



Institute for Alternative Futures
FORESIGHT SEMINARS ON HEALTH & INNOVATION



Misconceptions & Potential from The Human Genome

Meeting Report

Foresight Seminar Meeting, January 24, 2003
Room 902, Hart Senate Office Building

The Reality of Personalized Medicine Will Be Here Faster than Expected

The Foresight Seminar panel included:

- **Alan Guttmacher, M.D.**, Deputy Director of the National Human Genome Research Institute (NHGRI)
- **Allen David Roses, M.D.**, Senior Vice President, Genetics Research, GlaxoSmithKline
- **Christopher J. Webster, B.V.M.&S., Ph.D.**, Director, Regulatory Strategy and Intelligence at Millennium Pharmaceuticals
- **Robert Wells, J.D.**, Affymetrix is Vice President for Government Relations and Public Policy for Affymetrix, Inc.

Provocative Insights

By the end of the decade people will know something about their individual genetic makeup to craft a kind of personalized medicine. —Alan Guttmacher

What is predicted to redefine medical treatment by 2010 is going to be here by 2005 and be required by 2010. —Allen Roses

Improved Treatment Selection

Personalized medicine, whether achieved in 5 or 10 years, will have significant implications for the delivery of healthcare. **The map of the human genome is yielding better knowledge about the complex relationship between a disease, the patient's genes and drug sensitivity.** The result can be better treatment selection for patients so that those who are likely to experience side effects or no effects are identified in advance. The genomic era has begun and it will bring many changes along with personalized therapeutic decision making.

New System for Diagnosis

Disease classification has been based on symptoms more than a molecular understanding, but that will change. Already in cancer new subclassifications help guide treatments and this will come to other diseases as well. The ability to take a molecular view of disease will change how a diagnosis is made and what kind of treatment options will be offered. **Payment systems that reimburse based on diagnosis will have to change.**

Patient and Provider Roles

Many decisions about the value of a treatment will have to be made by patients whose genetic tests show their specific risks for hazards as well as likely benefits from a given therapy. Providers will need to guide them towards wise decisions, which takes time that needs to be compensated as well as a knowledge base. Education for both healthcare professionals and the public will need to support the understanding of genetic information and risk evaluation.

Dr. Allen Roses provided several examples employing this more sophisticated approach to treatment. He used one brief scenario to illustrate how patients in 2010 may walk into their doctor's offices and through sophisticated diagnostics learn that they have the type 27A form of arthritis (a subtype). A pharmacogenetics profile would be run that includes all the drugs or treatments for this type of arthritis. **Their doctors would then give them the result of their pharmacogenomic evaluation, which will provide possibly two or three treatment options each with a different ratio of effectiveness to side-effects.** The options may include a drug that is 99 percent effective, with a two percent chance of causing severe liver damage or a drug option that is only 67 percent effective with no major side-effects other than the discomfort of intermittent hiccups. While simple illustration points to a large change in the practice of medicine as well as the regulatory and reimbursement systems that support healthcare.

Future Policy Options

There is great potential from genomics, but its promise depends on several critical factors determining how soon the public can benefit. All the Foresight Seminar speakers agreed that barring genetic discrimination through legislation is key. Patients should also have their genetic information protected from misuse by health care providers. Congress has introduced several legislative options that attempt to achieve this, but no legislation has been passed. Congress lags behind twenty-five states that have laws protecting against such discrimination. Currently, the Senate is reviewing **S.16 Equal Rights and Equal Dignity for Americans Act of 2003**, which includes title VIII aimed at prohibiting genetic discrimination.

Congress can also encourage reform in healthcare reimbursement. As Mr. Wells noted at the Seminar, the **existing insurance payment system has been outstripped by medical innovations, and it has yet to consider reframing of disease classifications, improved treatments and future payment options.** The ability to give patients the optimum treatment should be an appealing opportunity for insurers—both public and private. However, the changes required to make such a shift present a considerable challenge.

Regulatory changes will be required to account for the new knowledge about safety and efficacy—not just for new medicines, but also for a host of existing products that include branded and generic drugs, OTCs (Over the Counter) and dietary supplements. **Congress will need to assign institutional responsibility for assessing the safety and efficacy of existing products once genomics has become a regulatory necessity.** Not only will new and more sophisticated drugs come to market, but drugs once considered too harmful for public consumption may be revived for the use of unique populations who can benefit from them. Additional questions will also loom about the role of FDA in a possible near-term future where patients have the information to take on more risk.

Action Items

Policy initiatives needed to advance the benefits of this genomic era include:

- Passing federal and state legislation that protects against genetic discrimination and gives patients control of their genetic information.
- Policy assessments of institutional responsibility for drug safety, efficacy and pharmacogenomic classification of products already on the market.
- Medicare and insurance reimbursement that accommodates new disease classification and creates incentives for cost-effective care with personalized therapeutic selection.

Additional Resources

[The National Human Genome Research Institute](#)

Read about the latest developments in genomics via The National Human Genome Research Institute, which supports genetic and genomic research, investigation into the ethical, legal and social implications surrounding genetics research, and educational outreach activities.

[Pharmacogenetics and the Practice of Medicine](#)

Nature Magazine article by Dr. Allen Roses on the use of pharmacogenetics, to profile variations between individuals' DNA to predict responses to a particular medicine. Also using this information to make decisions on the economic value of a simple, predictive medicine response profile, which will provide information on the likelihood of efficacy and safety of a drug for an individual patient, and altogether changing the practice and economics of medicine.

[IAF's ESRC Project on Genomics and Society: Priorities for Social Science Research](#)

The UK Government's Economic and Social Research Council (ESRC) commissioned a team led by the Institute for Alternative Futures (IAF) and the Centre for Research on Innovation and Competition (CRIC) to use the futures methodologies of forecasting and scenarios to explore the future of genomics and society. The aim was to provide a view of emerging issues in genomics and biotechnology, and to help identify areas where social science research related to genomics could make its greatest contribution.

[Personalized Medicine's Bitter Pill](#)

Technology Review article. Drugs tailored to an individual's genetic makeup promise to be safer and more effective, but they raise tricky economic and ethical questions.