Personalized medicine offers opportunity

NJ DIAGNOSTICS COMPANIES COULD BE AT THE FOREFRONT

BY DAVID AVITABILE — The concept of personalized medicine—defined as the right drug, for the right patient at the right time—is tailor-made for the current health care marketplace. It is estimated that 55 percent of drugs consumed in the U.S. don't work in the patients for whom they are prescribed, and as many as 80 percent of approved cancer therapies fail to provide positive outcomes in the patients who use them.

But personalized medicine, which uses genetic information to identify individuals who are likely to respond to a given treatment, can help improve the odds of therapeutic success while reducing side effects and treatment failures, thereby lowering health care costs.

It is little wonder, then, that advancing the development and use of personalized medicine is high on the government's agenda as it seeks to reform the health care system and rein in costs.

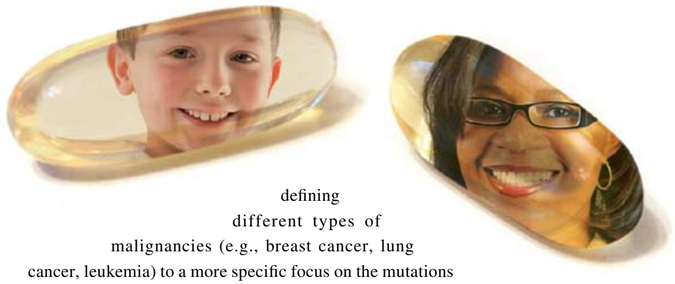
Those efforts have brought renewed focus to the field of diagnostics, which appears poised to capitalize on the advent of personalized medicine. Indeed, many diagnostics companies are experiencing major growth as personalized medicine gains traction. New Jersey is home to a number of major players in the diagnostics industry (see sidebar).

THE PROMISE OF DIAGNOSTICS

Using diagnostics, physicians can now determine which patients will respond best to a particular drug.

Instead of developing and marketing a drug to treat large segments of the population—the "one-size-fits-all" blockbuster approach—diagnostics enables the identification of patient subtypes who will respond to a specific treatment.

There has been great progress in this area as a result of advances in the understanding of biomarkers. These biological molecules—which are present in blood, other body fluids, or tissues—indicate normal or abnormal processes, and can identify whether a patient has a particular condition or disease. The U.S. Food and Drug Administration (FDA) has identified 32 distinct biomarkers. Biomarkers are particularly useful in oncology, a field that is moving away from broadly



defining different types of malignancies (e.g., breast cancer, lung cancer, leukemia) to a more specific focus on the mutations that cause those diseases; this focus allows oncologists to target treatments to individual patients based on the presence or absence of certain mutations.

More widespread use of diagnostic technologies can help lower health care costs by reducing wasteful spending on treatments that do not work for certain patient populations. It may also promote earlier intervention with appropriately targeted therapies, enabling more effective (and less costly) treatment by initiating therapy at a point when the chances for a cure or remission are greater.

Diagnostics can also help life sciences companies improve the efficiency and success rate of their clinical development programs. By testing drugs in patient populations most likely to respond to those treatments, based on the presence of specific biomarkers, biotechnology and pharmaceutical companies can generate more robust efficacy and safety data, thereby improving their chances of gaining FDA approval. The personalized medicine approach may also help companies "resurrect" drugs that failed in earlier clinical trials by resubmitting them for FDA approval in smaller sub-populations of patients most likely to respond to the treatment.

MAKING PERSONALIZED MEDICINE A REALITY

Today, companies are making greater use of companion diagnostic assays that are paired with new drug compounds in the early stages of research and development. The assays use genetic information to identify patients who are or are not likely to respond to treatment, thereby optimizing study populations and improving the speed and efficiency of clinical trials.

Diagnostics-driven personalized medicine is particularly attractive to drug companies adjusting to the post-blockbuster era, as targeted therapies can help reduce development costs and increase return on R&D investment. This approach should also appeal to insurers and other third-party payors, as the elimination of wasteful prescribing and "trial and error" medical care can help reduce their costs as well.

Greater use of diagnostics can also curb health care spending by shifting the emphasis from reactive to preventive care. By helping physicians identify patients with specific risk factors for disease, diagnostics can enable implementation of lifestyle modifications and other risk-reducing interventions before symptoms appear or worsen, thereby limiting expenditures for drug therapy, hospitalization and follow-up care.

Personalized medicine and preventive care are trends to watch as policymakers seek to make health care more efficient and cost-effective. Advances in—and greater use of—diagnostic technologies will help life sciences companies, payors, physicians, and patients meet the health care challenges of the 21st century.

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A look at some of New Jersey's diagnostics companies

New Jersey is home to several diagnostics companies, including:

GE HEALTHCARE MEDICAL DIAGNOSTICS

HEADQUARTERS: Princeton, Mercer County
WEB SITE: www2.gehealthcare.com
ABOUT THE COMPANY: Markets a wide range of products that are used in x-ray imaging, ultrasound, computed tomography scanning, magnetic resonance imaging, and nuclear and molecular imaging. Also offers the "Medcyclopedia," (Medcyclo.com) a website covering more than 18,000 medical topics.

ORTHO CLINICAL DIAGNOSTICS

HEADQUARTERS: Raritan, Hunterdon County
WEB SITE: www.orthoclinical.com
ABOUT THE COMPANY: Serves the transfusion medicine community through development and commercialization of instrument systems and reagents that screen blood and enable blood-typing. Also supplies clinical laboratories with patented dry-slide technology and systems for use in in vitro diagnostic testing, as well as enhanced chemiluminescence technology and systems offering immunoassay testing capabilities across several disease categories.

BD (BECTON, DICKINSON AND COMPANY)

HEADQUARTERS: Franklin Lakes, Bergen County
WEB SITE: www.bd.com
ABOUT THE COMPANY: Develops, manufactures and sells products and instruments used for diagnosing infectious diseases. BD Diagnostic Systems' products are used in the clinical market to screen for microbial presence, grow and identify organisms, and test for antibiotic susceptibility. In the industrial market, Diagnostic Systems' products are used for the testing of sterile and non-sterile pharmaceuticals and medical devices, for environmental monitoring, and for detecting food pathogens.

ROCHE

HEADQUARTERS: Nutley, Essex County
WEB SITE: www.roche.com
ABOUT THE COMPANY: Markets diagnostic products for a wide range of disease areas, including cancer, cardiovascular disease, diabetes, emergency medicine, infectious diseases and osteoporosis. Also offers diagnostic solutions in the areas of blood gas analysis, blood screening, electrolytes analysis, immunochemistry, microarray technology, neonatal intensive care, pharmacogenomics, and other applications.

QUEST DIAGNOSTICS

HEADQUARTERS: Madison, Morris County
WEB SITE: www.questdiagnostics.com
ABOUT THE COMPANY: Offers routine and specialty laboratory tests and services in anatomic pathology, gene-based testing, genetics/heritable diseases, oncologic and hematologic disorders, cardiovascular disease, endocrine system disorders, infectious diseases, and toxicology. Also provides laboratory services in connection with clinical research trials on new drugs.