

Personalized Genomic Medicine and the Rhetoric of Empowerment

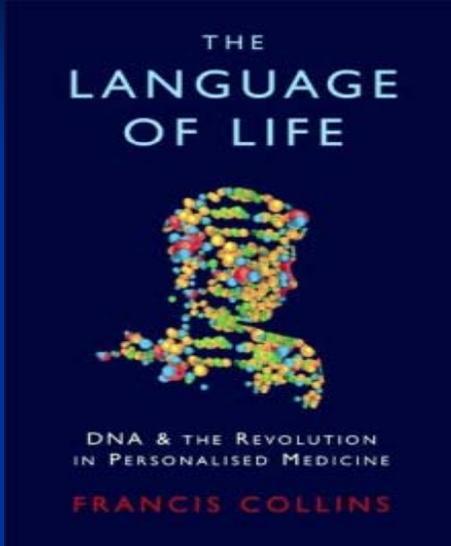
Tuesday, April 12
2011 ELSI Congress, Chapel Hill, NC

Eric T. Juengst
UNC-Chapel Hill

Michael Flatt
Case Western Reserve University

Federal Support for Personalized Genomic Medicine

- Elias Zerhouni: NIH “roadmap”
- Michael Leavitt: HHS visionary reports
- Teri Manolio: NHGRI “Grand Challenges” for getting “Genomics to Health”
- Food and Drug Administration, the Center for Medicare and Medicaid Services, and the Centers for Disease Control: Collaborative work with stakeholders in personalized medicine



THE LANGUAGE OF LIFE

DNA & THE REVOLUTION IN PERSONALISED MEDICINE

FRANCIS COLLINS

“We are on the leading edge of a true revolution in medicine, one that promises to transform the traditional “one size fits all” approach into a much more powerful strategy that considers each individual as unique and as having special characteristics that should guide an approach to staying healthy.”

(Collins 2010: xxiv)

Investigating Diseases, Discovering Cures

Lerner Research Institute

Cleveland Clinic GENOMIC MEDICINE INSTITUTE

Center for Personalized Genetic Healthcare

The Cleveland Clinic, Center for Personalized Genetic Healthcare helps individuals determine their personal risk for diseases that may run in their family, or their risk for passing a disease or medical condition on to their children. It is a comprehensive program that includes diagnostic, evaluation, testing, counseling, education and referral services.

For information on our *Genetics in Health and Disease* informational kick off event, [click here](#).

Our History

In 2005, Dr. Chans Eng came to the Cleveland Clinic and launched the Genomic Medicine Institute (GMI). GMI serves as the expert base for investigation and practice of genomic medicine by being a single platform for research, clinical care and outreach/education ultimately directed at genomic-based personalized genetic healthcare. The clinical branch of the GMI is the Center for Personalized Genetic Healthcare (CPGH). Presently, the CPGH is staffed by five geneticists and twelve

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About Us

The Duke Center for Personalized Medicine was established in 2010 to bring the benefits of personalized medicine to patients of Duke Medicine and beyond.

Advances in genomic and molecular medicine hold the potential to radically transform human health by enabling much more precise prediction, prevention, and treatment of disease on an individual level.

But realizing this potential requires a total rethinking of how health care is delivered—from designing new models of care that incorporate unprecedented technologies and a greater focus on prevention, to changing financial reimbursement to support these models, to empowering patients to play a leading role in their care.

The Center's mission, therefore, is to:

- Develop, test, and disseminate effective, evidence-based clinical tools and care models for delivering personalized medicine
- Educate patients, providers, policymakers, and the public about genomic and personalized medicine
- Empower patients to understand their unique health needs and access resources that will help them achieve optimal health



S. 976: Genomics and Personalized Medicine Act of 2007

110th CONGRESS
1st Session

To secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments.

IN THE SENATE OF THE UNITED STATES
March 23, 2007

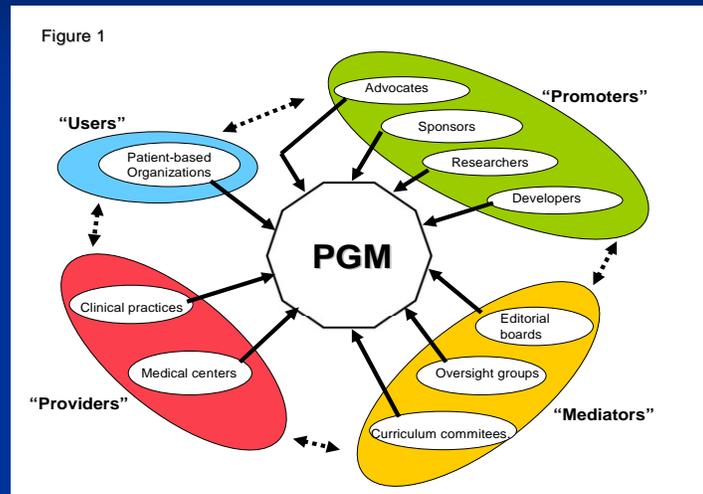
Mr. OBAMA (for himself and Mr. BURR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

Re-individualization of Medicine

- “Healthcare today is in crisis: it is expensive, reactive, inefficient, and focused largely on one size fits all treatments for events of late stage disease. *The answer is personalized, predictive, preventive and participatory medicine.*”

(PMC 2009: 6, *emphasis added*)

The Co-Production of Personalized Genomic Medicine as a Boundary Object in Social Space (!)



Personalized Medicine

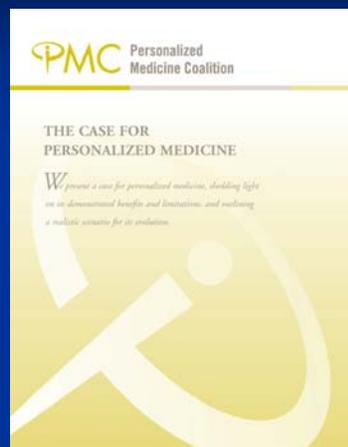
- “Personalized healthcare is envisioned as a comprehensive approach, incorporating gene-biological information to understand each person’s unique requirements for health maintenance, disease prevention and therapy tailored to genetic or molecular profiles. In addition, it includes consideration of each individual’s environment, health-related behavior, culture and values. *Thus, personalized healthcare promises to be predictive, preventive, and pre-emptive, with the potential to transform current healthcare into a value-based, patient-centric healthcare system.*”

(Xu et al. 2008: 457, *emphasis added*)

Virtues of “P4 Medicine”



- Personalized
 - Precisely-targeted, “individualized” via molecular identity
- Predictive
 - Preemptive, through prognosis and “early detection”
- Preventive
 - Proactive, with focus on “optimizing” health/wellness
- Participatory
 - Patient-centered, empowering patients to take control

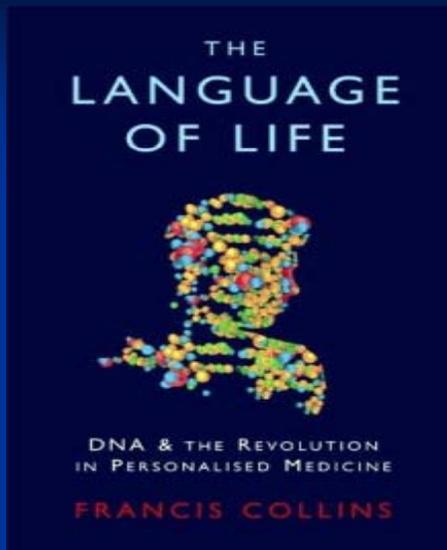


As the Personalized Medicine Coalition stresses in describing PGM, “it is proactive and participatory, engaging patients in lifestyle choices and active health maintenance to compensate for genetic susceptibilities.”

(PMC 2009: 2)

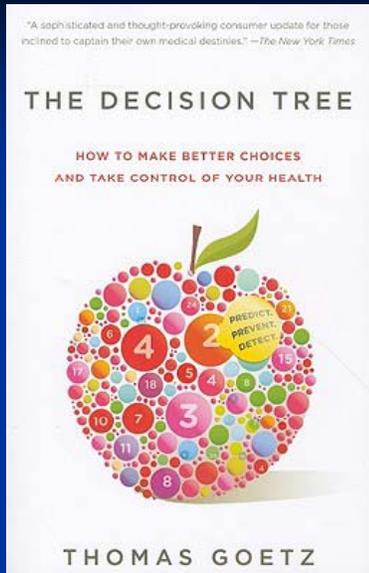
D-T-C marketing of PGM

- Navigenics: “There’s DNA. An then there’s what you do with it. ...revealing your genetic predisposition for important health conditions and empowering you with knowledge to help you take control of your future health.”
(Navigenics 2009)
- DecodeMe: “Getting to know your personal genome will empower you and provide you with a road map to improve your health.”
(deCodeMe 2009)



“The success of personalized medicine will come about only when we each take responsibility for our health. Health care providers can help, but they cannot drive your bus. Each chapter of this book has concluded with a list of things you can do now to take full advantage of the potential for personal empowerment. If you follow these recommendations, you will truly be on the leading edge of this new revolution. But the edge will keep moving, and so it will be essential to upgrade your own knowledge base periodically.”

(Collins 2010: 278)



- “Designating physicians as gatekeepers for genetic information isn't just disempowering - it's basically sticking healthcare in a time capsule for a decade or more, until physicians get up to speed.
- This persistent paternalistic streak also reflects a lack of faith in the ever-more empowered patient, who is eagerly scouring the Internet for the latest research concerning their condition.
- Like it or not, patients are not going to stop trying to understand ourselves, and our health better. What our genomes might tell us is just one more piece of the puzzle.”

(Goetz 2010)

http://www.huffingtonpost.com/thomas-goetz/dna-test-is-your-dna-dang_b_616568.html

Internalized Empowerment

“Since being given the results of my test, my initial feelings of fear and depression have gradually been replaced by a sense of empowerment ... “There is no need to worry, providing you change your lifestyle’ [the doctor] kept repeating. So that is what I have decided to do. I now have the greatest possible incentive to change my way of life.”

Maitland (quoted in Harvey 2009: 372)

How this is a virtue?

Ultimately, the results of the HGP ... will profoundly alter our approach to medical care, from treating disease that is already advanced to a preventative mode focused on identification of individual risk. **This should permit early initiation of changes in lifestyle and medical surveillance, preventing individuals from becoming ill in the first place.**

(Guyer and Collins 1993: 147)

A Moral Stand Against Paternalism?

“Your genome is yours to manage as you like.”
(Knome 2008)

“We believe that your genetic information should be controlled by you... Though we store and help you interpret it, your genetic information is yours to have and explore. 23andMe provides you with all your data and will never withhold it from you.”

(23andMe 2008)

Or Virtue of a necessity?

- Is patient empowerment a good thing because it is the right thing to do, or because it is the only way that PGM has any chance of actually improving health outcomes?
- Is this a prudential virtue being dressed up as a moral claim?

Pharmacogenomic rebuttal

- Pharmacogenomic testing to optimize drug regimens goes beyond lifestyle planning as a result of PGM.
- It is not clear that patient control will increase beyond existing medical practices of shared decision-making and informed consent.

Why it matters

- Empowerment goes beyond achieving health goals because it confers:
 - New rights and privileges which are coupled with
 - New complementary responsibilities, which help
 - Ensure that empowered patients make the right kinds of health-producing choices.

From rights to responsibilities

- “At DNA Direct, we believe that testing is about empowerment – your body and your health are ultimately your responsibility and your genes offer tremendous insight into personal, medical and lifestyle choices.”

(Ryan Phelan, Founder & CEO of DNA Direct)

In Conclusion

- Most of the ELSI discussion of PGM has focused on the external constraints that challenge its success: provider education, test efficacy, social repercussions. But even the internal virtues of PGM require attention as things move forward.
- If there PGM provides no extra leverage to patients to take control their health care from health professionals, it does not “empower”.
- To that extent, it does not impose any extra responsibilities either.

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