Sand in Your Genes: Opportunities and Challenges for Personalized Medicine in Florida

By HEIDI A. SORENSEN AND NATHANIEL M. LACKTMAN

Florida businesses, particularly those in the life sciences and healthcare industries, should pay particular attention to emerging opportunities in the field of personalized medicine. There is the potential for significant growth, but investors and business owners will want to familiarize themselves with some of the challenges associated with this fusion of genetics and healthcare.

Personalized medicine is a field of medical treatment and research that uses a patient's individual genetic and health information to better optimize that patient's healthcare. Personalized medicine includes products and services that rely on the sciences of genomics and proteomics. The products and services are targeted to individuals based on their specific genetic code in order to provide a tailored approach. These practices use preventive, diagnostic, and therapeutic interventions based on genetic tests and family history information. Ultimately, the goal of personalized medicine is to improve health outcomes and the healthcare delivery system, as well as the quality of life of patients.

Advances in biotechnology have allowed researchers to create increasingly accurate genetic profiles at affordable costs. These genetic profiles can help researchers predict an individual's likelihood of suffering from certain illnesses or genetic conditions, as well as provide specific treatments to combat those illnesses. With the potential to treat disease on the genetic level, it is no wonder that personalized medicine has the power to significantly change the practice of modern medicine.

Public Support for Personalized Medicine

Congress has already taken steps in support of personalized medicine. On May 28, 2010, Reps. Patrick J. Kennedy (D-RI), and Anna Eshoo (D-CA), introduced H.R. 5440, the Genomics and Personalized Medicine Act of 2010. The Act is intended to expand and accelerate genomics research, improve the accuracy of disease diagnosis, increase drug safety, and help identify novel treatments. The Act would create an Office of Personalized Health Care within the Department of Health and Human Services (HHS). The Act would promote research grants and a national biobank to advance the field of personalized medicine, as well as public/private advisory committees to evaluate genomic applications, carry out a comparative analysis of laboratory review requirements, and evaluate other potential barriers to the implementation of personalized medicine.

In addition to the Genomics and Personalized Medicine Act, HHS has maintained a Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) studying the clinical, public health, ethical, economic, legal, and societal implications of genetic and genomic technologies and applications, including personalized medicine. After a decade in operation, HHS recently determined that the SACGHS had fulfilled its mandate. However, the SACGHS produced a number of comprehensive research reports on personalized medicine, and its recommendations will likely have a meaningful influence on future policies and regulations in this emerging industry.

Developments and Growth Opportunities in Florida

Technological and scientific advances in personalized medicine, in connection with public and private industry support, have served to increase the speed of research in the field. A number of significant personalized medicine research institutes have targeted Florida as a home for new campuses. Continued attention to this issue will likely prompt further government efforts to encourage and promote personalized medicine.

One example of a Florida business that has actively embraced personalized medicine is the Moffitt Cancer Center in Tampa. Moffitt's "Total Cancer Care" program is an approach to enhancing access to evidence-based, personalized cancer treatments and information/decision tools for patients and clinicians. The program is one of the largest cancer tumor bio-repositories and data warehouses in the United States dedicated to the development of personalized medicine. Moffitt earned the 2010 Leadership in Personalized Medicine Award from the Personalized Medicine Coalition for its work in putting the concepts of personalized medicine into practice for the benefit of patients.

In 2009, California-based Scripps Research Institute opened Scripps Florida, a research institute in Palm Beach County. The 30-acre Scripps Florida institute conducts research in advanced technologies of genomics and proteomics, spearheaded by its Translational Research Institute. Scripps Florida also has one of four molecule-screening centers in the United States, supported by the National Institutes of Health ("NIH"), to rapidly test a library of chemicals against specific proteins.

Earlier this year, the Jackson Laboratory announced plans to open a personalized medicine campus near Naples, Florida. Working with the University of South Florida, Jackson Lab's translational genetics research institute is slated to be built on a 50 acre site, projected to launch in 2011 and then expand to a permanent campus by 2013. The research institute would focus on personalized, gene-based treatments for diseases such as cancer, Alzheimer's and diabetes. The campus would anchor a 700-acre "biomedical research and education village," envisioned as housing a mix of commercial, academic, and research tenants.

The Burnham Institute for Medical Research, with a campus in Orlando, has engaged in major initiatives related to personalized medicine. Burnham has expanded its traditional research areas (cancer and neurodegenerative and inflammatory diseases) into areas such as obesity, diabetes and metabolic research. Another example of collaborative business, Burnham has partnered with the clinical research institute at Florida Hospital to conduct research on the metabolic systems of the hospital's diabetic patients. Burnham also operates a NIH molecule-screening center and is increasing the center's capabilities to screen 2.2 million chemicals daily.

Challenges and Considerations

Although the growth opportunities are significant, a number of legal, ethical, and business considerations accompany issues of genetic testing procedures, payer coverage issues, and patient privacy protection, among others. A few of these challenges are briefly addressed below.

Patents and IP Licensing. Personalized medicine often seeks to match a patient's genetics with the best therapy, directly linking the diagnostic and therapeutic industries.

Personalized medicine companies wishing to protect their research and development should be concerned with the patent eligibility of inventions connecting a genetic marker to a treatment or alternative option. Indeed, the SACGHS has advocated for exemptions from patent infringement liability, as well as an advisory body on the clinical health impact of gene patenting and licensing practices, on the grounds

(CONTINUED ON PAGE 13)

Sand in Your Genes, *continued from page 12*

that patent restrictions impede patient access to personalized medicine technologies. *See* "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests," HHS Secretary's Advisory Committee on Genetics, Health and Society (April, 2010) at www.oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf. Businesses should be attuned to potential changes in examination standards for patent applications because such changes can influence strategies for patent filing and enforcement.

Coverage and Reimbursement. Securing payer coverage and reimbursement is an essential step for the industry. Currently, many insurers do not provide payments for personalized medicine treatments not deemed medically necessary for the diagnosis or treatment of *existing* medical conditions, despite a growing acceptance of the benefits. To convince health insurers to pay for coverage, it is important to establish the clinical benefits and cost savings of the particular personalized medicine product or service. Insurers might require, as a condition of coverage, adequate demonstrations of favorable results specific to a particular population. Insurers might also require that clinical trials demonstrate clinical efficacy for a particular population.

The outlook for coverage and reimbursement for personalized medicine is optimistic. The SACGHS recommends that the Centers for Medicare & Medicaid Services (CMS) adopt a process for coverage, coding, billing, and payment of genetic tests under established diagnostic testing benefits. Medicare payment and coverage would help ensure continued investment and innovation in genetic and genomic technologies and incentivize providers to use these important tools effectively to improve patient treatment outcomes. Similarly, payment policies designed to reward the use of clinical decision support tools would promote the use of genetic information in the primary care setting. The integration of genetic services into primary care may help promote a shift toward preventive care that can lower costs and improve public health.

FDA Scrutiny. As expected, the U.S. Food and Drug Administration (FDA) will scrutinize the personalized medicine industry and individual personalized medicine products such as drugs, biologics, and devices. Two key concerns regarding FDA clearance for personalized medicine are the investigation phase of the product and developing proper clinical trials to demonstrate the safety and effectiveness of a personalized medicine product for a limited patient population. Businesses should engage experienced healthcare and life sciences counsel to help navigate the FDA process.

Health Information Sharing and Privacy. As personalized medicine products become more widespread, businesses will need to be attuned to the security and privacy requirements contained in the Health Insurance Portability and Accountability Act (HIPAA). The significant accumulation and use of patient health data, including protected health information (PHI), is an important and unavoidable part of personalized medicine. Recent revisions to the HIPAA regulations have dramatically raised the stakes in the event of an inadvertent, improper disclosure or breach of PHI.

These new regulations require, among other things, immediate and ongoing attention to security breaches and, under certain circumstances, reporting of the breach.

Marketing to Consumers. Another concern is the manner in which personalized medicine businesses go about marketing their products and services to consumers. When federal healthcare program reimbursements are involved, there is the need to comply with the federal Anti-Kickback Statute (as well as Florida's corollary state statutes). In addition, there are other restrictions under both federal and Florida law regarding how healthcare products and services may be marketed and advertised to consumers. The SACGHS issued a report highlighting some concerns about genetic technologies that are already marketed directly to consumers (*e.g.*, genetic history testing). *See* "Direct-to-Consumer Genetic Testing," HHS Secretary's Advisory Committee on Genetics, Health and Society (April, 2010) at www.oba.od.nih.gov/oba/sacghs/reports/SACGHS_DTC_Report_2010.pdf. The report recommends a number of steps to reinforce the importance of disclosing realistic and accurate information describing the benefits, risks, and limitations of genetic testing to help minimize the potential harm of inappropriate direct-to-consumer genetic testing. Businesses in the personalized medicine industry should keep abreast of changing restrictions on how their products and services may be marketed to consumers.

Conclusion

Developing a vibrant biotechnology industry is an important part of Florida's continuing efforts to create a diverse, knowledge-based economy. Research institutions and public-private partnerships in personalized medicine have been and continue to be, critical in helping attract research, biotechnology, and pharmaceutical companies to Florida. Although the opportunities for growth are significant, businesses are advised to enlist the help of experienced healthcare and life sciences legal counsel to address the compliance, operational, and regulatory challenges implicit in the developing personalized medicine industry.

The authors would like to thank Judith Waltz, Antoinette Konski, and Robert Slavkin for their contributions to this article.

Nathaniel M. Lacktman is an associate attorney in the Tampa office of Foley & Lardner LLP, and a Certified Compliance & Ethics Professional (CCEP). He is a member of the firm's Health Care Industry Team and the Government Enforcement, Compliance & White Collar Defense Practice. He may be reached at NLacktman@Foley.com.

Heidi A. Sorensen is Of Counsel with Foley & Lardner LLP, and is the former Chief in the Administrative & Civil Remedies Branch of the Office of Counsel to the Inspector General at the United States Department of Health and Human Services. She is a member of the firm's Health Care, Life Sciences, and Senior Living Industry Teams. She may be reached at HSorensen@Foley.com.