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# Growing focus: Making the drug fit the disease

## New law promotes personalized medicine, could help state companies

by Robert Rand | Staff Writer

A few relatively obscure provisions in the new federal health care reform law could hold great promise for dozens of Maryland bioscience companies.

While the law's most controversial elements concern insurance coverage, the Patient Protection and Affordable Care Act also promotes the growing — and potentially lucrative — field of personalized medicine. It's based on the idea that when it comes to drugs and diagnoses, one size doesn't necessarily fit all. For example, an array of individual biological factors may make one cancer patient respond better to one treatment, while another patient would benefit from another drug.

The new federal law directs the National Institutes of Health to award "contracts, grants, or cooperative agreements" to drug companies and biotechs, among others, to "accelerate the development of high need cures, including through the development of ... biomarkers that demonstrate the safety or effectiveness of medical products."

Currently, close to half of all prescribed medicines don't effectively treat a particular patient's disease, according to Judith Britz, executive director of the Maryland Biotechnology Center. That's particularly true for chronic conditions such as autoimmune diseases, diabetes and hypertension, she said.

"It's a fundamental problem in our health care system," Britz said during a recent panel discussion on personalized medicine that she moderated for Women in Bio, a trade group. Often, medicines are prescribed on a trial-and-error basis, she said in a later interview. When the initial treatment doesn't work, another is prescribed.

About $350 billion is spent annually on ineffective medicine, according to one of the panel presenters, Marie-Claude Marchand, vice president of pharma and key accounts for Qiagen, the Netherlands diagnostics company whose North American headquarters are in Gaithersburg and Germantown. In 2007, Qiagen acquired Digene of Gaithersburg, which developed a test for human papillomavirus for $1.6 billion.

Personalized medicine, based on the use of biomarkers, can help reduce those wasted health care dollars, Marchand said.

Biomarkers are found in the blood, urine, saliva or cells, and are biological molecules such as DNA, RNA, proteins or small peptides, which are small units of proteins, Britz said. When properly analyzed, their presence can help diagnose a patient's condition and indicate the correct treatment — the first time.

But of the tens of thousands of biomarkers, "only a handful have been approved" for use by the Food and Drug Administration, according to David Wholley, director of the Biomarkers Consortium, a project of the Foundation for the National Institutes of Health.

Focus on cancer

Among the conditions being targeted by personalized medicine is cancer. And among the companies focusing on researching biomarkers for cancer treatment and diagnosis are two in Maryland: A&G Pharmaceutical of Columbia and **BioMarker Strategies** of Baltimore.

A&G — with 20 employees, revenues of $1.9 million last year and equity financing of $9 million from the Maryland Venture Fund and others — focuses on discovering what are called theranostic targets to help predict a patient's therapeutic response to particular treatments.

In addition, theranostics can save drug companies time and money in their clinical trials for new treatments, said Ginette Serrero, CEO of A&G, at the Women in Bio seminar.

And by using theranostic targets, companies can "monetize the diagnostic while developing the therapy," Serrero said.

**BioMarker Strategies**, also privately held, was co-founded about four years ago by Scott Allocco, the company's president. With nine employees, it recently doubled its space at the Johns Hopkins University Science + Technology Park in Baltimore, to 2,500 square feet.

With about $4.3 million in investments raised, plus up to $2.3 million from a recent Small Business Innovation Research grant from the National Cancer Institute, the company is developing its SnapPath biomarker platform to analyze still-living tumor cells removed from cancer patients.

"Ten years ago, it was enough, when you went into the hospital with a suspected tumor, to have a biopsy," Allocco said. The tumor might have been surgically removed, and then a tumor sample was prepared for a slide, which a pathologist would analyze through a microscope to make a diagnosis.

Oncologists using his company's technology, however, can analyze live cells to get much more detailed molecular information about the tumor before treatment, Allocco said.

"It's to make sure that only patients with the correct biomarker profile get a particular drug, versus those with a different biomarker profile who won't benefit from [that] drug," he said.

Like others in the field, **BioMarker Strategies** hopes to partner with a drug company to develop companion biomarker strategies.

"The good news about the new bill is the growing recognition that biomarkers play a role in personalized medicine, and hopefully in the future there will be more calls for grant submissions for biomarker-based topics," Allocco said. "We're eager to see more grant opportunities."

Blockbuster model not working

Of the 400-plus life sciences companies in Maryland, about 200 focus on drug development, with 25 to 50 developing diagnostic devices and tests, and many are involved in biomarker work, Britz said.

As the drug development companies enter preclinical work, the Food and Drug Administration is requiring them to consider diagnostic markers, she said.

"The FDA wants to understand if one size fits all" when it comes to new treatments, Britz said.

The world's major pharmaceutical companies, which historically focused on developing and marketing blockbuster drugs that could treat millions, are "embracing personalized medicine more," Marchand said. "Pharma is reviewing its business model."

"The blockbuster model is not working anymore," Wholley said.

Other players in the health care industry are looking at biomarkers, too.

"Health plans will use information from biomarkers to manage patient care," said Allocco, a former vice president of government affairs at **Coventry Health Care** of Bethesda.

"They could deny claims if the patients haven't had the diagnostic test to show that a drug will or won't work," he said. "The tests will become a managed-care tool for the health insurance industry."