

**Personalized Medicine: A Challenging Revolution in Healthcare**  
*FDLI Insider Piece Analyzes Promise, Pitfalls of Customized Care*

Personalized medicine, which uses genetic information to tailor treatments to specific individuals, is a revolutionary healthcare option, filled with potential but also containing serious challenges for average patients, writes Beryl Lief Benderly, in an *Insighter* piece posted on [www.fdpi.org](http://www.fdpi.org), the website of the Food and Drug Law Institute (FDLI).

In the *Insighter* piece, *Personalized Medicine: A Challenging Revolution in Healthcare*, Nina Scribanu, MD, associate professor of pediatrics and director of the division of genetics at the Georgetown University Medical Center, tells FDLI that much work remains in the development of personalized medicine before patients can receive the full benefits of its potential.

However, the article asserts, genomic medicine is clearly rocketing forward. “This is our chance to transform medicine from ‘one-size- fits-all’ to a potentially personalized approach,” said Francis Collins, MD, PhD, director of the National Human Genome Research Institute, in testimony before Congress. “Already, healthcare providers can test whether some of us carry DNA variants that predispose us to certain diseases, and new research efforts could help to expand this capability and possibly offer better opportunities for preventive measures. If illness does occur, doctors will have more powerful tools to identify the molecular causes, and to prescribe medicines based on individualized genetic information.”

Genetic information already is helping doctors to individualize some treatments. One genetic test, for example, can determine which patients with hepatitis C need drug therapy for 48 weeks as opposed to the conventional 24 weeks. Another can distinguish women with breast cancer who are likely to relapse and therefore would benefit from chemotherapy from those unlikely to relapse, who do not need these expensive and toxic drugs. Other tests differentiate breast cancer patients likely to benefit from the drug herceptin from those likely to suffer adverse side effects. Yet other tests can help doctors prescribe appropriate dosages of powerful drugs by identifying individuals who metabolize them quickly, at an average rate, or not at all.

But Scribanu maintains that “there is insufficient support for young people to go into clinical practice” of genetic medicine. “Much of the talent is going to private companies” that develop and market tests rather than into clinical care that uses this knowledge with individual patients, she explains. “This is a field that needs support,” Scribanu concludes.

FDLI and the American Association for the Advancement of Science (AAAS) are sponsoring a national conference, *Personalized Medicine: Promises and Challenges*, June 20, 2008, at AAAS Headquarters in Washington, D.C. The meeting will include a high-level roundtable discussion in the morning and a seminar on legal, regulatory and policy issues on personalized medicine in the afternoon.

For more information on the personalized medicine conference, visit [www.fdpi.org](http://www.fdpi.org) or contact Michael Levin-Epstein, Editor-in-Chief, (202) 222-0897 or [mdl@fdpi.org](mailto:mdl@fdpi.org)

The full text of the *Insighter* piece is posted at [www.fdpi.org](http://www.fdpi.org)

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