

The George Washington University
Washington, DC

September 19, 2006

“The idea that we practice medicine that doesn’t take into consideration the individual is quite irrational. We don’t think of buying shoes in a single size for heaven’s sake, so why should we be satisfied with one-size-fits-all medicine?” asked Francis Collins, MD, PhD, director of NIH’s **National Human Genome Research Institute**.

Dr. Collins was the keynote speaker at **Personalized Medicine: From Promise to Practice**, a half-day forum held at The George Washington University to discuss the challenges and opportunities of personalized medicine—the ability to more fully analyze a patient’s unique medical history and genetic makeup to allow physicians and researchers to better predict, detect and treat disease.

State of the Art of Personalized Medicine

Sponsored by Research!America in partnership with Roche and the George Washington University School of Public Health and Health Services, the forum’s first session explored the current challenges facing personalized medicine. Ruth Katz, JD, MPH, dean and Walter G. Ross Professor of Health Policy at **The George Washington University School of Public Health and Health Services**, delivered opening remarks on the link between personalized medicine and public health: “Understanding similarities and variations within and across groups is as much a building block of personalized medicine as it is of public health.” She added, “Just as personalized medicine can promote healthier communities, public health can advance the science of personalized medicine.”

A distinguished panel representing the public and private sector emphasized that personalized medicine is broader than genomics—encompassing a patient’s medical history, lifestyle and environmental factors. Yet moderator Susan Dentzer of **PBS’ “The NewsHour with Jim Lehrer,”** pointed to the need to counter the expectation that genetic information is a medical “tarot card.” Caroline Kovac, PhD, **IBM Life Sciences**, agreed, noting that people with the same genetic variation won’t necessarily get the same disease nor have the same disease progression.

Stephen Chanock, MD, of the **National Cancer Institute** observed, “I think we’re now at a new age where in a sense we have to ... think that all diseases are 100 percent genetic and 100 percent environmental. And it’s really a question of how those interactions are taking place.”

Kovac said current clinical trials examine thousands of patients, but a personalized medicine approach might require information from hundreds of thousands of patients, creating logistical, privacy and security challenges to gather, store and analyze such volumes of data.

Panel One

State of the Art of Personalized Medicine

Kenneth Buetow, PhD, Center for Bioinformatics, NIH
Stephen Chanock, MD, National Cancer Institute
Richard Frank, MD, PhD, FFPM, GE Healthcare
Evan Jones, Digene Corporation
Bruce Korf, MD, PhD, University of Alabama at Birmingham
Caroline Kovac, PhD, IBM Life Sciences

The panelists agreed that the United States is not as far along as other countries in advancing key aspects of personalized medicine, particularly in the area of collecting patient data. Kovac said countries like the United Kingdom and Australia are building databases to help physicians and researchers better diagnose and prevent a wide range of diseases and conditions. On the challenges of compiling such data on a broad scale, Richard Frank, MD, PhD, of **GE Healthcare** noted, “Solving the interoperability problem will be a key enabling logistical factor, but then we also have to understand how important it is that we take patients’ data in such a way that they don’t feel threatened.”

Panelists underscored the importance of finding a reasonable balance between safeguarding a patient’s privacy with the benefits of information sharing as electronic health records become more widely used. Bruce Korf, MD, PhD, of the **University of Alabama at Birmingham Department of Genetics**, said that education is essential for not only patients, but for the medical profession: “Most physicians in practice today were trained in an era where ... the kinds of technologies we’re talking about were not really in the curriculum at all. I, however, am optimistic that over time, this will sort itself out.”

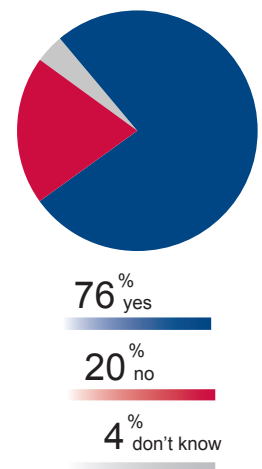
Evan Jones, chair and chief executive officer, **Digene Corporation**, said diagnostic information and therapeutic approaches will have to be critically integrated to see success in personalized medicine. He said, “One of the tricks here is going to be to apply these tools in the right areas where we can really affect clinical outcomes in a meaningful way.”

Kenneth Buetow, PhD, of **NIH’s Center for Bioinformatics**, said information-sharing among research institutions is another key to realizing the promise of personalized medicine. He urged the evolution of research culture from individuals to networks of researchers, where data from clinical trials are “made accessible to people outside of my individual laboratory, outside my individual organization so that the whole can be more than the sum of the parts, so that everyone can build on that.” For scientists who share their findings, panelists said it was important that intellectual property be protected.

Results of a Research!America poll released at the forum found that three in four Americans (76%) want Congress to enact legislation that protects genetic information from being used to discriminate against them (see figure 1). **Research!America** President Mary Woolley presented the poll findings, noting, “Americans are just becoming familiar with ‘personalized medicine,’ a field still in its infancy. We

Americans Think Congress Should Protect Genetic Information

Some people say that a person’s genetic information must be protected by federal law in order to prevent employers and health insurers from using that information to discriminate against individuals. Others say that the current health privacy laws are sufficient. Do you think Congress should pass a law to specifically protect a person’s genetic information?

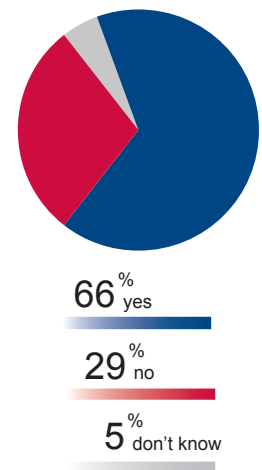


SOURCE: Your Candidates—Your Health Survey, 2006
Charlton Research Company for Research!America

Figure 1

Americans Willing to Donate Genetic Material for Research

In order for scientists to study the differences that cause disease, they need to compare many individuals’ genetic information. Would you be willing to donate genetic material such as a saliva or blood sample for this purpose?



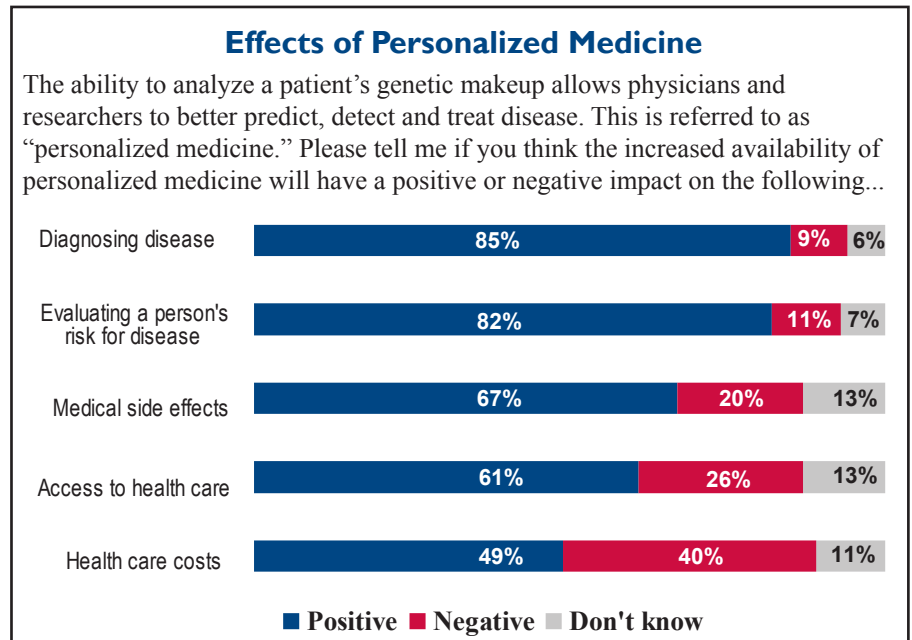
SOURCE: Your Candidates—Your Health Survey, 2006
Charlton Research Company for Research!America

Figure 2

need to identify what is needed in terms of policies, research and public education to realize the promise of personalized medicine.”

The poll found that two-thirds of Americans would be willing to donate their own genetic material to help scientists study disease (see figure 2).

An overwhelming majority thought increased availability of personalized medicine would bring improvements in diagnosing disease (85%) and in evaluating a patient’s risk for disease (82%). Almost half (49%) believed that personalized medicine would help control health care costs (see figure 3). Full poll results are available at www.researchamerica.org.



SOURCE: Your Candidates-Your Health Survey, 2006
Charlton Research Company for Research!America

Figure 3

Where Do We Go from Here?

The forum’s second panel considered the promise of personalized medicine. Panelists portrayed the promise of personalized medicine as achieving better outcomes, earlier diagnoses and smarter treatments—extending life and extending health.

The panel agreed that the commitment of legislators is critical for this promise to become reality.

Janet Woodcock, MD, **U.S. Food and Drug Administration**, said, “It’s going to require a lot of leadership and commitment.” She urged policy makers to “come together and say we must go in this direction ... because this is the right thing to do for the public.”

Citing the need for public policy to be driven by science, M.J. Finley Austin, PhD, **Roche**, emphasized that “if you don’t take that science-based perspective and don’t have a realistic handle on what the science can and can’t deliver, you’re going to end up with policies that aren’t going to be very effective.”

Several panelists stressed the importance of arming the FDA and NIH with more resources to handle the new technological demands that a personalized medicine approach may require. Phillip S. Carney, Jr., MD, MPH, of **Kaiser Permanente**, said a key to advancing the promise of personalized medicine is the electronic health record. “The electronic medical record ... will help us develop high-quality, cost-effective medicine and keep affordability within reach of everybody.”

Panel Two

Where Do We Go from Here?

M.J. Finley Austin, PhD, Roche

Phillip S. Carney, Jr., MD, MPH, Kaiser Permanente

Daniel Perry, Alliance for Aging Research

Stephen Ubl, AdvaMed

Thomas Wildsmith, MAAA, FSA, Actuary, Hay Group

Janet Woodcock, MD, Food and Drug Administration

Panelists discussed the economic barriers that advocates of personalized medicine may face in transforming the business model of drug development and marketing. Some saw a challenge for drug companies developing more targeted medicines for smaller patient populations in seeing enough return on investment to channel funds back into research. Carney said, “We need to really figure out how we’re going to tell the story of value added, of better patient care.” Austin noted, “That drug’s still bringing the same absolute value to society, just to a smaller group of people.”

To encourage payers to reimburse for personalized tests and treatments, actuary Thomas Wildsmith, MAAA, FSA, of the **Hay Group**, urged, “Demonstrate to [payers] that the treatment course of giving them ...one of a menu of interventions driven by the testing is more effective and lower-cost than a one-size-fits-all treatment—because that’s what they really care about.”

Stephen Ubl, president, **Advamed**, said he would stretch the definition of personalized medicine to “include the full spectrum of medical technology.” For the public, he added that “to the extent that more and more of these tests become available, it is being proactive, it is demanding more in the health care system, it’s demanding more of your practitioner and demanding more of technology.”

Ultimately, according to several panelists, the push for personalized medicine may be driven by demographics. Daniel Perry with the **Alliance for Aging Research** described the “silver tsunami” of baby boomers soon eligible for Medicare. With some 75 million new Medicare recipients by 2029, the need to conquer a host of chronic, age-related diseases will be greater than ever.

Panelists concluded that the rising cost of health care in the U.S. will be a central concern in the adoption of a more personalized approach to medicine. With the nation spending about \$1.5 trillion on health care, Perry suggested, “There is a lot of concern that we’re not getting the value for it.” He cautioned that the U.S. cannot afford to miss “the potential for intervening and ultimately preventing some of the health problems that people are going to have.”

Looking ahead, Austin commented, “We’re still going to be dealing in a world of probabilities, but hopefully what we can do is reduce the error bars and increase the certainty around those probabilities of what’s going to work best for you as a patient, as well as what’s going to work more broadly in the public health arena.”

Mary Woolley of **Research!America** concluded the forum by calling for the public and private sectors to make a renewed commitment for more research into personalized medicine to make the promise of this approach an everyday reality.

ABOUT RESEARCH!AMERICA

Research!America is the nation’s largest not-for-profit public education and advocacy alliance working to make research to improve health a higher national priority. For more information, see www.researchamerica.org.



1101 King Street, Suite 520
Alexandria, VA 22314-2960

703-739-2577 phone / 703-739-2372 fax
800-366-CURE

www.researchamerica.org
info@researchamerica.org