



# findings brief

## Pharmacogenomics: an Assessment of Market Conditions and Competition

Pharmacogenomics is the study of how inherited variations in genes dictate a person's reaction to a drug.<sup>1</sup> Pharmacogenomic (PGx) studies are used to discern an individual's susceptibility to disease, based on their gene makeup, and enable physicians to identify and rule out patients that will have an adverse reaction to a drug by comparing a drug treatment with a genetic test. Not only do PGx products and services stand to reduce adverse drug reactions, they have the potential to: 1) speed the approval process for drugs, reducing the cost of clinical trials (by using genetic tests to target a defined patient population); 2) reduce the length of time patients are on medication; 3) reduce the number of medications patients must take in order to find an effective therapy; and 4) reduce of the effects of disease in the body through early detection.<sup>2</sup>

Due to its unique properties, the current health care market poses challenges that may hinder widespread adoption and slow development of PGx. Research conducted by Louis F. Rossiter, Ph.D., at the Schroeder Center for Healthcare Policy at the College of William & Mary, examined the current market system to determine whether or not PGx could flourish in the current financing, delivery, and payment

environment. According to Rossiter, "PGx products and services may be used inefficiently because the current system relies more on a trial and error approach, rather than on an individualized one which is offered by PGx." Additionally, PGx faces challenges in the way of competition from large pharmaceutical firms, the absence of a "blockbuster drug" to motivate investment in research and development, and a lack of cost-effectiveness studies that could encourage adoption and public and private reimbursement of products and services.

Price and distribution are also potential challenges. Because a majority of PGx products and services are administered in private physician practices, they do not have the same established distribution channels as traditional treatments, which are provided via pharmacies. Furthermore, PGx-related treatments can be expensive, and cost and lack of reimbursement may make these treatments cost-prohibitive.<sup>3</sup>

The objective of Rossiter's study was to explore whether the current payment system has the necessary features to allow PGx to reach its maximum treatment potential. In order to meet this objective, the researchers: 1) summarized PGx products and services currently on the



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market or that were scheduled to be on the market in the near term; 2) interviewed key informants to identify the mechanisms by which suppliers bring PGx to the market; and 3) studied the implications of financing and organization of the delivery system for PGx.

### Methods

In order to identify the companies involved in PGx products and services, the researchers focused on publicly available databases constructed for investors. Once the companies were identified, they were then organized into pharmaceutical and research companies, biotechnology companies, and various sizes of capital PGx companies. Next, each company's pharmaceutical products, diagnostic tests, and devices were categorized according to where they were in the manufacturing cycle—those currently in the market; those pre-market or in phase III human clinical trials; and those still in the research pipeline.

After each company's major products were categorized, the researchers identified a pool of interview candidates drawn from the group of companies whose products were in the market or pre-market stages, key industry leaders, and scientists. The researchers determined the scope and content of the interview questions with the input of an expert advisory committee. In each of the 35 open-ended interviews, the researchers sought information related to market competition, financing, research strategy, and mergers and acquisitions.

### Findings

#### Products

When the research team asked interviewees to describe the current market for PGx products and services, they found that few products were on the market. However, many more were in the pre-market stage of approval at the FDA. Although the future looks promising, the lack of cost-effectiveness studies and competing products that are easier for physicians to administer remain challenges for PGx products and may keep them from reaching their potential.

#### Players

The research team identified four major stakeholders in the PGx field: genetic analysis companies; molecular diagnostic companies; research and manufacturing companies; and distributors. Genetic analysis companies develop the systems and technology to handle genetic material and are integral in demonstrating early linkages between genes and potential drug treatments. Molecular diagnostic companies manufacture the test that determines whether or not a particular drug therapy is safe for the body. Research and manufacturing companies integrate the information learned from genetic analysis companies with the tests from the diagnostic companies in order to conduct clinical trials as well as bring the products or services to the market. Finally, the distributors bring easy-to-use genetic test kits and information packages directly to physicians and patients.

With regard to the role of competition in the PGx market, the researchers found that competition occurs at both the market and physician level. At the market level, researchers found a major challenge to PGx products and services is grounded in the current pharmaceutical business model. The PGx model relies upon the administration of a genetic test to rule out candidates that would be adversely affected by a drug—a model that is in direct conflict with the pharmaceutical business model, which benefits most from high-volume sales to as many patients as possible. “Arguably, it is the reversal of pay-for-performance,” says Dr. Rossiter. In fact, there could arguably be an incentive for large firms to neglect targeted PGx therapies in favor of the existing model.

Findings indicated that the reimbursement system is a potential area for opportunity. If payers recognize value by coupling the genetic test with the drug therapy, the realized benefits might propel the widespread use of PGx. An alternate scenario could include small and large firms working in harmony toward potential worthwhile partnerships.

In the competition for physician confidence and utilization, the researchers found that PGx products face competition from other

treatments on the basis of price, potential side effects, survival rates, and confidence in the targeting of biomarkers. Ultimately, however, the researchers suspect that the drug (traditional or PGx) that offers the highest survival rate with the lowest amount of side effects will prevail, without regard to price. This is especially true for products to fight so-called “dread” diseases, such as cancer.

#### **Delivery**

In terms of future distribution, the researchers found that a majority of PGx products will be distributed as they are currently, through large research and manufacturing firms. However, the role that physicians will play in the distribution channels is less concrete, as some may be hesitant to learn and utilize the sometimes complex information required to administer PGx out of their offices. Genetic testing companies may be able to ease the burden on physicians by developing more user-friendly product packaging. It is also possible that the physicians’ role would be marginalized by an increasing pharmacist presence – as pharmacists have an existing infrastructure and knowledge base in this area.

#### **Financing**

The findings indicated that financing of PGx would likely continue to stem from private investors until clear cost-effectiveness and outcomes data are available. Additionally, the current cost-containment environment, which focuses on reducing the cost per unit, and the absence of a blockbuster PGx product may hinder future private and public funding of PGx product and service development. Federal funding for the development of tests to rule out drug use in patient populations may be justified if cost-effectiveness data can support such an initiative. In terms of reimbursement, Medicare and Medicaid typically have low rates of reimbursement for tests, but relatively high reimbursement rates for drugs. This poses a challenge for PGx products which are inextricably linked to a genetic test.

In terms of cost-effectiveness, the researchers found a variety of likely scenarios that may ensue. PGx could be cost-effective given potential savings gleaned from streamlined development or marketing of PGx. Additionally, the gene analysis platform would render drug discovery for PGx much less costly compared with traditional drug discovery. Similarly, the societal and liability-related benefits of a targeted drug therapy could prove to be cost-effective. However, the barriers (blockbuster drug competition, regulatory hurdles) may be too great to overcome, undercutting the notion that PGx can be cost-effective.

#### **Conclusions**

This study finds that the existing U.S. payment system is not designed for, and is therefore inadequate for, PGx products and services to reach their maximum treatment potential. The researchers encourage policymakers to discuss and consider reforms to the current financing and payment systems in light of the potential for positive health outcomes. “With the widespread adoption of PGx, a simple genetic test may prevent countless adverse drug events, hospitalizations, disability, and death,” says Rossiter.

The results of this study indicate that more funding should be directed toward PGx cost-effectiveness research. Only with additional funding directed toward health services research, can society truly experience the greatest value offered by PGx.<sup>4</sup>

#### **Policy Implications**

The challenges faced by PGx and other specialty drugs therapies have caught the attention of Congress. Representative Henry Waxman (D-Calif.) has expressed an interest in pursuing a call for an independent policy center, modeled after the United Kingdom’s National Institute for Health and Clinical Excellence, that would be charged with evaluating new drugs and treatments based on costs and benefits.<sup>5</sup> This study’s findings add a fresh perspective to existing evidence calling for such reform.

### Next Steps

“The current payment systems are inadequate for the emerging science,” says Rossiter. Diagnosis-related groups, ambulatory patient classes, resource-based relative value scales and other fee schedules are not set up to reward value and reduce risk. These findings support the development of a new payment system that pays more for competing technologies that lower system costs and reduce the risk of current drugs and therapies. Additionally, the findings support a methodology that would factor confidence levels for comparative evidence into the payment for technology, such as pharmacogenomics, when it substitutes for existing treatments.

### About the Author

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### Endnotes

- 1 Pharmacogenomics Factsheet. National Center for Biotechnology, National Library of Medicine, National Institutes of Health. <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html>.
- 2 Baker, T. “The 5 stages of biotechnology management,” *Biotechnology Healthcare Journal*, 2., 1., February 2005, pp. 45-50.
- 3 Adams, K.T. “Biologics and benefit design: what’s new for ‘06,” *Biotechnology Healthcare Journal*, February 2006, pp. 28-35.
- 4 Moses III, H. et al. “Financial anatomy of biomedical research,” *Journal of the American Medical Association*, 294., 11., September 2005, pp. 1333-1342.
- 5 Anand, G. “As biotech drug prices rise, U.S. hunts for solution,” *Pittsburgh Post-Gazette*, Wednesday, December 28, 2005.