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BY AVI KULKARNI AND NELIA PADILLA

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**P**ersonalized medicine (PMx), medical treatment tailored to specific patient populations based on their genetic or molecular biology profiles, has long been heralded as the next big thing in healthcare. It's been about 16 years since Genentech launched Herceptin, a drug for breast cancer patients with a specific genetic mutation. At the time, Herceptin seemed to usher in a revolution for how drugs would be developed and patients would be cured.

In that new version of care, drugs could be tailored to a patient's specific biochemical profile, dramatically improving efficacy rates and reducing the system-wide costs and complications associated with one-size-fits-all medications. For pharmaceutical manufacturers, this approach had the potential to improve sales and profits through a radically new business model: differentiated products for segmented populations (see "A Strategist's Guide to Personalized Medicine," by Avi Kulkarni

and Nelia Padilla McGreevy, *s+b*, Winter 2012).

But despite the occasional success story, PMx is largely seen today as the dog that did not bark. With a few exceptions, such as Herceptin, there are few PMx success stories. This is true for several reasons.

First, health insurers remain unconvinced of PMx's merits. One would expect these companies to push hard for personalized medicine, considering that they are the main beneficiaries of more efficient healthcare. Yet most payors seem to believe that the economic benefits of PMx are relatively small. The few PMx-based therapeutics now on the market are much more expensive than conventional therapies—and the prices don't always translate to proportionately better outcomes, such as higher survival rates. For example, Bristol-Myers Squibb released a new metastatic melanoma therapy called Yervoy in the U.S. in 2011. Yervoy costs US\$120,000, but in Phase III trials, it added only about 3.7 months of survival time.

In addition, many pharma companies have been hesitant to make the necessary investments in personalized medicine. The steep costs required, including best-in-class PMx development and commercialization capabilities, seem out of proportion to the small markets for each drug. Cancer drugs are the exception, but pharmaceutical companies have focused less on the genetic causes of other diseases. That makes PMx a costlier and riskier proposition.

More broadly, the technologies required to support PMx (to identify and quantify all the molecular markers and mutations in the body that are linked to specific diseases) are still in their infancy. The cost of sequencing the human genome has decreased, but the analysis needed to interpret the data is still expensive. And even the truest of believers are forced to admit that the next step—the molecular analysis of proteins and our understanding of the human proteome (the protein makeup of individual cells and genomes)—is many years from completion.



Even when molecular markers are identified, their absolute clinical relevance is hard to establish. Diagnostic technologies can alert scientists to certain biomarkers in the body, but not how they interact with one another and their environment to cause disease. Currently, clinical relevance has been established for an infinitesimally small number of the millions of biomarkers that the human body is capable of generating.

Finally, the reason success stories are so rare is a notable reluctance among physicians to adopt PMx. Medicine is a cautious discipline, understandably, and in some cases PMx requires practitioners to dispense diagnoses and treatments based on complex molecular changes. For example, in the 10 years since Genomic Health launched its pivotal Oncotype DX test, which can determine the recurrence risk of breast cancer and assess the likely benefit of certain types of chemotherapies, it has faced steep resistance from the medical community. Even though Oncotype DX has been proven as medically relevant technology, and been widely reimbursed by payors, analysts estimate that it is used on only half of all eligible patients.

### Realizing the Promise

Despite these problems, the widespread use of PMx in the clinic isn't as hypothetical as it may seem. While researchers, doctors, regulators, payors, and pharmaceutical companies argue among themselves, three solutions are emerging with the potential to help clear the PMx logjam.

#### Easing regulatory standards.

Regulatory bodies such as the U.S. Food and Drug Administration (FDA) could greatly reduce the hurdles for PMx development. In order

to balance the FDA's mandate to ensure the health and safety of the public with the objective of encouraging innovation, some experts have proposed an approval system in which drugs and diagnostics could be released onto the market under a provisional approval scheme using existing regulations for diagnostic tests. Meanwhile, patients' real-world experiences could be analyzed to improve promising clinical claims. This system would be a minor modification to existing regulations and guidelines, but it would allow drug and diagnostics developers to get to market quickly in order to test their products in the real world.

**Retooling pharma's capabilities for the long term.** Many pharmaceutical companies do not realize how much overlap there is between the

handheld imagers or scanners and biometric devices. This expansion is likely to be the solution that will exert the most influence in moving U.S. healthcare to a PMx future. For example, mobile health sensors have already begun to change the lives of people with chronic diseases. Patients with certain cardiovascular diseases are the best examples: Body surface measurements of heart rate, electrical conductance, and tissue water retention are being coupled with mobile devices such as smartphones to keep the patients and their doctors aware of their health at all times.

Such patient-centric devices can also be combined with molecular biomarkers. For acute coronary syndrome patients, for example, physicians can now evaluate certain gene

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capabilities required for success in PMx and their existing capabilities in drug development and commercialization. One company that invested in PMx found that the incremental cost of new capabilities was less than \$150 million, an amount that could easily be absorbed within the company's \$4 billion annual R&D budget. Notably, companies must think of PMx as a long-term play. Those that practice PMx for a majority of programs in development tend to have better drug portfolios and superior economics over several years.

**Expanding PMx applications to include patient-centric devices.** Increasingly, PMx involves patient-centric equipment such as personal,

markers and cardiac proteins before making treatment decisions or prescribing anticlotting medications, and can continue to track patient progress using wireless cardiac monitors. This approach, applied to atrial fibrillation, is already helping to overcome resistance in the medical community. Doctors can see these devices producing usable information—allowing them to treat patients in real time. This grounds the PMx experience for them—a big improvement over waiting for a sample to be run through a black-box device that spits out a list of molecular markers.

The companies taking the first productive steps in mainstreaming PMx through mobile health devices

are not medical firms but rather technology players such as Apple and Google. These players have brand names that consumers recognize and trust (compared to medical device companies that have little share of consumers' minds), and they understand how people want to interact with technology. Increasingly, this applies to areas of health and wellness. For example, Nike's FuelBand body monitor, which users wear on their wrist and which connects to a cloud-based app wirelessly, has made it easy to track activities like walking and running. Samsung's Galaxy S5 smartphone contains a heart-rate sensor. Even technology that isn't specifically equipped with diagnostic apps is being used by scientists. One group of researchers is developing an app that uses Google Glass as a wireless diagnostic tool.

Technology companies are now outpacing medical device makers, which are still addressing complex clinical issues and using sales reps to sell to doctors but have little direct interaction with patients as consumers. In fact, tech players are slowly migrating from the consumer and enterprise markets into the more scientific realm. Even though it will mean maneuvering through the FDA's complex device regulations, they are starting to develop devices that have clinically actionable data and results. In South Korea, for example, regulators debated whether or not the Samsung Galaxy S5 should be treated as a medical device because it contains a heart-rate sensor. Ultimately, they decided not to do so—but a similar debate is ongoing in the United States as the FDA tries to determine how to regulate comparable devices.

The migration of technology

companies into healthcare is a needed intermediate step that will help PMx become mainstream, converting it from a science, technology, and engineering domain to a consumer-oriented function. It will help make PMx simpler and more elegant, with fast product cycles, appropriate prices, and a great ability to respond to changes in market demand. Moreover, the mainstreaming trend may also help solve the problem of distracted payors. Insurance companies will not be leading us into the PMx future, but seeing it successfully introduced may allay their concerns about whether PMx is worth paying for.

Ultimately, the PMx companies of tomorrow may be familiar names from today: technology companies that design not just smartphones and software but also devices like glucose-measuring contact lenses or mobile heart sensors. For pharmaceutical firms—and all other healthcare players—that means PMx could finally live up to its potential. +

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