

- Pass GINA.
- Recognize that this has been a U.S.-centric discussion and that we need to further examine the global perspective.
- Meet with the Secretary of HHS and leadership in all of the agencies to broaden communication and advance solutions.

Notes for Day Two

1. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).
2. *Guidance for Industry and FDA Staff Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions*. FDA (September 14, 2007). See <http://www.fda.gov/cdrh/oivd/guidance/1590.pdf>. *Draft Guidance for Industry, Clinical Laboratories, and FDA Staff In Vitro Diagnostic Multivariate Index Assays*. FDA (July 26, 2007). See <http://www.fda.gov/cdrh/oivd/guidance/1610.pdf>.
3. Morgan, Marie A., Driscoll, Deborah A., Zinberg, Stanley, Schulkin, Jay, and Mennuti, Michael. *Impact of Self-Reported Familiarity With Guidelines for Cystic Fibrosis Carrier Screening*. American College of Obstetricians and Gynecologists (June 2005).
4. See <http://www.cettprogram.org/>.
5. Clinical Laboratory Improvement Amendments (CLIA) Regulations, 493.1417, *Standard; Clinical consultant qualifications*.

Conclusion

It is clear that this is an area ripe with possibility. It is also clear that lack of leadership and communication in and among federal agencies and other stakeholders, a lag in the time regulation takes to catch up to innovation, and competition across all stakeholder groups has left much fruit on the vine, but with the potential for demise rather than success.

We opened this space to invite truth and honest interactions. We achieved that goal, the result of which is the prior list of recommendations. Following this meeting, a number of companies, academic groups, and advocacy organizations came together to work out concrete recommendations for alternative models. Federal agencies invited input from these and other groups. The community has taken action on each recommendation, some more than others.

The most difficult aspect of releasing the great potential of genetics and genomics as it moves into medicine is not the science, nor the intellectual endeavors. The most difficult task is encouraging honest interactions that will result in the best solutions. Society needs appropriate regulation—benchmarks of the truth that make sense and make products safe. Innovators and entrepreneurs need the same truth—what makes sense and what is safe to pursue. Healthcare providers need assurances that their services will be reimbursed fairly, and they need quality information and guidelines in a timely manner. Timely in this age means quickly, along the lines of the responsiveness of other industries in the information age. Finally, consumers need safe and effective tests, as well as an understanding that they have to be involved in the process from clinical trials to policy-making, both formally and informally.

We are truly excited about the power of diagnostics, from simply knowing the name of a disease (ask any family who has traveled the ‘diagnostic odyssey’) to understanding risk, determining prognosis, managing treatment and planning life events. We eagerly anticipate the solutions that will emerge from keeping our eyes on the prize, and we knowingly step up to the task of working with the broader community for safe, effective testing, and the integration of more genetics and genomics into medicine.

Update: On May 21st, 2008, the Genetic Information Nondiscrimination Act (GINA) was signed into law by the President after near-unanimous votes in the U.S Senate and the U.S. House of Representatives.

GINA is federal legislation that provides protections against genetic discrimination in health insurance and employment settings. Current laws do not adequately protect individuals from genetic discrimination. Due to this lack, individuals have been fearful of the misuse of their genetic information. This fear has prevented people from accessing their genetic information. Individuals’ lack of testing denies them important medical information that they could otherwise use to proactively manage their health. The fear of discrimination has also caused a large number of people to opt out of clinical trials, which leads to slower development of treatments and beneficial drugs.

GINA provides legal protections for every individual in the nation. With these protections in place, individuals can feel free to avail themselves of genetic testing and use that information to make more robust medical decisions. Researchers can also select from larger pools of clinical trial participants, thus expediting the research and development process for new therapies. The health insurance protections offered by GINA roll out 12 months after the bill is signed. The employment protections can be fully realized 18 months after the bill signing.