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FOREWORD: PREDICTIVE HEALTH TECHNOLOGIES

Gail Javitt, J.D., M.P.H.*

Personalized medicine – a recurrent theme in this issue as well as very much on the minds of policymakers in Washington – has always conjured in my mind the image of Marcus Welby, M.D., that kindly general practitioner from the 1970s who dispensed homespun wisdom along with medical advice.[1] Dr. Welby portrayed a physician who integrated information about his patients' physical symptoms and their environmental and lifestyle influences to arrive at a course of treatment individually tailored to his patient. Sound familiar? Or, as my father, a physician from that era has asked me, "Hasn't the practice of medicine always been personal?"

In fact, while the goal of medicine always has been to provide treatment appropriate to the individual patient, it is anticipated that advances in genetic research and diagnostics will provide doctors and patients powerful new tools to achieve that goal. Pharmacogenetics, a key component of personalized medicine, seeks to understand the impact of genetic differences on individual response to pharmaceuticals. As scientists learn more about the role of genetic variation in health, it will become possible to develop safer, more effective therapies. More broadly, new understandings about the role of genetics in disease will provide information to individuals

* Gail Javitt, J.D., M.P.H., is Law and Policy Director, Genetics and Public Policy Center; Research Scholar, Berman Institute of Bioethics; and Adjunct Professor, Georgetown University Law Center.

1 ENCYCLOPEDIA OF TELEVISION 1416, 1416-17 (Horace Newcomb, ed. 2004).

about health risks they or their children may face and interventions they may undertake to avoid or mitigate such risks. Knowledge about individual genetic variation may also enable doctors to identify those particularly at risk to harm from environmental exposure.

The issues raised by the contributors to this symposium issue of the *Houston Journal of Law and Policy*, and the way in which they are resolved by policymakers, will have a profound impact on the kind of medical care we receive in the future. And, indeed, as some of the authors point out, there have been a few early "success stories," notably the availability of a test to determine whether women with breast cancer are likely to benefit from the drug Herceptin. With proper stewardship, the knowledge gained from advances in genetic research and diagnostic technologies indeed may lead to significant individual and public health improvements. But, as the articles in this symposium issue also ably elucidate, there are many ethical, legal, social, and policy hurdles that must be vaulted in order to fulfill pharmacogenetics' mantra of the right drug to the right patient at the right time.

Leading off the issue, authors Jennifer Girod and Andrew R. Klein pose a question most appropriate for a legal audience, namely, how will personalized medicine affect the legal system's ability to address the consequences of human exposure to toxic substances? As they explain, knowledge of genetic variation potentially may be used to predict who is at increased risk for developing illness as a result of a toxic exposure. Such information can be a double-edged sword. On the one hand it could be used to help the person avoid toxic exposures, e.g., in the workplace. On the other hand, such information could be used as a defense by the alleged responsible party (e.g., the employer) to avoid liability on the basis that the genetic predisposition, and not a substandard working environment, caused the individual's illness. Ideally, new knowledge regarding genetic susceptibility to disease following environmental exposures should be used to create safer working conditions for all employees, to the benefit of both employees and employers. For this reason, the 2008 Genetic Information Nondiscrimination Act (GINA), which prohibits employers from requesting or requiring genetic testing as a condition of employment or using genetic information in employment decisions, creates an exception for workplace

monitoring, providing such monitoring is voluntary. However, GINA does not address what, if anything, an employer can do if an employee fails to give consent to be tested under these circumstances. It will therefore be important that regulations implementing GINA provide adequate guidance as to what would be acceptable responses by an employer to such a situation.[2]

The second article in this issue, by Gary E. Marchant and Jason S. Robert, dives into the thorny ethical, legal, and social issues arising from the use of genetic testing to diagnose and predict complex disorders, particularly disorders manifesting in childhood. Using autism as an example, the authors examine the consequences of identifying presymptomatic genetic markers of susceptibility to autism. As they point out, research involving children raises special human subjects concerns, and it will be important to ensure that parents and children receive adequate information about the research and the consequences of its findings before being asked to participate. The authors also raise concerns about the use of genetic markers in autism prediction, diagnosis, and treatment, including concerns about whether tests will be accurate and reliable, whether adequate counseling will be provided to parents, whether parents will interpret accurately the information about their child's risk, whether genetic testing will be reimbursed by insurers, and whether testing will be performed prenatally or preconception to avoid the birth of a child with autism. As they rightly conclude, "genetic testing of complex disorders such as autism will present not only greater scientific complexity but also more complicated ELSI issues."

The third article, by Bruce Patsner, describes the current "regulatory black hole" that exists in the absence of Food and Drug Administration (FDA) oversight of predictive medical products, including genetic tests. He explains that most genetic tests today are not regulated by the FDA and instead are offered by laboratories as "home brew" tests without third party review to evaluate their safety and effectiveness. As Patsner describes, FDA's current policy of "enforcement discretion" has disturbing consequences: He

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2 Genetics and Public Policy Center and Council for Responsible Genetics: Comments on proposed rule to implement Title II of the Genetic Information Nondiscrimination Act of 2008, *available at* http://www.dnapolicy.org/resources/finalcommentsGPPCCRG.pdf.

highlights as one example the offering of fetal genetic screening tests with predictive claims that he describes as "not entirely true." He ends with the hope, which I share,[3] that the new leadership in Washington will spur the FDA to protect the public from dubious genetic tests currently in the marketplace.

Finally, the article by Mollie Roth explores the importance of the drug label in communicating pharmacogenetic information, and criticizes FDA handling of the relabeling of Warfarin, an anti-clotting drug, to include pharmacogenetic information. Specifically, the author argues that the FDA should have included information in the label about the availability of genetic testing to determine whether patients have genetic variants that put them at increased risk for an adverse reaction to the drug. Roth speculates that the lack of an approved test for the genetic variants (see Patsner article for an explanation of why such tests are not regulated) may have made the agency cautious about being more directive about testing. But, she cautions, "In the absence of clear, articulated and standardized approaches to regulating the approval and labeling of drugs, it is likely that the progress of personalized medicine will be impeded as a result of manufacturers hesitating to move into this new development paradigm." I share this sobering conclusion. In order to realize the promise of personalized medicine, the drug label must, where supported by the scientific evidence, provide health care providers with clear, actionable information on what test to use in which patients and for what purpose before they prescribe a particular course of treatment. Clear and consistent guidance by the FDA about including pharmacogenetic information in the drug label will be crucial to provider education.

The articles in this symposium demonstrate that we are only at the very beginning of the journey toward genetically personalized medicine, and that the road ahead contains potholes, inadequate road signs, and poor lighting. At the same time, with the proper engineers and cartographers, the genetic information unleashed by the Human Genome Project could pave a smoother, more efficient, and – yes –

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3 Gail H. Javitt, *In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests*, 62 FOOD & DRUG L. J. 617 (2007), *available at* http://www.dnapolicy.org/resources/Javitt_FDLJ.pdf.

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