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A Strategist's Guide to Personalized Medicine

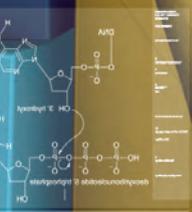
Breakthroughs in pharmaceutical innovation are poised to change the prevailing business model of the industry — with dramatic effects on healthcare costs and practice.

BY AVI KULKARNI AND
NELIA PADILLA MCGREEVY

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by Avi Kulkarni and
Nelia Padilla McGreevy

ONE OF THE MOST INNOVATIVE MEDICATIONS of recent years is Novartis's imatinib, which is marketed as Gleevec. Introduced in 2001, it set a record for the fastest approval time by the U.S. Food and Drug Administration (FDA), and in 2011 had US\$4.3 billion in sales. Imatinib was the first of a new class of drugs that act by inhibiting a specific enzyme — in this case, a receptor called tyrosine kinase — that is characteristic of particular cancer cells. Because only certain cancers will respond to imatinib, it is prescribed only for patients identified by specific diagnostic tests (for example, the Philadelphia chromosome abnormality test).

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Imatinib is an example of the products emerging from a new pharmaceutical field known as personalized medicine, or PMx: the tailoring of drugs and other treatments to specific populations, based on their genetic profiles or other differentiating factors. (We use the abbreviation *PMx* to echo *Rx* for prescription medicine and *Dx* for diagnostic tests.) The underlying technology for PMx marries advances in diagnostic biotech, such as rapid gene sequencing, with a profound expansion of scientists' understanding of molecular disease pathways. Another example is Genomic Health's Oncotype DX breast cancer test, introduced in 2004, which uses an analysis of multiple genetic variations to determine which cancers are likely to recur for a particular individual. It also indicates which patients are likely to benefit from chemotherapy. The results of this test can help physicians avoid prescribing drugs with no medical value; because those drugs often have severe side effects, the test greatly benefits patients as well.

The concept of personalized medicine is only 15 years old, and it does not have a perfect track record; some of its medications have failed to get regulatory approval or to be profitable in the marketplace. But where it has proven successful, it is creating a fundamentally new value proposition for healthcare businesses. It represents a game-changing trend for healthcare providers (hospitals and individual physicians); payors, including Medicare and private insurance; and patients, who can have a far more participative role in their own care than they would without PMx. When physicians and patients can draw upon a wealth of genetic and biological data, personalized therapy will become the norm, not the relatively rare occurrence it is today.

The greatest impact of this new approach to indi-

vidualized diagnosis and treatment will probably be felt in the pharmaceutical industry. Leading pharmaceutical companies have long relied on innovation to expand the frontiers of better health — and to financially sustain their businesses. But that capacity for launching new products is under severe strain today. Many pharmaceutical companies have recently seen their research and development productivity erode. Biotech startups have struggled to turn their scientific advances into viable drugs. Companies have resorted to alternatives such as vaccines, preventive care, and geographical outreach for profits, but no pharma industry breakthrough has come along recently to create a promising pipeline of new products. PMx offers the potential for just that sort of breakthrough.

Thus, despite the disruptive nature of personalized medicine, the pharmaceutical industry is emerging as a driving force in this field. The list of early PMx adopters includes some industry giants: Roche, Pfizer, Novartis, and Lilly. The field is also populated with upstart companies such as Genomic Health, XDx, and Prometheus Labs that offer specialized approaches to segmenting disease, as well as the recognized pioneers in personal genomics: 23andMe, deCODE Genetics, and DNA Direct. In adopting PMx, they are all embracing a new healthcare model that emphasizes segmentation of patients, and decisions and practices tailored to individuals or small groups. Although this approach might lead to smaller revenue pools for pharmaceutical producers, PMx can actually improve their profits. A business model based on differentiated products can reduce the system-wide costs and complications of one-size-fits-all medications, provide new opportunities for marketing, and establish new efficiencies in production and distribution.



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Success and Disruption

As an example of the impact of personalized medicine, consider the evolution of treatment for human immunodeficiency virus (HIV), the retrovirus that causes AIDS, during the 1990s and 2000s. Physicians found that by grouping patients into smaller subsets based on (1) the subtype of their HIV infection, (2) their body's response to the infection, and (3) the stage of the overall infection, they could prescribe the best tailored therapy cocktail for each patient. This combination of prescribed diagnostics and pharmaceuticals has been a remarkable success story. It has improved quality of life for patients and extended the average life expectancy of newly diagnosed HIV patients by 20 to 25 years.

HIV infects different patient groups in different ways; for a patient diagnosed with it, a physician must choose from more than 20 different antiviral agents in six unique drug classes. While undergoing antiretroviral therapy, patients are monitored with advanced diagnostic blood tests every three to four months to assess the severity of infection and confirm that the virus is being suppressed. Some of these tests can predict how individual patients will respond to specific therapies, thus increasing their odds of survival. For instance, Selzentry, an antiretroviral drug developed by Pfizer, works by binding to and thereby blocking the CCR5 receptor, which is found on the surface of certain human cells and is necessary for the entry of the virus into the host cell. But in some people, HIV can use other receptors instead, which would render Selzentry ineffective. Therefore, before Selzentry can be prescribed, patients are given an HIV tropism test called Trofile to determine whether the drug will be effective for them.

Personalization of anti-HIV drugs benefits all con-

stituents. Payors and governments maximize the value of therapies on the market, squeezing the best effects from the cheapest anti-HIV drugs. Physicians and clinicians, who have had to rethink their management of HIV/AIDS treatment, have dramatically improved success rates. Patients are the ultimate beneficiary: An HIV-positive test used to be a short-term death sentence. Now HIV is considered a chronic, manageable disease, with treatment costs that are considered acceptable and affordable, even in sub-Saharan Africa.

Pharmaceutical companies have also benefited greatly. The PMx approach to HIV/AIDS treatment, for example, has helped make Gilead Sciences Inc. (with a market cap of \$38 billion) the world's second-largest biotech company, after Amgen Inc. The use of companion diagnostics allowed Gilead to improve the overall efficacy of its portfolio of drugs for HIV/AIDS, cementing its lead in that market.

But of all the constituents, pharma companies face the greatest disruption from personalized medicine. It forces them to adopt a new business model with a counterintuitive value proposition, requiring unfamiliar new capabilities to make it work. For many pharma companies, PMx means changing established practices in all aspects of the business — from the earliest stages of target identification and drug discovery, through clinical development, regulatory approval, commercial development and operations, and marketing and sales.

PMx is only one of several strategies that pharmaceutical companies will adopt in the next few years. Some will seek to retain the same business model even as their innovation pipeline dwindles. They will use their marketing capabilities to sell so-called branded generics, off-patent versions of their own former block-



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busters, accepting lower margins in return for high-volume sales. Others will play the specialty pharmaceuticals game, repurposing old drugs in new delivery systems for different diseases than those for which they were originally approved. This is a well-established low-risk model that investors understand.

But a number of pharmaceutical companies will adopt the personalized medicine paradigm. They recognize the competitive advantage that could accrue from a segmented customer base with structures, processes, and capabilities to match. They are just unsure about how to leap ahead into practice.

That is why they need a plan for implementing personalized medicine. To be successful, they will need to take into account three elements of their current reality: first, the prospects for innovation; second, the right value proposition; and third, the capabilities needed to deliver on that proposition.

A New Form of Pharma R&D

Back in the age of economies of scale, most drug companies' business models depended on producing therapies for the largest number of people with unmet medical needs: cimetidine (GlaxoSmithKline's Tagamet) for excess stomach acid, lovastatin (Merck's Mevacor) for high cholesterol, and naproxen (Bayer's Aleve) for aches and pains. Even biotech's early successes, starting in the 1970s, were conceived as mass-market products: epoetin alfa (Amgen's Epogen) for anemia, recombinant insulin (Lilly's Humalog) for diabetes, and etanercept (Pfizer and Amgen's Enbrel) for autoimmune diseases like rheumatoid arthritis and psoriasis. Each represented a multibillion-dollar franchise sustained for many years — and together, they reduced many causes of early mortality, helping raise the average human life span.

But an aging population also means that chronic diseases — including immune-mediated diseases such as cancer, metabolic diseases such as diabetes, and neurological diseases such as dementia — have become more prevalent. Unlike the acute killers of previous generations, these diseases tend to affect people in a relatively heterogeneous manner. Depending on their genetic makeup, people are susceptible to different dis-

ease strains and may respond in different ways to the same medication. For illnesses like these, the healthcare system can no longer afford a trial-and-error approach to pharmaceutical research, in which physicians attack diseases with one compound after another in hopes of finding one whose benefits to the patient will outweigh its side effects.

With personalized medicine, segmentation begins at the research stage. A PMx team seeks out patient populations that can be identified using biomarkers. A biomarker is a measurable substance in an organism — a gene, protein, or other biological element — whose presence has been linked to a pathology, such as cancer or autoimmune disease. A biomarker may also be a genetic variant that indicates an individual's potential response to a particular drug. Drugs are tailored to relatively small, well-defined patient groups, segmented by these markers; the Dx enables the Rx.

This type of pharmaceutical research first led to a marketable product in 1998, when the FDA approved Herceptin — a breast cancer drug developed by Genentech. Herceptin works in only about 25 percent of breast cancer patients. Ordinarily a drug that did not work for three-quarters of the patient population would have failed to win regulatory approval. But researchers at Dako AS, a diagnostics company based in Denmark, devised an accompanying assay (an analysis of the presence of a substance or genetic indicator) showing elevated levels of a protein marker called HER-2 in patients who responded. The FDA approved the medication for only that group of people. Herceptin is now a drug with yearly sales of \$6 billion.

Since Herceptin, companies have used pharmacogenomic assays (tests based on genetic biomarkers) to resuscitate drugs that would have failed clinical trials or to manage the potential danger of side effects. Because many cancers are prompted by mutations in the genetic code, oncology has been the most fertile early ground for these drugs. For example, Erbitux and Vectibix were developed for colorectal cancer, but they work only in people whose tumors have a mutation in the EGFR gene and a normal KRAS gene, and thus are prescribed only after positive responses to assays for those variants.

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Personalized medicine could be applied to a wide range of chronic diseases. As knowledge of the human genome expands, new and old drugs alike can be made more viable through genetic testing. Strattera (atomoxetine), a drug used for attention-deficit hyperactivity disorder, was linked to liver damage for patients with a mutation in the CYP2D6 gene. It is now marketed with a pharmacogenomic assay to rule out this population. Warfarin and Plavix, two blood thinners, can cause excessive bleeding among patients with particular genetic variations. Testing can show which patients should get other medicines.

All this innovation still represents what might be called version 1.0 of personalized medicine: diagnostic tests applied only after a drug's development to salvage or increase its value. Industry leaders now are moving toward another form of PMx innovation — call it version 2.0 — in which new drugs are developed concurrently with companion diagnostics. Under this R&D model, researchers identify target patient subgroups in advance and design drugs for these specific populations.

PMx 2.0 has been held back, somewhat, by cost. The first human genome sequence cost \$3 billion and took many years to completely map. But now the costs are shrinking, and the effectiveness is growing at an exponential pace. Several companies offer personal genome sequencing for a few thousand dollars or less; within 10 years, it is reasonable to expect that sequencing a personal genome will take an hour and cost perhaps \$300, or less than an MRI. It is not too much of a reach to foresee cell phone-sized devices that can analyze a single drop of blood for 500 biomarkers.

As it becomes more prevalent, the pairing of diagnosis and therapy will yield big gains in R&D produc-

tivity. The patient subgroups that stand to benefit from a drug will be identified in advance of clinical trials. This could lead to a meaningful improvement in the average response rate for drugs, which is currently 50 percent across all categories and just 22 percent in oncology. That improvement, in cancer alone, would more than compensate for the cost of diagnostic technology.

A New Business Model

The rise of personalized medicine provides pharmaceutical companies and healthcare providers with a value proposition different from the one they're accustomed to. The standard pharmaceutical mass-marketing approaches, with global distribution and advertising, are too expensive and cumbersome for personalized therapies. Moreover, decisions about the use of personalized prescription drugs are made by a relatively small number of sophisticated payors — hospitals, major providers, or large payors — and not by general practitioners, who are disinclined to prescribe drugs that will not be reimbursed by Medicare or private insurance.

As PMx 2.0 unfolds, popular demand will drive its growth. Because it takes into account each patient's unique pathophysiology; the biochemistry of the tumor, bacteria, or virus; and the individual's ability to properly react to and metabolize different drugs, it will represent a step change in medical confidence and in protection against side effects.

Already, the appeal of personalized medicine is changing the way people spend their own money on healthcare. In 1996, for example, when Myriad Genetics Inc. launched BRACAnalysis, a predictive test for hereditary breast and ovarian cancer, Medicare and private health insurance did not reimburse for its cost.

In August 2012, GlaxoSmithKline paid \$3.6 billion to acquire Human Genome Sciences, one of the earliest companies to mine the genome in search of innovative drugs.

The Essentials of PMx Practice

The experience of biopharmaceuticals suggests that seven processes and practices are required for proficiency in personalized medicine. Together, these could become the basis of a distinctive capability for a company in this field.

1. Biomarker discovery and identification. The first step is to identify a biological trait that indicates the presence or progression of a disease. Next, develop a test that can detect the presence or quantity of these biomarkers. That test becomes the diagnostic. Costs need not be excessive because many relevant biomarkers have been discovered and classified by academic and independent research labs and are available in public databases. The art lies in establishing biomarkers' clinical utility by separating the disease signal from biochemical noise.

2. Assay development. Create in vitro tests that scale beyond the laboratory setting to clinical or commercial use. Develop assays on all major technology platforms and

across multiple analyte and sample types, such as tissues, bodily fluids, and DNA/RNA and other proteins. Map the patient's journey from diagnosis to treatment, and use Dx tests to develop efficient patient-disease stratification.

3. Cross-functional (Rx and Dx) regulatory and clinical expertise. Drugs that are aimed at patient subsets and paired with companion diagnostics make new demands of regulators, so applicants must come prepared. Start by building optimal indications — explanations of the diseases the drug is licensed to treat — and labels, which are the FDA-compliant texts that specify how the drug should be used. Introduce these materials early to key opinion leaders in the relevant field of medicine.

4. Pricing, reimbursement, and billing systems. Develop a sophisticated knowledge of health economics modeling, and cultivate policy experts. Base your projections on the idea that patients who gain no benefit from a drug will not take it; this will cut costs throughout the healthcare system. The right drug to the right patient at the right time is a powerful value proposition.

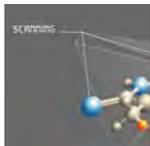
5. Partnership selection and

management. Biopharmaceutical companies are accustomed to outsourcing research, development, and clinical trials. But PMx is different. It involves partnership capabilities that many companies do not possess. A partnership for a companion diagnostic test, for example, has regulatory, quality control, legal, marketing, and sales aspects, involving both the test and the drug. It is critical to define in advance how much value the drug contributes versus how much the enabling diagnostic contributes, and to build a win-win model for the Dx and Rx participants.

6. Marketing. A pull-based strategy requires a knowledge-intensive effort aimed at key opinion leaders and decision makers. You will also need to reach out to national and regional payors.

7. Sales. Retrain your sales force to be conversant in complex science, including genomics, proteomics, and bioinformatics. Revenues from each drug will be spread over fewer patients and total prescriptions, so each staff member will need to manage a larger number of products.

—A.K. and N.P.M.



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Nonetheless, many patients paid the \$3,000 expense out of pocket. So many of them forwarded the receipts to their insurers and argued on behalf of the test that BRACAnalysis is now commonly reimbursed.

People have shown a willingness to pay for many other personalized forms of healthcare as well. Hundreds of thousands of people have opted for a system known as “concierge medicine.” They pay \$59 a month, or more, for 24/7 access to a physician’s advice and counsel, without other types of insurance included. Thousands more flock to alternative medicine, despite the lack of clinical evidence. At least in part, patients are attracted by the perception that alternative medicines are tailored to individual attributes. (For example, some popular medical self-care books propose different regimes of food and herbal remedies based on blood type.)

Personalized medicine will change the way individuals learn about their health. It will lead to more involvement of patients in managing their therapy, and better tracking of patient activity during and after treatment. Today, any newly diagnosed cancer or autoimmune disease patient can consult countless online forums devoted to his or her disease. The information there runs the gamut from accurate and helpful to well-meaning but inadequate to utterly fallacious. Genentech discovered early on with Herceptin that innovative, proactive educational materials are essential to successful PMx. Similarly, Gilead, the world leader in HIV/AIDS drugs, has a long tradition of working with AIDS activists — including some who massed angrily in front of its headquarters in the 1990s — to enlist them in spreading information about the drugs and the varying effects of each drug on different individuals.

To realize the business potential in personalized medicine, pharma companies will need to emphasize diagnostics — which, historically, has been a very different business from pharmaceuticals, with far lower profit margins, making it unattractive to drug companies in the past. Most pharma companies do not have the requisite Dx identification, development, or commercialization capabilities to play effectively in this

space, and will have to build, buy, or borrow them.

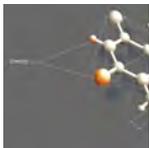
Fortunately for the companies, version 1.0 of personalized medicine has already raised the value of diagnostic tests. In the past, they typically sold for \$300 or less. Today, some tests, such as Oncotype DX, produced by Genomic Health, are priced at about \$4,000. This test is expensive because it is based on years of proprietary genetic research and multiple large-scale clinical trials to confirm its predictive capability. Even so, it is seen as affordable; without it, chemotherapy is far more expensive and toxic.

Several leading pharma companies are beginning to build or buy the capabilities required to fulfill the goals of the patient-centric model. For example, Novartis acquired Genoptix for \$470 million in 2011 — a deal that demonstrated, to many in the industry, that the largest companies were interested in PMx. In August 2012, GlaxoSmithKline paid \$3.6 billion to acquire Human Genome Sciences, one of the earliest companies to mine the genome in search of innovative drugs.

As the bidding for diagnostics assets accelerates, some target companies are likely to be overvalued, and some acquirer companies may overpay. But sitting on the sidelines is not a viable option. Payors and physicians are increasingly unwilling to support drugs with only a fractional response rate. Moreover, the PMx promise to raise R&D productivity while improving patient outcomes is simply too compelling to ignore.

The Capabilities System of Personalized Medicine

One way to think of PMx capabilities is as a set of new instruments that will provide new insights into disease and treatment. But just as ultrasounds and CT scans have not displaced stethoscopes and thermometers in



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the physician's bag, the tools of PMx do not supplant traditional competencies such as those of medicinal chemistry, molecular biology, and high-throughput screening; they augment them.

The capabilities that distinguish a company in personalized medicine are not just tools, of course; they represent combinations of processes, technologies, knowledge, skills, and organization that have been developed over time. Nor can they be thought of in isolation. Distinctive capabilities are always cross-functional. For example, a pharmaceutical company may decide to develop its prowess in a particular type of medical practice, such as oncology, immune system disorders, or mental illness. This will necessarily bring together professionals in genetic research (for biomarker discovery and development), patient outreach, finance (for development of pricing and economic models for stratified patient populations), and sales and marketing (for working with clinics). These are not separate processes and systems; personalized medicine requires synchronized adjustments in every part of the value chain from discovery to development to commercialization to life-cycle management.

After 20-odd years of business process reengineering, most pharma company managers understand how to make structural changes, though they are often blasé or cynical about the ultimate benefits. Personalized medicine could also require changing hearts and minds because it affects the character of an enterprise. Although individual companies will develop new capabilities in their own way, all successful PMx initiatives will need to include these imperatives:

- **Encourage a mind-set in which personalization is not an option but a necessity** — even in the face of the

inevitable failures that occur with new drug candidates. Assume that all molecules in the pipeline will be tailored to specific patient populations; non-tailoring will become the exception.

- **Retain flexibility.** Place a premium on portfolio management skills, determining as early as possible which molecules to advance from research to development, and when to drop a hitherto promising candidate for which the PMx case is weak. Similarly, remain technologically agnostic; don't commit to only one biotechnology research platform.

- **Embed PMx capabilities within the existing capabilities system.** In an era of constrained spending and a vital need for R&D efficiency, essential PMx capabilities must be identified and integrated into the existing value chain. Build the kind of organizational discipline that eschews drug candidates with a potentially large market but lower probability of success. Favor smaller-market drugs that are more likely to succeed. With this approach, you may reap many benefits, such as faster clinical trial enrollment, faster achievement of goals, lower clinical costs, and greater likelihood of success.

- **Access new capabilities through partnerships** — for example, for diagnostics development and commercialization. Ensure access to world-class diagnostics without significant capital outlays by collaborating with assay developers and other companies. Understand that these are truly strategic partnerships that share fully in the creation of value; they are not the routine outsourcing of a fungible function.

- **Build a sales force with new capabilities.** Sales teams will need to pair targeted therapies with sophisticated diagnostic tests. In addition, they will need to be well versed in biological and disease pathway intelligence, and well informed about patient segment attributes that can impede successful treatment.

Managing a Disruptive Innovation

Like all innovations, personalized medicine has been the focus of a great deal of hype, and it is worthwhile to take a few steps back to put it in perspective. It may be oversold at times — particularly in oncology, where it has been heralded as the next “cure for cancer.” Because

Today's healthcare leaders can play a major role in disrupting their own businesses, as IBM did when it introduced its personal computer.

cancer is many different diseases, with many different modulators and multiple mutations even within a single tumor site, personalized medicine cannot be that kind of cure. It will never be a panacea.

But it also is not a placebo. Eric Topol, a cardiologist and geneticist, and the current director of the Scripps Translational Science Institute in La Jolla, Calif., paints an optimistic picture in his recent book, *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care* (Basic Books, 2012). He proposes the integration of basic PMx tools — such as biomarkers for specific pathways and specialized diagnostic technologies — into everyday life. Perhaps biomarker-sensitive devices embedded in mobile phones could detect cancer cells circulating in the blood or warn people of an imminent heart attack.

Topol also says that many of these innovations must overcome the medical community's profound resistance to change. In *The Innovator's Prescription: A Disruptive Solution for Health Care* (McGraw-Hill, 2009), Harvard Business School professor Clayton M. Christensen and physicians Jerome H. Grossman and Jason Hwang suggest that PMx could be disruptive in a way that the healthcare industry cannot long ignore. "The advent of precision medicine," write the authors, "heralds product-line fragmentation in pharmaceuticals. Volumes per therapeutic compound will drop significantly, as the number of therapeutic compounds expands. Blockbuster drugs will become rare. This will necessitate a reshaping of the business model of today's major pharmaceuticals companies because — to borrow words from oil exploration, in the future there will be fewer big gushers to cover the costs of drilling a lot of dry holes."

An ongoing theme in Christensen's work is that the leading practitioners of an old order tend to be the victims of disruption, not the initiators. But *The Innovator's Prescription* proposes that today's healthcare leaders can educate themselves and play a major role in disrupting their own businesses, as IBM did when it introduced its personal computer. There may not be much time to make the shift; across many disease areas, PMx and novel diagnostics are already changing the practice of medicine, and are already accepted as a new way to play in the life sciences market. That is why personalized medicine should be on the senior agenda of every pharmaceutical company. Major new capabilities are not built overnight, and mind-sets are slow to change. Some leading companies are already moving, and so are major stakeholders like payors and providers. The time to act is now. +

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