

SPECIAL ADVERTISING FEATURE

AT THE HILL/ACLA POLICY BRIEFING

The Innovation Revolution in Genetic Testing

MADE POSSIBLE BY THE MAPPING OF THE HUMAN GENOME, PERSONALIZED MEDICINE MIGHT JUST BE THE REMEDY TO HELP FIX A BROKEN HEALTH CARE SYSTEM AND MEND AN AILING ECONOMY.

While the Republican and Democratic viewpoints on the Affordable Care Act could not be more different, both sides seem to wholeheartedly agree on an innovative new health strategy: Personalized medicine, made possible by the mapping of the human genome, is a dramatic example of American ingenuity that pushes the boundaries of science and medicine – and in the process, is helping to save lives, mend a broken health care system, and improve the economy. At least that was the common view expressed by two House members from Texas who are also members of the House Energy and Commerce Health Subcommittee.

Speaking at a March 17 Capitol Hill policy briefing, “The Innovation Revolution in Genetic Testing”, sponsored by The Hill newspaper and the American

“GENETIC TESTING HAS TREMENDOUS IMPLICATIONS — NOT JUST TO HEALTH CARE, BUT TO HOW WE SAVE MONEY, HOW WE ADVANCE THE ECONOMY.”

— Rep. Charles Gonzalez (D-TX)

Clinical Laboratory Association’s Results for Life Campaign, Rep. Charles Gonzalez (D-TX) and Rep. Michael Burgess, MD, (R-TX) shared common ground in their enthusiasm for the medical and cost-saving breakthroughs afforded by genetic testing. Also joining the discussion were Kenneth Sisco, MD, PhD, medical director for Quest Diagnostics Nichols Institute, explaining how genetic testing enables physicians to find the right, most cost-effective treatment; and Cynthia Kimball, a patient who, like her four sisters, personally benefitted from the genetic test that revealed them to be

carriers of the BRCA1 breast cancer mutation.

“As policymakers, both Mike (Rep. Burgess) and I know it is imperative that our colleagues consider this tool of genetic testing and how it might answer

the big questions related to fixing our broken health care system,” said Rep. Gonzalez. Genetic testing “is the flashpoint of the new era of rapid advancement in medicine,” he added.

An Example of American Ingenuity

“As an American, I am immensely proud that the mapping of the human genome was completed in

“THE DOCTORS OF TOMORROW WILL BE LIVING IN THE GOLDEN AGE OF MEDICINE...AND THIS (GENETIC TESTING) WILL BE A PART OF IT.”

— Rep. Michael Burgess, MD (R-TX)

2003 and is ongoing,” said Rep. Gonzalez. “The feat continues the tradition of American ingenuity in the realm of medical advancement.” The US is the country that developed the polio vaccine, the artificial heart, the artificial lung, heart transplants, and the MRI, he noted.

“The potential positive impact that the continued development of the bio-medical industry in general, and genetic testing specifically, could have on our economy is very important as it has the potential to reduce health care costs,” Gonzalez said.

Personalized Medicine a Game-Changer

Looking over his 25-year career as a physician, Rep. Burgess observed the dramatic changes that he has witnessed in the practice of medicine. “Nowhere has that change been more rapid and dramatic than in clinical genetics,” he said, because it has been punctuated by the cracking of the genetic code in the late 1990s.

The ability to tailor treatment to the individual’s unique genetic fingerprint allows physicians to personalize treatment, Rep. Burgess explained, recalling a discussion with Elias Zerhouni, MD, former director of the National Institutes of Health (NIH): Dr. Zerhouni described the “four Ps” of medicine of the future. It will



Genetic testing is a dramatic example of American innovation that improves health and reduces costs, says Rep. Charles Gonzalez (D-TX) at the policy briefing sponsored by The Hill and ACLA.



The ability to tailor treatment to the individual’s unique genetic fingerprint allows physicians to personalize treatment, says Rep. Michael Burgess, (R-TX): “It’s a game changer.”

Genetic Testing for Cancer Risk: Find a “Previvor”, Save a Life, Impact a Family Tree



Cynthia Kimball advocates for BRCA1-2 testing at a policy briefing by The Hill and ACLA. Inheriting the gene mutation dramatically increases the risk of breast and ovarian cancer. “Empowerment to make decisions is a gift,” says Kimball.

Thinking that something was terribly wrong to have three out of five sisters in the same family diagnosed with breast cancer in their 30s, Cynthia Kimball’s doctors finally took a family history — on the maternal side.

“My mother is negative, and they are shocked,” said Kimball, a patient advocate for BRCA1-2 testing, speaking at the March 17 Capitol Hill briefing on innovation in genetic testing. “The gene mutation comes from my father’s side.

Out of seven people in our family, six are BRCA1 positive: my father, myself, and my four sisters.”

There is a long legacy of hereditary breast and ovarian cancer on Kimball’s father’s side of the family, going back three to four generations. “I have physicians who say, ‘We don’t see patients like you.’ And I say, ‘Yes, you do. Are you taking a family history? And if you are, are you taking both the mom’s side and the dad’s side, and also ages?’”

Gifts from the BRCA Test

Kimball talks about the positive impacts that genetic testing has had on her life, and the gifts that have come from that. She and her family have started

the Kimball Family Foundation, for example, to educate the public about genetic testing for hereditary breast and ovarian cancer.

If someone tests positive for the mutation but does not yet have cancer, they can do something about it, she said. They can be “previvors” — not survivors.

“Empowerment to make decisions is a gift. As soon as I found out I was BRCA1 positive, I could have preventive surgeries to reduce the risk of getting breast and ovarian cancer. I was at very high risk for both.”

Calling adversity a character builder, and also a gift, Kimball is now an outspoken and informed advocate for BRCA 1-2 genetic testing. She also is pursuing a doctorate in the study of cancerous behaviors in the workplace.

“One of the best gifts is to find a previvor, save a life, and impact a family tree. I have six nieces and nephews, and they will start to test for BRCA1. We now have an answer — and that is such a gift. We know it’s been going on in our family, and we know where this cancer has come from.”

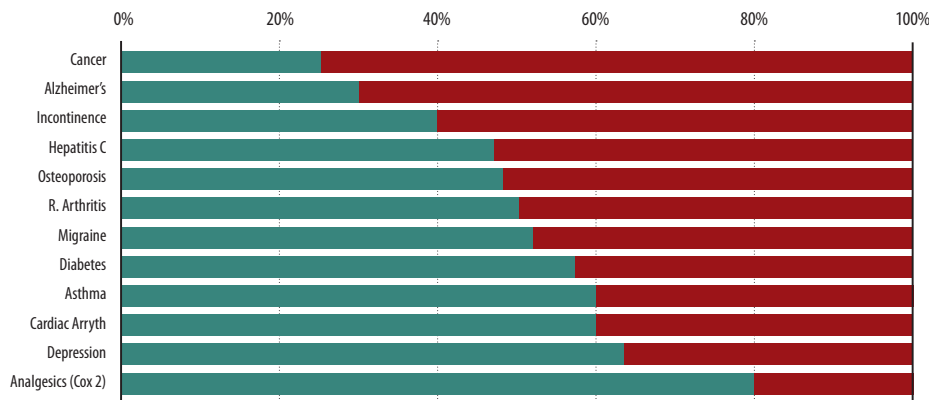
“And now we can stop it.”

SPECIAL ADVERTISING FEATURE

BETTER TARGETING VIA GENETIC TESTS = BETTER PATIENT RESPONSE AND RELATED COST SAVINGS

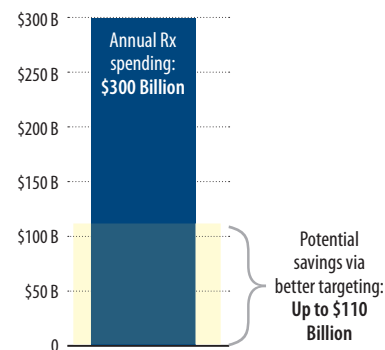
Roughly 20-75% of patients do not respond to pharmaceutical treatment. The chart below (left) indicates the rate of patient response to drug therapy for a number of conditions—green reflects an effective patient response; the red reflects non-response. Often, the reason for the lack of an effective response by the patient is a molecular mismatch between the patient and the drug.

Better targeting through genetic testing could significantly improve that, potentially saving as much as \$110 billion per year (below right).



Source: Aspinall, Harvard Business Review, October, 2007; Spear, Trends in Molecular Medicine, May 2001

Patient response rates to drug therapy Effective Response Non-Response



Source: Aspinall, Harvard Business Review, October, 2007; Spear, Trends in Molecular Medicine, May 2001; IMS, 2010

be more “personalized” to an individual’s genetic structure, and because care is personalized in this way it will be more “predictive”; and if you can predict you can “prevent”; and of course, you will have to “participate” in your own care to a degree, he said.

Such personalization also can significantly cut health care costs by reducing the risk of adverse drug reactions, “which have been reported to cost the US \$136 billion yearly,” said Rep. Gonzalez.

The Right Answer is Cost-Effective

As medical director for Quest Diagnostics Nichols Institute, Kenneth Sisco, MD, PhD, quoted Albert Nichols, MD, the founder of the Institute, as saying, “The right answer is cost-effective.” Genetics can help us find the right answers, said Dr. Sisco, by being better able to match the treatment to the unique DNA of the individual. “Trial and error medicine is a way of the past,” he added.

Cost Savings up to \$110 Billion

Each year the US spends about \$300 billion on pharmaceuticals, but some studies suggest that anywhere from 20% to 75% of patients do not respond appropriately to the drug. Reasons for this include drug interactions and incorrect dosing. But roughly half the time, it is due to a molecular mismatch between the patient and the pharmaceutical.

Better targeting means potential savings of up to \$110 billion, said Dr. Sisco. “That’s only scratching the surface.”

Dr. Sisco presented other examples of cost-savings due to better targeting of drugs:

Metastatic colorectal cancer: Because of a genetic mutation called KRAS, 40% of patients suffer serious side-effects and cannot benefit from a standard cancer

“THERE IS AN INNOVATION REVOLUTION COMING. WE’RE PART OF IT. WE HAVE TO BELIEVE IN IT. WE HAVE TO INVEST IN IT.”

— Dr. Kenneth Sisco, Quest Diagnostics Nichols Institute

drug used to treat colorectal cancer. A genetic test can identify these patients. Projected savings by avoiding the use of this drug in patients who won’t benefit is about \$700 million per year, he said.

Breast cancer: About 30% of breast cancer patients have an overabundance of what is known as the HER2 protein; regular chemotherapy does not work for these patients. Genetic tests can identify women who have this gene mutation so they can receive a genome-based drug that reduces the risk of death by 33% and the risk of recurrence by 52%. The cost drops by some \$24,000 per patient when genetic tests are used to guide treatment, according to an economic modeling study in the Journal of Clinical Oncology.

Enabling the Golden Age of Medicine

Calling genetic testing a “game-changer” that doctors need to be prepared for, Rep. Burgess said physicians will soon be living in “the golden age of medicine.”



“The right answer is cost effective,” says Kenneth Sisco, MD, PhD, medical director for Quest Diagnostics Nichols Institute. Genetics can help us find the right answers, he adds.

Their ability to relieve human suffering will be unlike anything that a doctor has ever known in the history of man. And this (genetic testing) will be a part of it.”

“Imagine the dream,” Dr. Sisco said, pointing to potential advances in treating cancer and predicting inherited genetic diseases. “There is an innovation revolution coming. We’re part of it. We have to believe in it. We have to invest in it.”

THE HILL POLICY BRIEFING WAS UNDERWRITTEN BY THE AMERICAN CLINICAL LABORATORY ASSOCIATION, ITS ASSOCIATE MEMBERS, AND ITS EDUCATIONAL ARM, RESULTS FOR LIFE.



The American Clinical Laboratory Association is a not-for-profit organization that is the leading advocacy group for the clinical laboratory industry. ACLA’s goals are not only to advocate on behalf of its members, but also to encourage high standards of excellence in the quality, service, and ethical conduct of its members. www.clinical-labs.org 202.637.9466



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