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Personalized Medicine Overview
HealthTechNet

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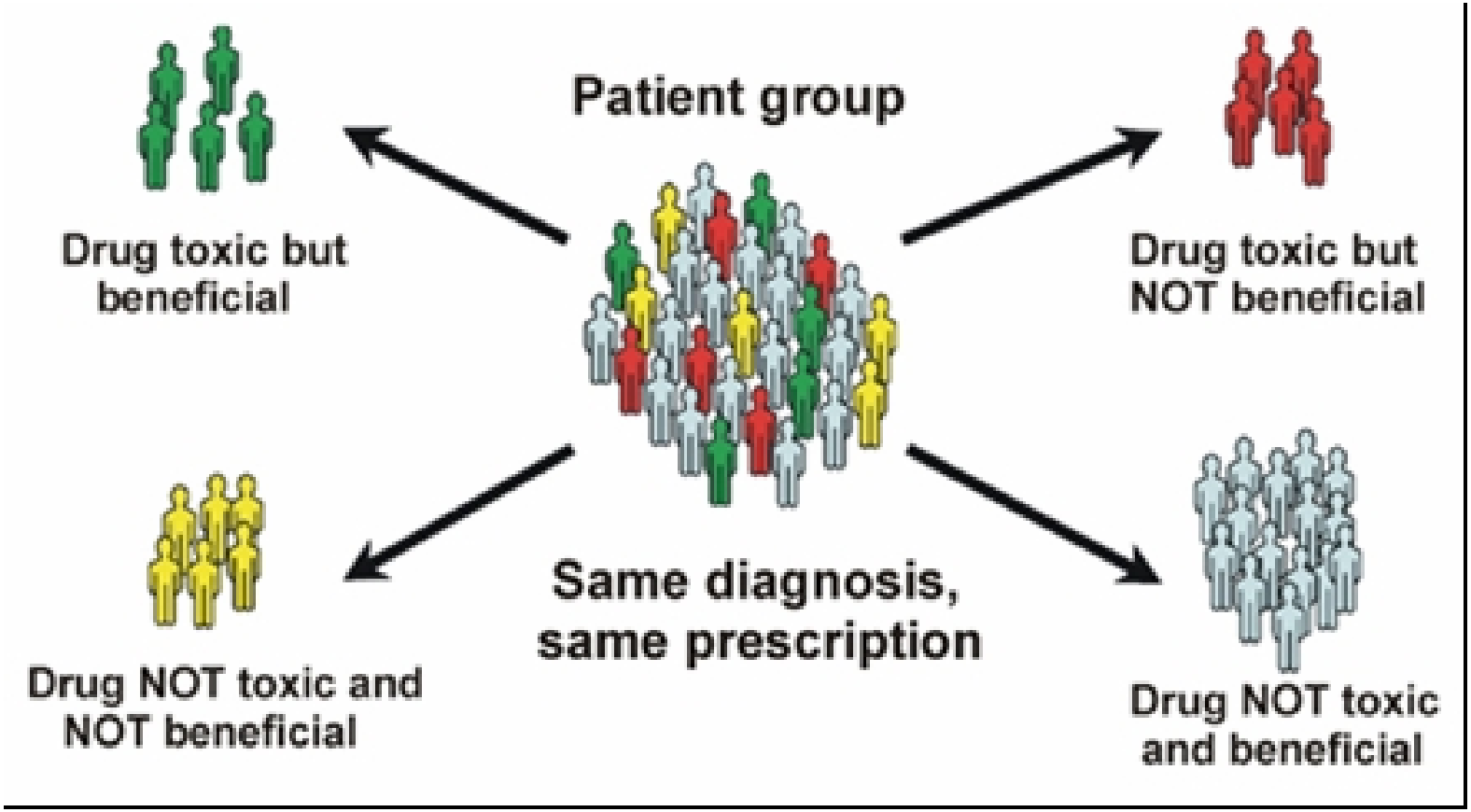
What is personalized medicine?

- Personalized medicine is a rapidly advancing field of healthcare that is informed by each person's unique clinical, genetic, genomic, and environmental information. Because these factors are different for every person, the nature of diseases—including their onset, their course, and how they might respond to drugs or other interventions—is as individual as the people who have them.

What is Personalized Medicine?

- Personalized medicine is about making the treatment as individualized as the disease. It involves identifying genetic, genomic, and clinical information that allows accurate predictions to be made about a person's susceptibility of developing disease, the course of disease, and its response to treatment

Why Personalized Medicine?



Advantages of Personalized Medicine

Specific advantages that personalized medicine may offer patients and clinicians include:

- Ability to make more informed medical decisions
- Higher probability of desired outcomes thanks to better-targeted therapies
- Reduced probability of negative side effects

Advantages of Personalized Medicine

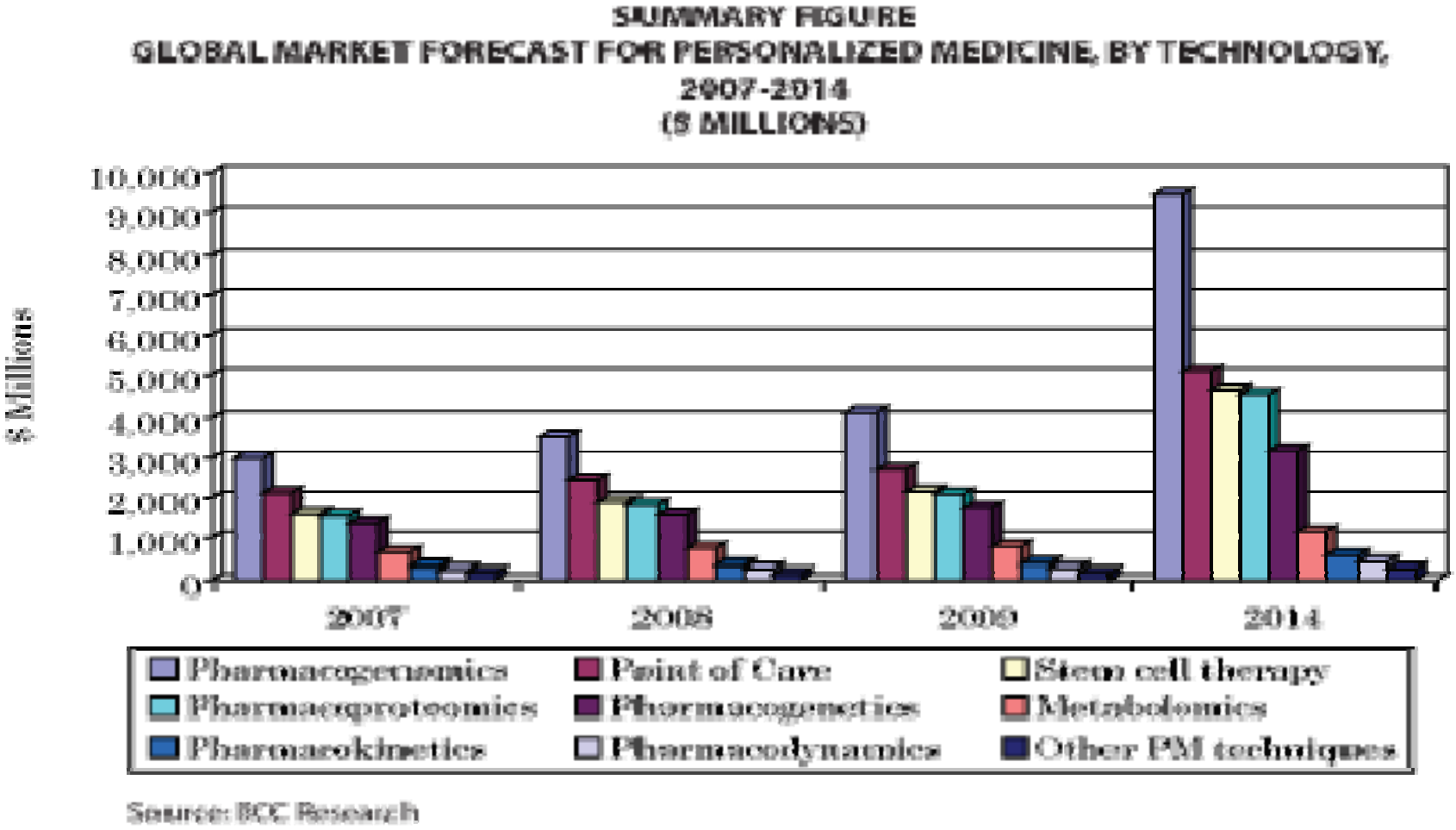
- Focus on prevention and prediction of disease rather than reaction to it
- Earlier disease intervention than has been possible in the past
- Reduced healthcare costs

From Hype to Grind

- Human genome mapped in 2003
- Hype - new cures around the corner
- Hype gives way to recognition that most conditions are more complex than hoped – probably a complex combination of various genomic markers and mutations as well as environmental drivers.
- Focus shift to proteomics, etc.

From Hype to Grind

Market Size



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Scope of Personalized Medicine

- Medicine – Pharma/Biotech
- Medical Devices
- Protocols

For:

- Behavioral Health
- Physical Health
- Both Testing And Treatment

Testing

- Diagnostic Testing -Only type covered by Medicare
- Carrier Testing – for reproductive planning
- Predictive Screening – for downstream cost and potential mitigation planning

Predictive Testing

Researchers are actively investigating the genomic and genetic mechanisms behind—and developing predictive testing for—such diverse medical conditions as:

- Infectious diseases, from HIV/AIDS to the common cold
- Ovarian cancer
- Cardiovascular disease

Predictive Testing

- Diabetes
- Metabolic abnormalities
- Neuropsychiatric conditions, such as epilepsy
- Adverse drug reactions
- Environmental exposure to toxins

Testing

- A genetic test is a “medical device” to the FDA.
- FDA approval indicates the test is accurate for identifying existence of the genetic marker – nothing to do with what it means or how it’s used.
- Less than 100 of approximately 3000 existing genetic tests are FDA approved.

Coding for Tests

- Most CPT codes for genetic tests are generic – not test specific.
- AMA is creating test specific codes for the top 50 tests.

Related Legislation - GINA

- The Genetic Information Non-Discrimination Act of 2008 (GINA) prohibits the use of genetic/genomic information by health insurance companies for determining a person's eligibility for insurance or determining insurance premiums—as well as by employers for making decisions about functions such as hiring and firing, assigning jobs, and promoting and demoting.

Related Legislation - GINA

- However, the measures in the law do not apply to life insurance or long-term care insurance, and the US military is also exempt.

Related Legislation - GPMA

- The Genomics and Personalized Medicine Act-2010 was introduced in the U.S. Congress to address scientific barriers, adverse market pressures, and regulatory obstacles.

Related Legislation - GPMA

The stated aim of the Genomics and Personalized Medicine Act is:

- 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, and for other purposes.

Related Legislation - GPMA

The OPH: Coordinating Personalized Medicine. GPMA 2010 would create an Office of Personalized Healthcare (OPH) within the Department of Health and Human Services (HHS). OPH would be responsible for:

- recommending which personalized medicine products should be regulated, and what roles and responsibilities should be assigned to the FDA vs. CMS

Related Legislation - GPMA

- coordinating the activities of various federal agencies and private and public entities
- development of a long-term plan to accelerate the research and development of personalized medicine products
- Coordinating the spending of lots of money

Related Legislation - GPMA

- **A National Biobank**. GPMA 2010 would create a national biobank to collect and integrate human biological specimens and biobank data. “Biobank data” includes health information, demographic genotype, molecular profile data, and environmental data.

Clinton Rubin Health Care

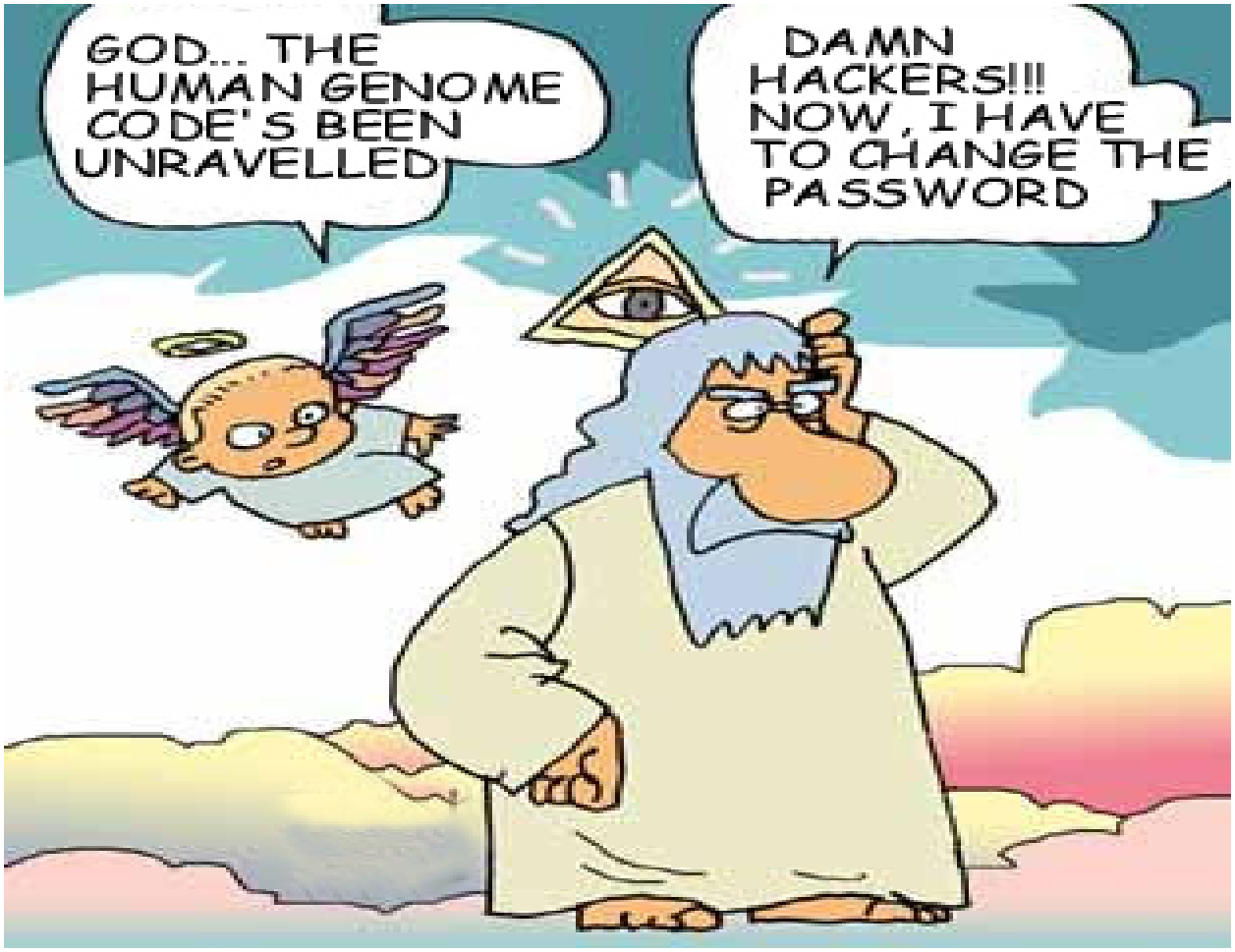
The Irony of "Evidence Based Medicine"

- Once meant that people with similar conditions should be treated similarly according to what seemed to work the best for the most people. You should treat a condition in Peoria the same way you treat the same condition in Poughkeepsie if Poughkeepsie has better outcomes.

The Irony of "Evidence Based Medicine"

- Just as the industry was starting to make headway on this objective we have come to understand that it isn't people with similar conditions who should be treated similarly, it is people with similar CAUSES of similar conditions and who would LIKELY RESPOND to a particular treatment that should be treated similarly.

Oh Oh!


GOD... THE HUMAN GENOME CODE'S BEEN UNRAVELLED
DAMN HACKERS!!! NOW, I HAVE TO CHANGE THE PASSWORD