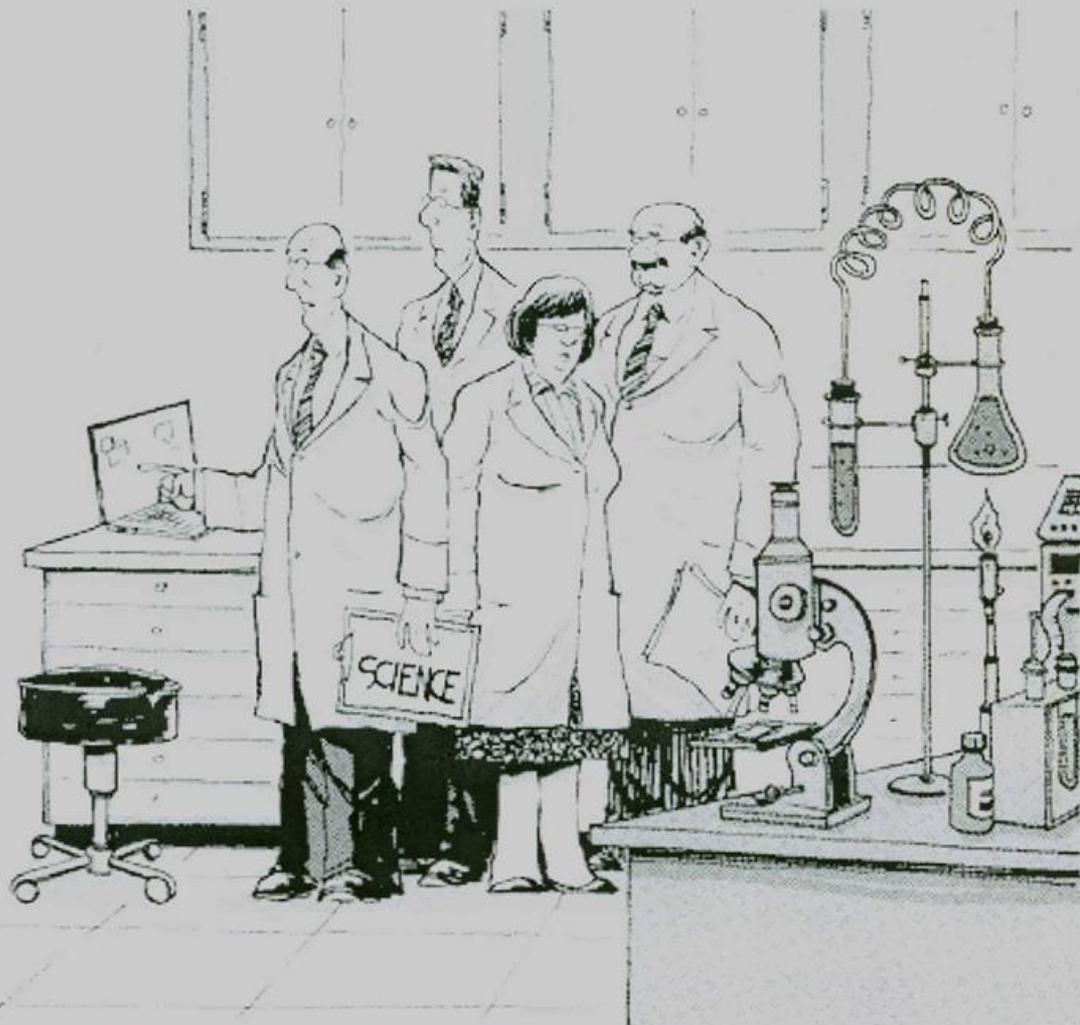
UNIVERSITY; LINDA BARTLETT/ANCI, NIA/NIH

Committed to Science and to Improving Health

“Here at the National Institutes of Health and at universities and research institutions across this country, you are demonstrating our capacity not just as a nation, but as human beings to harness our creativity and our ingenuity to save lives, to spare suffering, to build a better world for ourselves, our children and our grandchildren.”

President Obama at NIH September 30, 2009





"WAIT... YOU ACTUALLY WANT OUR ADVICE? THE LAST GUY CALLED US NERDS AND BROKE OUR GLASSES."

What Health Care Reform Means For...

- NIH
 - Comparative Effective Research
 - Cures Acceleration Network



Desperately Seeking Cures

How the road from promising scientific breakthrough to real-world remedy has become all but a dead end.



Breakthroughs and Breakdown

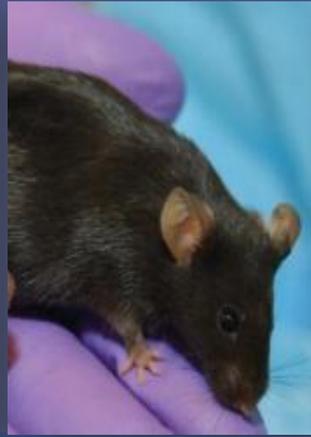
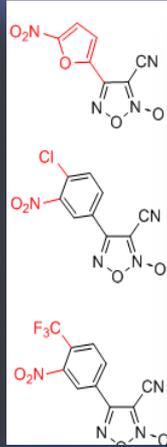
Drugs that changed lives, for better or worse

By [Sharon Begley](#) and [Mary Carmichael](#) |
NEWSWEEK

Published May 14, 2010

From the magazine issue dated May 31, 2010

From 1996 to 1999 The U.S. food and Drug Administration approved 157 new drugs. In the comparable period a decade later—that is, from 2006 to 2009—the agency approved 74. Not among them were any cures, or even meaningfully effective treatments, for Alzheimer's disease, lung or pancreatic cancer, Parkinson's disease, Huntington's disease, or a host of other afflictions that destroy lives.



Disease

Target ID

Assay Dev.

HTS

Probe to Lead

Pre-Clinical

FDA IND

Ph. I

Ph. II

Ph. III

FDA Review

NIH Molecular Libraries Initiative

NIH TRND

NIH RAID

Pharma, Biotech, NIH Clinical Center, CTSAs

New NIH FDA Partnerships

New NIH-FDA Partnership

- NIH FDA Joint Leadership Council
 - Improve translational research
 - Make our science “regulatory review ready”
 - Speed development of new medical products
- Joint Regulatory Science Initiative
 - 59 letters of intent
 - \$6.75 M



New NIH-FDA Partnership

- Public Consultation: June 2, 2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0233]

The National Institutes of Health and the Food and Drug Administration Joint Leadership Council: Stakeholders Meeting; Request for Comments

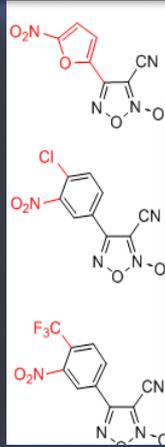
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting, in conjunction with the National Institutes of Health (NIH), to solicit comments from interested persons on how the agencies can more effectively collaborate to advance the translation of biomedical research discoveries into approved diagnostics and therapies as well as promote science to enhance the evaluation tools used for regulatory review. A newly formed NIH-FDA Joint Leadership Council will help ensure that regulatory considerations form an increasing component of biomedical research planning, and that the latest science is integrated into the regulatory review process.

DATES: The public meeting will be held on June 2, 2010, from 8:30 a.m. to 12:30 p.m. Persons interested in attending the meeting must register by Wednesday, May 26, 2010, at 5 p.m. e.s.t. (see section III of this document).

Cures Acceleration Network



Disease

Target ID

Assay Dev.

HTS

Probe to Lead

Pre-Clinical

FDA IND

Ph. I

Ph. II

Ph. III

FDA Review

NIH Molecular Libraries Initiative

NIH TRND

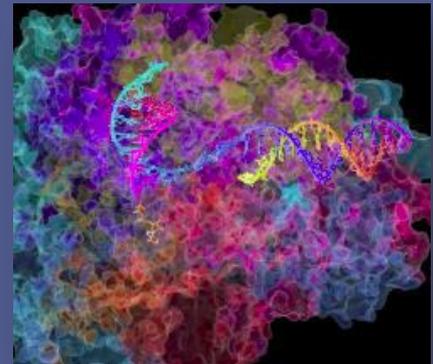
NIH RAID

Pharma, Biotech, NIH Clinical Center, CTSAs

New NIH FDA Partnerships

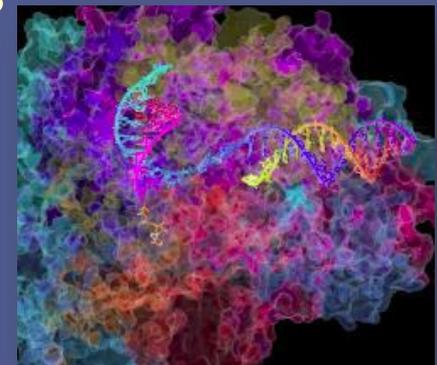
A Bold New Paradigm: The Cures Acceleration Network (CAN)

- Goal: dramatically advance development of new treatments and cures for debilitating and life-threatening diseases by reducing barriers between laboratory discoveries and clinical trials
- “promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.”



A Bold New Paradigm: The Cures Acceleration Network (CAN)

- Authorized budget for FY 2010: \$500M
- Situated in NIH Office of the Director
- Will provide flexible funding mechanisms
 - Grant Awards: up to \$15M per award; potential additional funding in subsequent years
 - Partnership Awards: up to \$15M, requiring matching funds (\$1 for every \$3 awarded by NIH)
 - Flexible Research Awards: DARPA-like research authority



Industry, Patient Advocates Support CAN

April 16, 2010

Honorable Tom Harkin
Chairman

Subcommittee on Labor-HHS-Education
Committee on Appropriations
United States Senate
Washington, DC 20510

Honorable Thad Cochran
Ranking Member

Subcommittee on Labor-HHS-Education
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Cochran:

We respectfully request that the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies include funding for the newly-enacted Cures Acceleration Network in the Fiscal Year (FY) 2011 Labor-HHS appropriations bill.

CAN Letter Signatories

- Abigail Alliance for Better Access to Developmental Drugs
- AIDS Institute
- Alexion Pharmaceuticals
- Alliance for Aging Research
- Alliance for Regenerative Medicine
- Alpha-1 Association
- Alpha-1 Foundation
- ALS Association
- ALS Therapy Development Institute
- Alseres
- Alzheimer's Association
- American Institute for Medical and Biological Engineering
- American Parkinson Disease Association
- Association for Clinical Research Training
- Association for Patient-Oriented Research
- Association of Academic Health Science Libraries
- AVAC: Global Advocacy for HIV Prevention
- Batten Disease Support and Research Association
- Benign Essential Blepharospasm Research Foundation
- BIO Ventures for Global Health
- Biotechnology Industry Organization
- Californians4cures
- CANN - Community Access National Network
- Celiac Disease Center at Columbia University
- Ceregene
- Citizens United for Research in Epilepsy
- Clinical Research Forum
- Coalition of Heritable Disorders of Connective Tissue
- Colon Cancer Alliance
- COPD Foundation
- Council for American Medical Innovation
- Cutaneous Lymphoma Foundation
- Cystic Fibrosis Foundation
- Digestive Disease National Coalition
- Dystonia Advocacy Network
- Dystonia Medical Research Foundation
- Easter Seals
- FasterCures
- Foundation for Sarcoidosis Research
- Friends of Cancer Research
- Genetic Alliance
- Global Healthy Living Foundation
- Harlem United Community AIDS Center, Inc
- Huntington's Disease Society of America
- Infectious Diseases Society of America
- International AIDS Vaccine Initiative
- International Foundation for Functional Gastrointestinal Disorders
- International Myeloma Foundation
- Interstitial Cystitis Association
- Juvenile Diabetes Research Foundation
- Kakkis EveryLife Foundation
- Leukemia & Lymphoma Society
- Lung Cancer Alliance
- Medical Library Association
- Michael J. Fox Foundation for Parkinson's Research Muscular Dystrophy Association
- National Disease Research Interchange
- National Health Council
- National Minority AIDS Council
- National MPS Society
- National Multiple Sclerosis Society
- National Parkinson Foundation
- National PKU Alliance
- National Tay-Sachs & Allied Diseases Association
- National Venture Capital Association
- NephCure Foundation
- New York Stem Cell Foundation
- Parent Project Muscular Dystrophy
- Parkinson Alliance and Parkinson's Unity Walk
- Parkinson's Action Network
- Parkinson's Disease Foundation
- PKD Foundation
- PXE International
- Rett Syndrome Research Trust
- Scleroderma Foundation
- Society for Clinical and Translational Science
- Spinal Muscular Atrophy Foundation
- SRI International
- Student Society for Stem Cell Research
- The Christopher and Dana Reeve Foundation
- Tuberous Sclerosis Alliance

A good cure requires
a good diagnosis



HIGH NEED CURE-

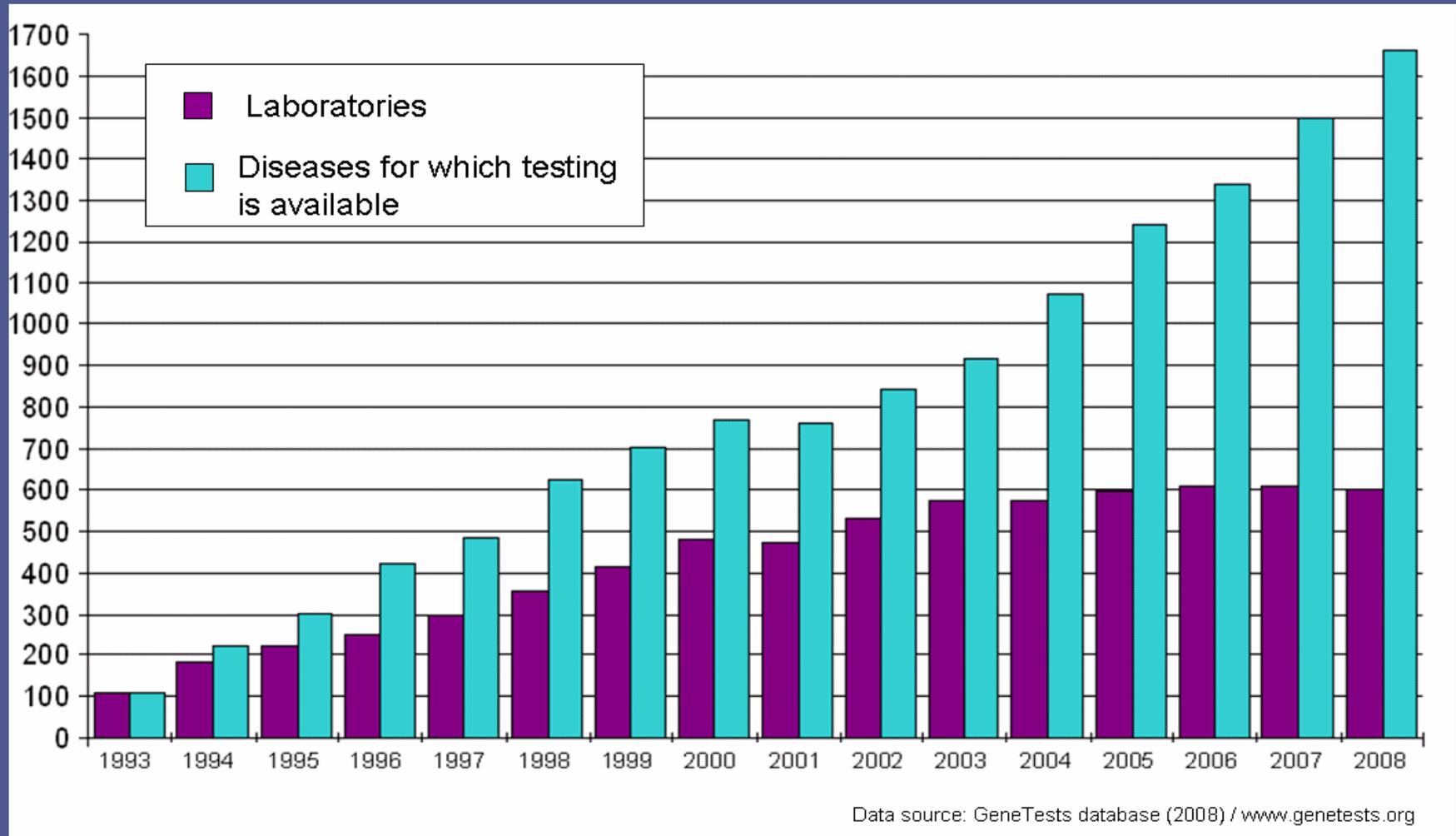
The term `high need cure' means a drug ..., biological product..., or device... that, in the determination of the Director of NIH--

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

Genetic testing has changed dramatically...

- Increase in number



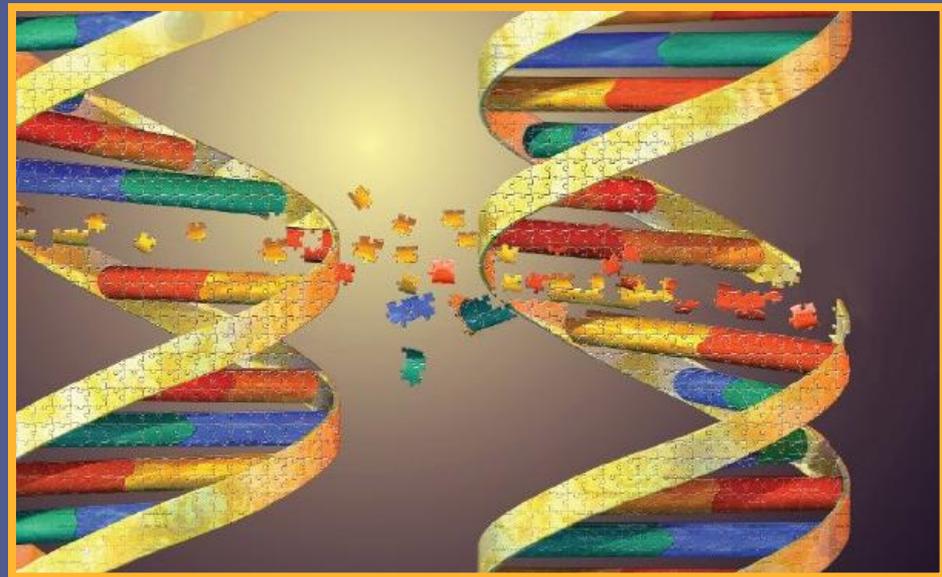
Genetic testing has changed dramatically...

- Increase in number
- Increase in complexity

Detection of single mutations
or massive chromosomal
alterations



Detection of millions of SNPs,
whole genome sequencing,
expression analysis, CGH, etc.



Genetic testing has changed dramatically...

- Increase in number
- Increase in complexity
- Increase in availability

The collage features several overlapping advertisements and logos related to genetic testing:

- GeneIwist**: Includes a pedigree chart, a pile of colorful pills, and a DNA double helix. Text: "GeneIwist", "Order Now!", "Learn about genetic testing for hereditary breast and ovarian cancer.", "CLICK HERE Purchase Online".
- Geneflink**: Includes a stylized DNA helix and the text "Geneflink™", "GENETIC BIOSCIENCES FOR IMPROVING THE QUALITY OF LIFE".
- GENOVATIONS**: Includes the text "GENOVATIONS™ Predictive Genomics for Personalized Medicine", "Custom Fit for Life!".
- NUGENIX**: Includes the text "NUGENIX™ CUSTOM FIT FOR LIFE", "Login to myCODE".
- LAB21**: Includes a blue container with a DNA helix and the text "LAB21", "An Amazing Opportunity".
- Gene - Testing Now Available**: Large stylized text.
- myCODE**: Includes the text "myCODE is my DNA".
- Navigenics**: Includes the text "Navigenics".
- GENETICS IS ABOUT TO GET PERSONAL**: Includes the text "don't panic, we're here to help".
- Your skin is as unique as your DNA.**: Text at the bottom right.



College Bound, DNA Swab in Hand

By TAMAR LEWIN
Published: May 18, 2010

Instead of the usual required summer-reading book, this year's incoming freshmen at the [University of California, Berkeley](#), will get something quite different: a cotton swab on which they can, if they choose, send in a DNA sample.

[Enlarge This Image](#)



The university said it would analyze the samples, from inside students' cheeks, for three genes that help regulate the ability to metabolize alcohol, lactose and folates.

Those genes were chosen not because

Questions?
Call us at **877-505-7374**



Your Personal DNA Report

"Our DNA results provided us peace-of-mind.
We've already taken action to reduce our risks"

WHY SHOULD I TEST MY DNA?

Know your past. Improve your future.
Enjoy the peace of mind knowledge brings.

WHAT'S INCLUDED?

Identify genetic health risks for up to 70 conditions and uncover your ancestral path. Plus more.

HOW DOES IT WORK?

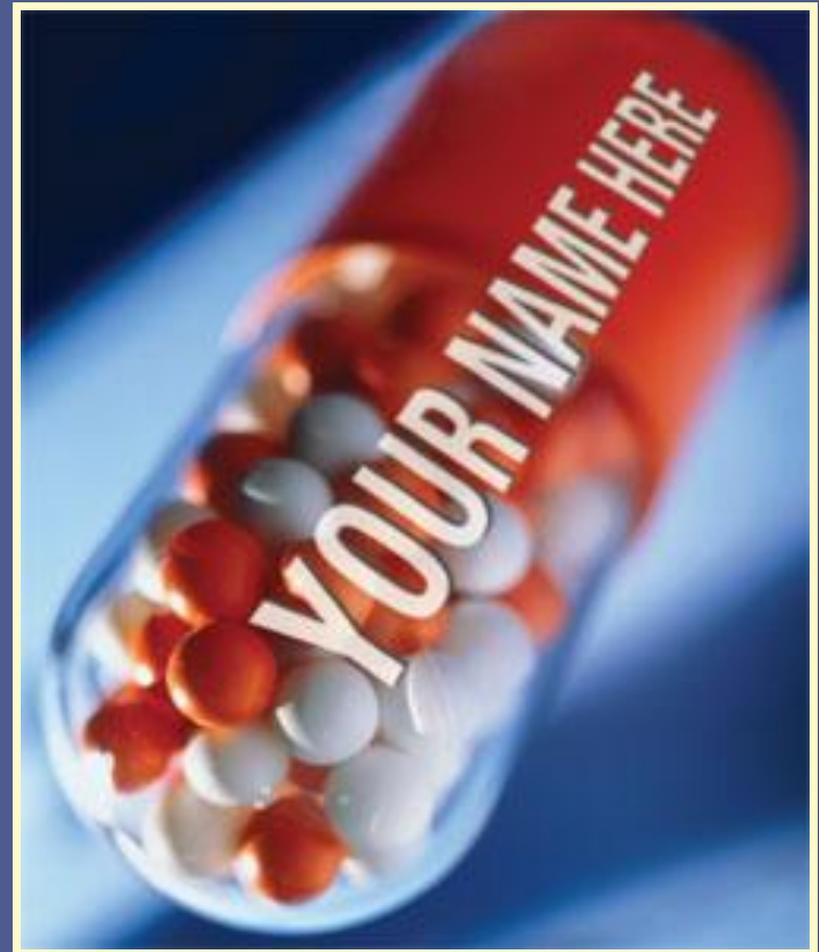
It's easy. Send us your saliva in the DNA collection kit we provide. Then access your DNA analysis online.

BUY THE KIT



Genetic testing has changed dramatically...

- Increase in number
- Increase in complexity
- Increase in availability
- Increase in clinical relevance



Clopidogrel (Plavix)

- Drug Functions:
 - Works by preventing platelets from forming clots
 - Must be activated by specific enzymes (P450)
- Clinical Observations:
 - Commonly used in patients at risk for heart attacks and strokes
 - *However*, it does **not** work for about **30%** of the U.S. population
- Research Question: *why is this drug ineffective in nearly 1/3 of the population?*

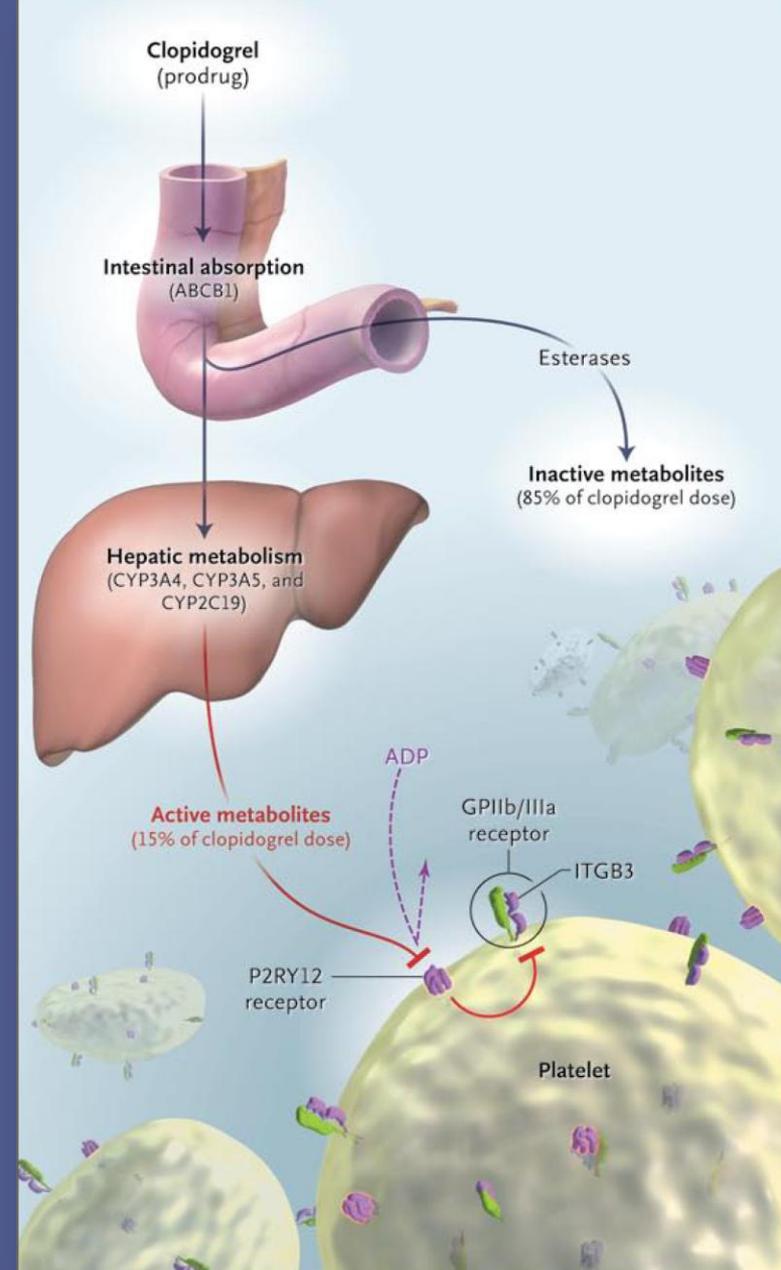


Image: T. Simon, C. Verstuyf, et. al, NEJM

Clopidogrel (Plavix): The Evidence

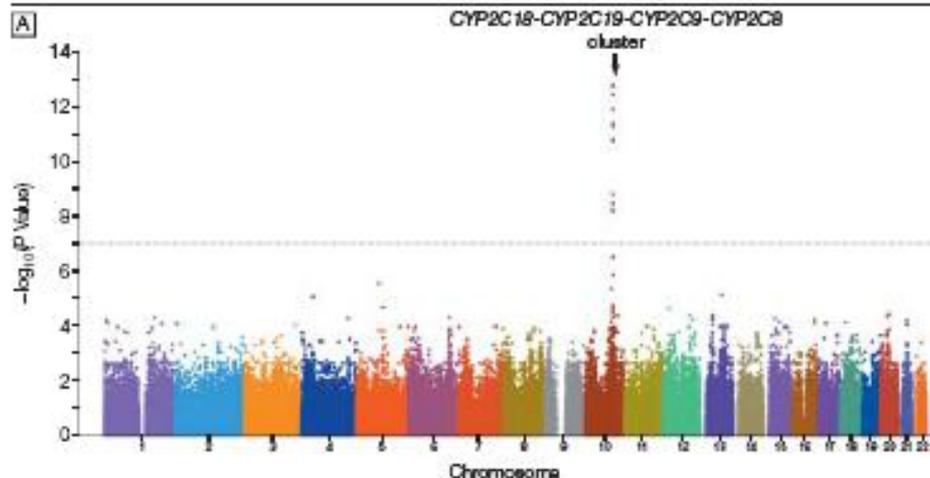
JAMA[®]

ORIGINAL CONTRIBUTION

Association of Cytochrome P450 2C19 Genotype With the Antiplatelet Effect and Clinical Efficacy of Clopidogrel Therapy

CYTOCHROME P450 2C19 GENOTYPE AND CLOPIDOGREL THERAPY

Figure 2. Genome-Wide Association Study of Adenosine Diphosphate–Stimulated Platelet Aggregation in Response to Clopidogrel



From Shuldiner et al.,
JAMA, 8/26/09, vol 302

Drug Relabeling: Clopidogrel

- November 1997: FDA approved clopidogrel for the reduction of atherosclerotic events
- May 2009: FDA added first pharmacogenomic information to label:
 - Based on literature data, patients with genetically reduced CYP2C19 function have lower systemic exposure to the active metabolite of clopidogrel and diminished antiplatelet responses, and generally exhibit higher cardiovascular event rates following myocardial infarction than do patients with normal CYP2C19 function
- November 2009: Precaution upgraded to a warning
- March 2010: Warning upgraded to a “Boxed Warning”

WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS

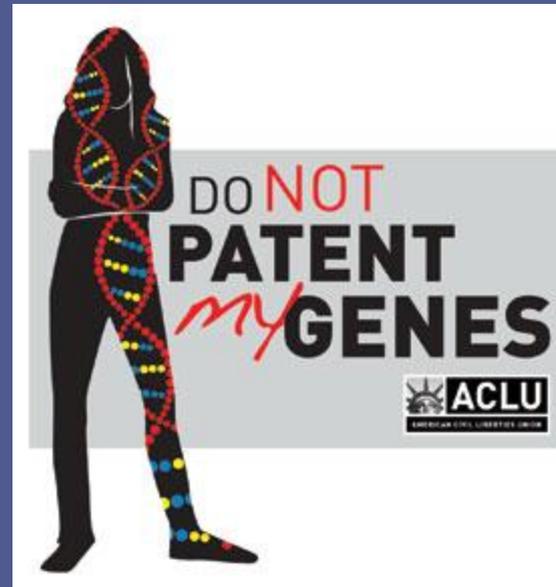
See full prescribing information for complete boxed warning.

- Effectiveness of Plavix depends on activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19.
- Poor metabolizers treated with Plavix at recommended doses exhibit higher cardiovascular event rates following acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) than patients with normal CYP2C19 function.
- Tests are available to identify a patient's CYP2C19 genotype and can be used as an aid in determining therapeutic strategy.
- Consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers.

Landmark Gene Patent Decision

March 29, 2010, Judge Sweet of the U.S. District Court for the Southern District of New York

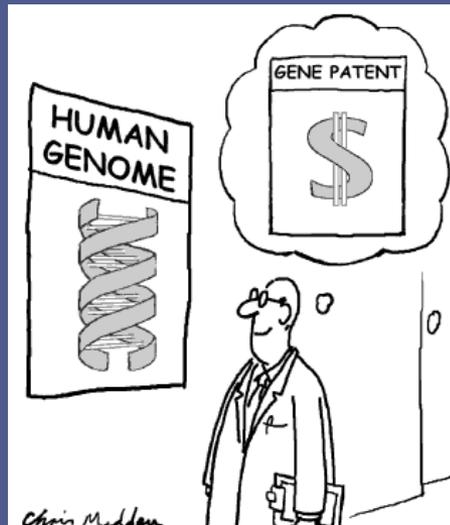
Association of Molecular Pathology (AMP) challenged the validity of fifteen claims contained in seven patents relating to the human BRCA1 and BRCA2 genes



Landmark Gene Patent Decision

The composition of matter claims, which are directed to “isolated DNA” containing sequences found in nature, are unpatentable subject matter under 35 U.S.C. § 101

The methods claims for comparisons of DNA sequences are abstract mental processes and thus the comparisons of DNA sequences are unpatentable subject matter under 35 U.S.C. § 101.



Landmark Gene Patent Decision

What does this mean for DNA diagnostics?

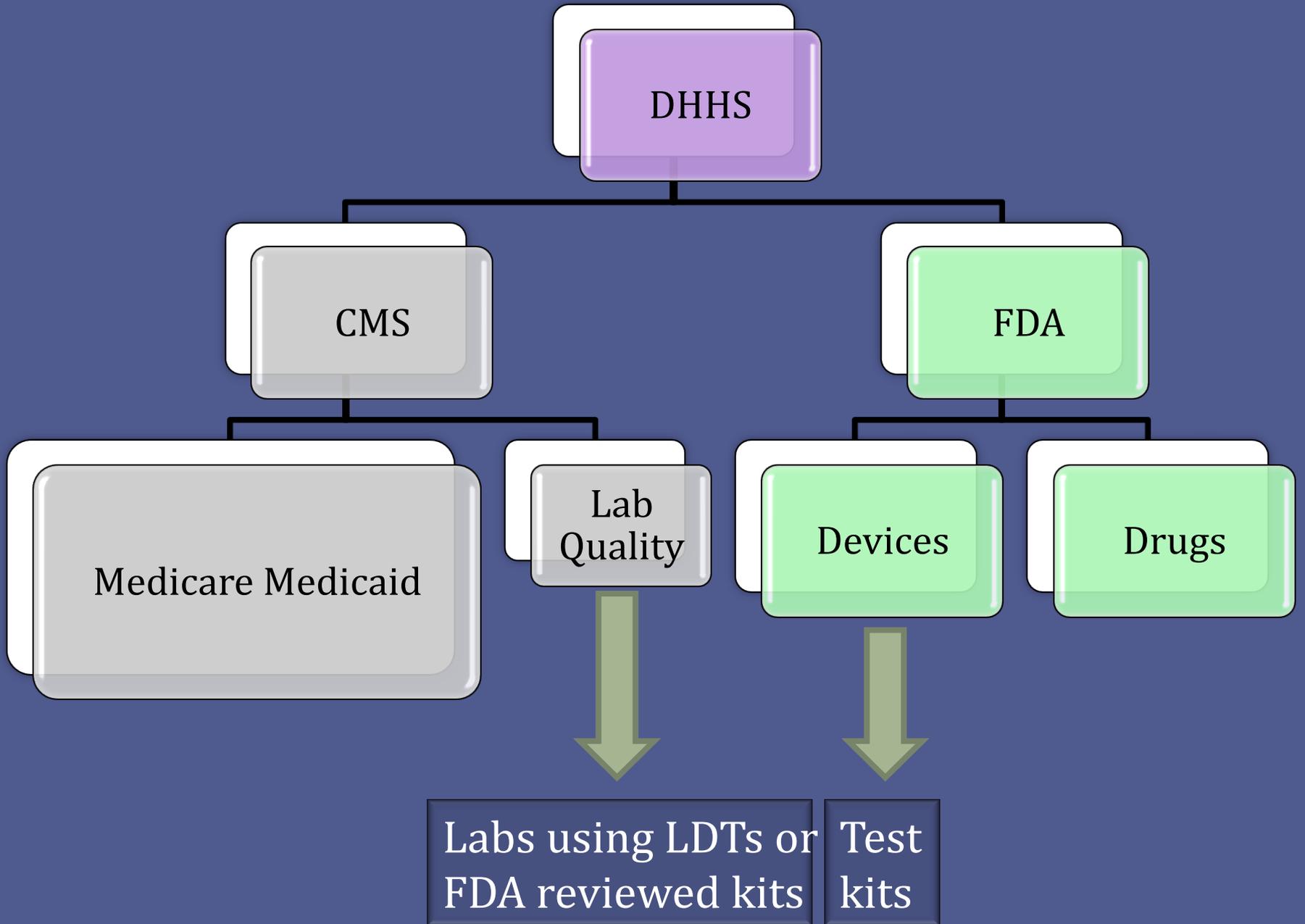
Will this avert the fate of having a \$1000 genome with \$50,000 royalty fees?

What about therapeutics?

Two types of Genetic Tests

- Level of regulatory oversight oddly disparate
- Difference not apparent to patients and health care providers.







The NEW ENGLAND JOURNAL of MEDICINE

“As the leaders of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), we have developed a shared vision for personalized medicine and a scientific and regulatory structure to support its growth.”



The NEW ENGLAND JOURNAL *of* MEDICINE

“NIH and the FDA will invest in advancing translational and regulatory science, better define regulatory pathways for coordinated approval of co-developed diagnostics and therapeutics, develop risk-based approaches for appropriate review of diagnostics to more accurately assess their validity and clinical utility, and make accurate information about tests readily available.”

House launches investigation into genetic tests

By [Rob Stein](#)

Washington Post Staff Writer

Wednesday, May 19, 2010; 3:43 PM

A congressional committee Wednesday launched an investigation into genetic tests being sold directly to consumers.

The House Energy and Commerce Committee and its subcommittee on oversight and investigations sent letters to Pathway Genomics Corp. of San Diego, 23&Me Inc. of Mountain View, Calif., and Navigenics Inc. of Foster City, Calif., requesting information about their tests. The move was prompted after Pathway announced plans last week to sell its genetic test through drug stores nationwide for the first time "despite concern from the scientific community regarding the accuracy of test results," the letters stated.

Walgreens, the nation's largest drug store chain, announced it was postponing plans to sell the test, however, after the Food and Drug Administration

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Congress of the United States House of Representatives

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energycommerce.house.gov

May 19, 2010

Ms. Anne Wojcicki
President
23andMe, Inc.
1390 Shorebird Way
Mountain View, CA 94043

Dear Ms. Wojcicki:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are examining personal genetic tests sold to consumers over the Internet. Recent press reports suggest that at least one genetic testing company is now seeking to sell these tests in retail locations, despite concern from the scientific community regarding the accuracy of test results.¹

In order to assist the Committee with its examination of this issue, we ask that you provide the Committee with the following information and documents for the period from January 1, 2007, to the present:

1. A chart listing the conditions, diseases, consumer drug responses, and adverse reactions for which you test;

F.D.A. Faults Companies on Unapproved Genetic Tests

By ANDREW POLLACK

Published: June 11, 2010

The [Food and Drug Administration](#) is cracking down on 23andMe and other companies that sell genetic tests directly to consumers.

The F.D.A. sent letters this week to five companies involved in that business, saying their tests are medical devices that must receive regulatory approval before they can be marketed.

“Premarket review allows for an independent and unbiased assessment of a diagnostic test’s ability to generate test results that can reliably be used to support good health care decisions,” Alberto Gutierrez, who leads diagnostic test regulation at the F.D.A., [wrote in the letters](#).

The letters, [posted on the F.D.A. Web site](#) on Friday, say the companies must apply for approval or discuss with the agency why certain test claims do not require such approval.

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CYRUS
JUNE 18



DEPARTMENT OF HEALTH & HUMAN SERVICES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Knome, Inc.
c/o Mr. Jorge Conde
Co-Founder & CEO
1 Main Street, Suite 530
Cambridge, MA 02142

JUN 10 2010

RE: KnomeCOMPLETE™

NIH is Building a Genetic Testing Registry

To improve research and public health through:

- Increasing transparency
- Increasing consumer, physician, and researcher access to information
- Increasing marketplace competition

Seeking broad public input on the design of the registry





GENETIC TESTING REGISTRY

With an increasing number of genetic tests available through laboratories, the National Institutes of Health (NIH) recognizes the importance of making information about these tests easily accessible to researchers, patients, consumers, health care providers, payers, and others. Therefore, NIH is initiating the development of the Genetic Testing Registry (GTR), a registry that will provide a centralized location for test developers and manufacturers to voluntarily submit test information such as indications for use, validity data, and evidence of the test's usefulness.

The overarching goal of the GTR is to advance the public health and research into the genetic basis of health and disease. As such, the Registry will have several key functions:

- Encourage providers of genetic tests to enhance transparency by publicly sharing information about the availability and utility of their tests;
- Provide an information resource for the public, including researchers, health care providers and patients, to locate laboratories that offer particular tests; and
- Facilitate genetic and genomic data-sharing for research and new scientific discoveries.

Interacting with stakeholders—such as laboratory test developers, manufacturers, health care providers, patient and consumer groups, and researchers—will be a critical part of developing the GTR.

Learn More

[Questions and Answers](#)

[News](#)

[Definitions](#)

[Governance and Oversight](#)

[Timeline](#)

[Background Reading](#)

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Seeking Input on....

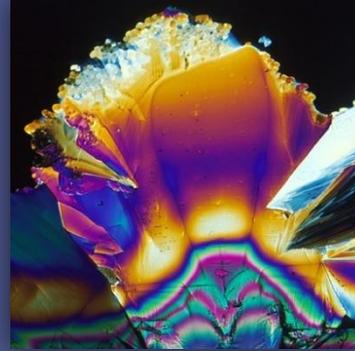
- Types of genetic tests that should/should not be included in the registry
- Potential uses of the Registry for researchers, patients, health care providers, clinical laboratory professionals, payers, and genetic testing entities, policy makers, and electronic health records
- Data elements to include in the GTR and information to collect for each element (e.g. lab certifications, **test** methodologies, intended use, analytical validity, etc.)
- Benefits and risks of sharing information about the availability, accessibility, scientific basis, validity, and utility of genetic tests

Seeking Input on....

- Processes to make data submission as easy as possible
- Benefits and risks that affect the decision to submit data to the GTR and factors that will best encourage submission of complete and accurate data
- Methods to ensure continued stakeholder input into the maintenance of the Registry
- Purposes for which the GTR would be used to support the professional efforts of respondents
- Other issues that NIH should consider in the development of the GTR

To realize the goals of personalized medicine....

- Expand the portfolio of translational research funded by the NIH
- Create information resources for patients and health care providers
- We need a nimble and flexible regulatory system for drugs, biologics and diagnostics
- We need to be able to include genetic information in labels in accurate and user friendly way
- We need to resolve the intellectual property issues
- We need an effective system to manage conflicts



NIH

*Turning discovery
into health*

