The Legal Intelligencer

THE OLDEST LAW JOURNAL IN THE UNITED STATES 1843-2015

PHILADELPHIA, TUESDAY, FEBRUARY 17, 2015

An ALM Publication

Precision Medicine's Impact on Standard of Care

BY DAN FERHAT AND JASON POORE
Special to the Legal

As author and philosopher Elbert Hubbard wrote, "One machine can do the work of 50 ordinary men. No machine can do the work of one extraordinary man." Proponents of precision medicine may disagree. The burgeoning science of precision medicine, generally defined as using genetic information about a patient's disease in diagnosing and treating the disease, is a movement toward relying less on physician judgment and experience and more on vast banks of clinical data. Thus, precision medicine could revolutionize the practice of medicine and the physician's role in patient care. One initial question is how this may change the standard of care in medical malpractice cases. Additionally, is there anything medical care providers should do to limit risk? Both of these considerations require an understanding of what precision medicine is and what it is expected to become.

On Jan. 30, President Obama unveiled details about his administration's precision medicine initiative. The objective of the initiative is to "pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge and therapies to select which treatments will work best for which patients," according to a press release. One of the key goals of the initiative is to usher in "a new era of data-based and more precise medical treatment" through the creation of vast databanks. These databanks will consist of clinical data from thousands of patients that can be interpreted and sorted by computer algorithms. Physicians can then refer to the results in diagnosing and treating patients.

For instance, Brigham and Women's Hospital in Boston explains the use of precision medicine in the practice of radiology in an article on its website titled "Can Big Data Save Your Life?":

"In the past, when referring physicians thought about what kinds of diagnostic imaging tests to do for patients, they relied largely on their own experience and their own clinical judgment, which was limited to the number of patients they had taken care of on their own. When our radiology department went digital, we gained the ability to investigate data from thousands of patients who have come into our hospital with similar signs and symptoms over the past 10 years. We can determine what diagnoses they had, what imaging tests they had, and decipher which imaging tests proved to be the most effective for them.

FERHAT POORE

DAN FERHAT *is a partner in the health care group of White and Williams. He defends hospitals, physicians, nurses and other health care practitioners against professional liability claims at the trial and appellate court levels. Contact him at ferhatd@whiteandwilliams.com.*

JASON POORE *is an associate in the litigation department. He represents various corporations in matters involving medical malpractice, toxic torts, products liability, construction litigation and general tort litigation. Contact him at poorej@whiteandwilliams.com.*

"Now, referring physicians can select diagnostic tests based on the experience of dozens of their colleagues and hundreds of thousands of patients who came before. This kind of decision support helps us to more quickly do the right thing for the right patient at the right time."

If the goal of precision medicine is realized as currently envisioned, physicians will be more dependent on technology and statistics in the diagnosis and treatment of disease than ever before. The legal question then becomes whether the standard of care will require a physician to follow statistical evidence without regard (or with less regard) to professional judgment. In order to establish the standard of care in virtually all medical malpractice cases in Pennsylvania, parties must obtain opinions from experts in the particular field at issue. These experts provide opinions based on their knowledge, training and experience. Of course, experts can draw upon medical literature and studies in assessing the standard of care, but none of the literature or studies are claimed to be "precise." The standard of care, therefore, is currently derived from the facts presented in each particular case and the medical judgment and opinions of medical experts on both sides.

Precision medicine and data-centric treatment could drastically change this legal paradigm. Medical malpractice suits will likely focus more on a review of data available at the time of treatment, and less on expert opinions regarding the physician's conduct.

For example, let us assume there is a database containing thousands of patient outcomes for prescription drugs used to treat migraines. When a physician wants to prescribe a drug for migraines, he or she would search the database for drugs that are effective in patients with the patient's same genetic markers. Using a complex algorithm, the database may produce statistics showing that 90 percent of patients with the same test results and symptoms respond well to drug A. The physician could then decide to prescribe drug B based on prior experience and the 10 percent risk factor associated with drug A. Let us also assume that the patient does not achieve the desired results and sues the physician for prescribing drug B instead of drug A.

What is the standard of care in this situation? Is the physician negligent for failing to automatically follow the results provided by the database? Most likely the case will focus less on the physician's medical decision-making and judgment based on the patient's clinical picture, and more on the physician's choice not to follow the 90 percent success rate provided by the database. Expert opinion regarding the physician's medical decision-making in light of the patient's presentation may have much less impact on standard of care and negligence concepts where precision medicine is the national paradigm. Furthermore, it is easy to imagine a jury viewing the 90 percent success rate as the clear deciding factor and finding against the physician based on this alone. While this is a very basic example, it demonstrates the potential shift toward a more formulaic standard of care in medical malpractice cases as precision medicine becomes more prevalent.

This raises several considerations for medical providers. First and foremost, a duty to review relevant databases may develop, which means that physicians and hospitals will need to ensure they have the most current and advanced technology. Physicians who fail to review the appropriate database before providing treatment could be considered negligent. Additionally, the more precise the data and data processing becomes, the more a physician will be tasked with relying on treatment recommendations provided by computer algorithms and less on his or her own professional experience and judgment. This may call for the retention of more information technology employees in medical facilities. Additionally, medical facilities may want to retain epidemiologists and statisticians in order to assess trends in the data, ensure study results are sound and accurate, and assist physicians with questions concerning data-driven outcomes. Retaining geneticists should also be considered in order to verify the results of complex genetic testing. Hospitals could also consider offering training programs on using available databases and related technologies.

While advances in precision medicine have the potential to benefit millions of patients and provide physicians in several areas of medicine with new tools in treating and diagnosing disease, the corresponding change in the physician's role in the practice of medicine should not be ignored. As physicians transition from rendering services based on experience and judgment to providing care based on data-driven outcomes, the standard of care in medical malpractice cases will likely evolve in kind. The extent of this evolution will largely depend on the success of precision medicine in treating disease and whether it is able to be applied through a widespread infrastructure.

Notwithstanding the significant benefits of precision medicine and other medical technologies, the independent judgment and analysis of a highly trained and skilled clinician should continue to be a key factor in diagnosing and treating disease, both inside and outside the courtroom. Indeed, while the precision medicine initiative is designed to garner more data, information and knowledge about patients' genetic makeup and environment, it was constructed to be a tool for clinicians to better understand their patients and to better predict the most effective treatments. It should not be considered a complete substitute for the independent judgment of experienced clinicians. •