Foreword

Vence L. Bonham
National Human Genome Research Institute, bonhamv@mail.nih.gov

Follow this and additional works at: https://scholarship.law.slu.edu/jhlp

Part of the Health Law and Policy Commons

Recommended Citation
Available at: https://scholarship.law.slu.edu/jhlp/vol3/iss1/3

This Foreword is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in Saint Louis University Journal of Health Law & Policy by an authorized editor of Scholarship Commons. For more information, please contact erika.cohn@slu.edu, ingah.daviscrawford@slu.edu.
FOREWORD

VENCE L. BONHAM*

[People have argued for years—does science make progress, and then the law has to conform, or does the law set the system, and then science has to follow it? It’s probably a mixture of both. In the end, science . . . seeks for truth. In the end law seeks for truth. And in the end, both of us use our disciplines to shape our destiny and to ensure human progress, and we must do this together.]

Justice Anthony Kennedy

As scientists attempt to keep pace with the discoveries of the complexities of the human genome and its function, the question of how the legal profession keeps pace with the technological and scientific advances resulting from the unraveling of the human genome becomes increasingly relevant. The genomic data produced in research laboratories and sequencing centers around the world is no longer only of value for the geneticists, epidemiologists, and bioinformaticians who mine the databases, it is also important for the public. Of equal importance is the ability of non-scientists to be able to make sense of this information. As new and exciting, yet intricate, data comes forth, so do important questions: How does this emerging science intersect with the law? How is the information disseminated or translated to the greater society?

* Vence L. Bonham, Associate Investigator, Social and Behavioral Research Branch, Division of Intramural Research, National Human Genome Research Institute and Senior Advisor to the Director of the National Human Genome Research Institute for Societal Implications of Genomics, National Institutes of Health, Bethesda, Maryland. Preparation of this foreword was supported [in part] by the Intramural Research Program of the National Human Genome Research Institute, National Institutes of Health. The content is solely the responsibility of the author and does not represent the official position of the National Human Genome Research Institute, NIH or Department of Health and Human Services. Direct correspondence to Vence L. Bonham, Social and Behavioral Research Branch, Division of Intramural Research, National Human Genome Research Institute, NIH, 31 Center Drive, Room B1B55, Bethesda, Maryland 20892-2070. E-mail: bonhamv@mail.nih.gov. The author is grateful for research assistance from Melissa Chong and the comments from Andre Pilon and Ori Lev.

The 21st Annual Saint Louis University Health Law Symposium, “Living in the Genetic Age: New Issues, New Challenges,” sought to engage both the students of Saint Louis University and the legal community in exploring the legal, social, and ethical implications of advances in genetic technology. Exploring the new understanding of the human genome and how it is influencing all facets of law and policy is an important area for legal scholarship. Where the legal profession is positioned in the genomic revolution is a multifaceted question. This Symposium issue presents the papers of four nationally recognized scholars, each discussing a different question of importance to the law as we have now entered the “genomic era.”2 Scientists are unraveling our understanding of the genome, and industry is developing new genetic and genomic technologies; however, lawyers must play a major role in framing the use of the new genetic and genomic information.

GENETIC INFORMATION NONDISCRIMINATION ACT

The Genetic Information Nondiscrimination Act of 2008 (GINA)3 is an example of diverse constituencies (e.g., researchers, biotech companies, genetic and disease advocacy groups) coming together with leaders on both sides of the aisle in Congress after a “13-year legislative saga”4 to draft and pass a genetic information nondiscrimination bill. The late Senator Edward Kennedy called the legislation “the first major new civil rights bill of the [21st] century.”5 It is too early to determine whether legal scholars will agree that the legislation actually provides citizens of the United States a new civil right. What is certain, however, is that how the law will be interpreted will be decided by the courts. Laurie Vasichek raises two important questions in her article, “Genetic Discrimination in the Workplace: Lessons from the Past and Concerns for the Future.” First, was the legislation necessary at all? Second, is the legislation enough?6 Some groups, representing the business sector and the insurance industry, opposed GINA, saying it was “an

2. Genomics is defined as “[t]he integrated study of the functions of genes, their regulatory signals, and their interactions with the environment and other genes.” Vence L. Bonham, Esther Warshauer-Baker & Francis S. Collins, Race and Ethnicity in the Genome Era: The Complexity of the Constructs, 60 AM. PSYCHOLOGIST 9, 10 (2005).
unnecessary and costly burden on employers.” They said that such discrimination was not a problem. Other groups said that without federal legislation, the public feared misuse of genetic information by health insurers and employers, and that the passage of the bill would help reduce fears of discrimination and result in a greater willingness by the public to participate in genetic research and receive genetic services. The scope of GINA is limited, encompassing the areas of employment and health insurance. GINA does not address life insurance, disability insurance, or long-term care insurance. GINA specifically excludes the military, where historically there have been examples of genetic discrimination against individuals who carry the sickle cell trait.

GINA reached a major milestone when agencies released interim final rules to implement the law. The Equal Employment Opportunity Commission (EEOC) issued interim regulations implementing Title II of GINA on March 2, 2009. The Act became effective on November 21, 2009. The interagency team comprised of the Internal Revenue Service, Department of Labor, and Department of Health and Human Services was tasked with implementing GINA Title I regulations, and issued preliminary rules on October 7, 2009.

As GINA becomes a part of our legal fabric, I believe that with time, we will answer Vasichek’s questions. As we enter a new decade, we will learn much about how we think about genetic information and privacy in the United States and across the world. Commentators, utilizing their legal and scientific lenses, are already focused on what, if any, additional legislation and agency regulations are needed.

8. Id.
16. Vasichek, supra note 6, at 14.
Although safeguarding genetic information from misuse by health insurers and employers is a key prerequisite to more individualized approaches to medicine, many other critical challenges remain. First and foremost, we need to ensure that genetic tests are safe, reliable, and marketed in a clear and truthful manner. There are important gaps in the oversight of genetic tests, and multiple advisory groups have called for regulatory reform to ensure the analytic and clinical validity of genetic tests. Clearly, our country’s substantial investment and innovation in genetic science ought to be matched by innovation in regulation.

Finally, we need to look carefully at other areas of our society in which it might be tempting to use — or misuse — genetic information.\textsuperscript{17}

GINA was a legislative battle that brought diverse viewpoints to the question of how much privacy should we have over the genetic information that makes up “our” genome? The rapid technological advances in the field of genomics and the dramatic reduction in the cost of genotyping are influencing the marketplace, including direct-to-consumer (DTC) genetic testing.\textsuperscript{18} These technological advances have removed the cost barriers to obtaining whole-genome data, thus exponentially expanding the range of research questions that geneticists can explore. The increased speed and accuracy of genetic analysis has made genome-wide association studies (GWAS)—statistical associations between known genetic variants and quantitative traits—a powerful research technique. This data is used by DTC genetic testing companies, such as deCode genetics, Inc.,\textsuperscript{19} Navigenics, Inc.,\textsuperscript{20} and 23andMe, Inc.,\textsuperscript{21} to assist their customers by providing them genetic data in the context of the latest scientific findings.\textsuperscript{22} As of December 29, 2009, 463 peer-reviewed research articles describing 2,186 single nucleotide polymorphisms (SNPs) associated with diseases and traits were reported, ranging from abdominal aortic aneurysm, addiction, diabetes, and narcolepsy, as well as height and weight.\textsuperscript{23} As soon as a

\begin{footnotesize}
\begin{enumerate}
\item[	extsuperscript{17}.] Hudson et al., supra note 4, at 2663.
\item[	extsuperscript{18}.] “Direct-to-consumer (DTC) genetic testing provides a consumer with access to his or her genetic information without necessarily involving a doctor in the process.” Cynthia Marietta & Amy L. McGuire, Direct-to-Consumer Genetic Testing: Is It the Practice of Medicine?, 37 J.L. MED. & ETHICS 369, 369 (2009).
\item[	extsuperscript{19}.] deCODE genetics, Inc., Home Page, http://www.decodeme.com (last visited Feb. 18, 2010).
\item[	extsuperscript{21}.] 23andMe, Inc., Home Page, https://www.23andme.com (last visited Feb. 18, 2010).
\end{enumerate}
\end{footnotesize}
paper is published demonstrating an association, companies can start testing for the association the next day. However, understanding the contribution of any SNP or set of SNPs to manifestation of a disease or trait is challenging even for scientists, so how can Internet-based companies communicate this information accurately to their customers?

THE INTERNET AND PERSONAL GENOMIC INFORMATION

The growth of the Internet both as a tool to disseminate genetic information and to facilitate social networks highlights interesting legal and ethical implications regarding the access to personal genetic information and privacy, as discussed by Sandra Soo-Jin Lee in her article, “Social Networking in the Age of Personal Genomics.” The new paradigm of DTC genetic testing and the ability to share your genetic information with others in your social network raises issues of privacy that extend beyond the individual being tested, to the biological family members of that individual. How does the new class of so-called “recreational genomics,” promoted by marketing strategies such as “spit parties,” intersect with clinical genetics and genomics?

The debate about the benefits and risks of DTC genetic testing has expanded into a conversation about whether having genetic information can cause unique risk of harm or not.

Information is generally considered a good thing. Information may of course lead to benefit through some action based on information. But, action can also lead to harm. We know about harm not only from everyday experience and common sense but also from the field of clinical medicine. Approaches to weigh harm vs. benefit have been developed in clinical medicine to aid doctors, patients and policy-makers in deciding whether to obtain and how to use certain kinds of information.

When personal genomics is used to improve health and prevent disease, the fundamental issues relating to benefit and harm of information are exactly the same as in the clinical medicine field of prevention. If information about risk or prognosis can be harmful in clinical medicine, is there a difference just because the health information is “genomic?”

27. David F. Ransohoff & Muin J. Khoury, Personal Genomics: Information Can Be Harmful, 40 EUR. J. CLINICAL INVESTIGATION 64, 64 (2010).
Professional societies have responded to this new model of DTC genetic testing with a yellow caution light and a message of "buyers beware." The American Medical Association (AMA) stated that "genetic testing should only be made available under the supervision of a qualified health care professional, that physicians be educated about DTC genetic testing, and that the FTC enhance its regulation of companies’ marketing." The American College of Medical Genetics (ACMG) stated:

The health care professional should be responsible for both ordering and interpreting the genetic tests, as well as for pretest and posttest counseling of individuals and families regarding the medical significance of test results and the need, if any, for follow-up. Due to the complexities of genetic testing and counseling, the self-ordering of genetic tests by patients over the telephone or the Internet, and their use of genetic "home testing" kits, is potentially harmful. Potential harms include inappropriate test utilization, misinterpretation of test results, lack of necessary follow-up, and other adverse consequences.

23andMe, in an open letter to the medical community, states:

At 23andMe our mission is to help our customers understand their own genetic information and how the current biomedical literature pertains to it.

Our service combines genotyping with a set of tools and features that depict each customer's personal information clearly, yet without distorting or misrepresenting our current understanding of how genes combine with environment and other factors to produce human traits and diseases. We also keep our service up-to-date by evaluating major genetic association studies as they are published in peer-reviewed journals, and incorporating them into our service after they have been satisfactorily confirmed.

What we do not and will not do is provide medical advice to our customers. Though our service delivers personalized data, the information it provides is tailored to genotypes, not to individuals. Initially, we will have no knowledge of our customers' vital signs, disease histories, family histories, environment, or any other medically relevant information.

These caveats aside, we at 23andMe believe that giving personalized genetic information to our customers can inspire them to take more responsibility for their own health and well-being. We also think our tools will serve to educate the lay public about genetics. At the very least, we

hope our product will stimulate conversation among doctors, patients and researchers about genes and their role in human health.30

Lee poses a question that the legal arena will play an important role in answering: What will the ‘democratization of the genome’ mean for health care and the future of large scale population-based genetic research? We are on the precipice of a new age of personal genomics for the majority of Americans, but how will the law respond? As we enter a new decade, the courts will grapple with various legal questions regarding access to, and control of, genetic information: Are DTC genetic testing companies engaged in the unlicensed practice of medicine? And what are the privacy issues involved in the changing model of maintaining health information from a paper-based medical record in a physician’s office to utilization of health care system electronic health records and Internet-based personal health records (PHR)31 maintained by the individual? The courts will be faced with balancing individual privacy rights with familial privacy rights. The courts will also struggle with the privacy rights of genetic information that individuals freely give to commercial entities and biomedical research databases, with the national security value of such information.

RACE, GENETICS, AND THE BIOMEDICAL ENTERPRISE

I have followed Jonathan Kahn’s work closely since he published his paper, “How a Drug Becomes ‘Ethnic’: Law, Commerce, and the Production of Racial Categories in Medicine,” in 2004 in the Yale Journal of Health Policy, Law and, Ethics.32 Kahn has challenged policymakers, scientists, and clinicians to comprehend how they frame commercial interest in the use of race in medicine and science. In the article in this issue “Beyond BiDil: The Expanding Embrace of Race in Biomedical Research and Product Development” he probes the use of race in patents and product development.33 Kahn explores what he describes as the regulatory clash of race and commerce: “Market differentiation is one type of commercial imperative driving the use of race in biomedical research and product

31. Personal Health Record is typically an Internet platform designed to provide the individual patients control of their health information. At their discretion, individuals can share health information with a wide range of Web applications, EMR systems, health and fitness devices, and with physicians and family members. For an example of a personal health record, see Microsoft HealthVault, Home Page, available at http://healthvault.com/personal/index.html (last visited Feb. 18, 2010).
development. More straightforward concerns for economy and efficiency may also be providing further impetus for continuing to use race in the face of genetic discovery.”

My own research has focused on the role of genomics in understanding the construct of race and social identity, and the use of genetics and race in the clinical encounter.

The first national study published about how physicians think about race and targeted pharmaceutical treatments was conducted with my colleagues. Our initial empirical research has found that physicians have a nuanced understanding of race-based therapies and a wariness of their use. Both black and white physicians in our qualitative study reported skepticism about the underlying premise of race-based therapies and uncertainty that physicians could use race to identify patients who would be the most likely to benefit from a drug. In general, the physicians included in the study did not believe that race was an adequate proxy for genetic variation in populations. Physicians’ appreciation of the challenges of applying race-based therapies in the exam room means physicians are not likely to be uncritical acceptors of race-based drugs that are marketed to them. Many physicians in the study expressed dismay at what they perceived to be the primary aim of race-specific pharmaceutical trials, namely, to get physicians’ attention for marketing purposes.

Nearly five years after the FDA approved BiDil, the first-ever drug targeted specifically to African Americans, we now have some data as to whether patients and health professionals embraced the drug. After thirty months on the market, NitroMed, the parent company of BiDil, announced that it had suspended sales and marketing activities for BiDil, and due to poor sales it underwent a restructuring that has led to a significant reduction in its workforce. The question is why has BiDil done so poorly? In the biomedical community, the approval of the drug touched off a debate over the utility of using race to determine treatment response. Will future medications targeted to a single racial or ethnic group be met with resistance in the medical community? What will be the legal ramifications of

34. Id.
35. Vence L. Bonham et al., Physicians’ Attitudes toward Race, Genetics, and Clinical Medicine, 11 GENETICS MED. 279, 279, 282-85 (2009).
36. Id. at 283-84.
37. Id. at 282-83.
38. Danielle Frank et al., Primary Care Physicians’ Attitudes Regarding Race-Based Therapies, 25 J. GEN. INTERNAL MED. (forthcoming 2010).
40. M. Gregg Bloche, Race-Based Therapeutics, 351 NEW ENG. J. MED. 2035, 2035-37 (2004); Richard S. Cooper & Bruce M. Psaty, Diversity and Inclusiveness Should Remain the Guiding Principles for Clinical Trials, 112 CIRCULATION 3660, 3660-65 (2005).
race-based therapeutics? How will a decision whether or not to provide a
patient a drug based upon race impact the standard of medical care?

The final Symposium paper is from Maxwell Mehlman, “Will Directed
Evolution Destroy Humanity, and If So, What Can We Do About It?”  
Mehlman raises the issue of how new technologies are influencing our
ability to manipulate, or enhance, our genetic germ line. He states, “[t]he
destruction of humanity as a result of ill-informed, overzealous, genetic
manipulation would undeniably be a dreadful calamity. If the threat is
serious, it certainly must be averted if possible.” His paper focuses on the
question of how this threat should be assessed, and specifically, what
methodological framework should be employed? For a number of years,
the debate about genetic enhancements has been the scholarly focus of
bioethicists. However, as more examples come to the marketplace it will
increasingly become a question for the law. How will the Courts define
enhancements? How will the Courts draw the distinction between a medical
treatment and a genetic enhancement? Who should prescribe
enhancements? What are the legal and ethical rights of a parent to make
decisions regarding genetic enhancements for their child?

LAW AND SCIENCE

Challenges,” raises multiple questions: What is, and what will be, the role of
lawyers in addressing the issues and challenges of the genetic age? How,
and indeed will, science and the law work together commonly to solve
societal questions?

To understand the law-science interface, it is necessary to look at the way
law responds to the stimuli of scientific developments—indeed, to look
generally at the way law is made and changed in our society.

Science, like all human activity, takes place within a societal environment
that provides incentives, deterrents, or neutrality with respect to the
particular activity. The institutions of government are the primary sources of
these influences and are vehicles for expressing law. In a developed society
it is primarily the law that creates the societal environment in which scientific
activity takes place.43

Living in the genetic and genomic age clearly presents new issues and
challenges for the law, and requires the legal profession to consider the
intersection of law and science in new ways. Training a new cadre of

41. Maxwell J. Mehlman, Will Directed Evolution Destroy Humanity, and If So, What Can
We Do About It?, 3 St. Louis U. J. Health L. & Pol’y 93 (2009).
42. Id.
43. Harold P. Green, The Law-Science Interface in Public Policy Decisionmaking, 51
lawyers with both an in-depth scientific and legal foundation is important for the future of genomics and its integration into society. I am a proponent of law school courses that study law and science, and multidisciplinary courses that bring law students together with graduate students in the basic sciences. However, I do not believe that professional and graduate school courses are the only answer. We need lawyers who think about science and its role in the practice of law, and who are capable of integrating the law into the development of science. This is not a new conversation, but in the genetic age, the number of questions for which interdisciplinary expertise is needed has increased. "The combination of law and science is, in short, a discipline of its own which includes but transcends the best of its constituent components."44 My hope is that students entering the legal field today will consider the genetic age as an opportunity to bring their expertise to bear; to shape our future in the genetic and genomic era.

EPilogue

I end this foreword, as we enter a new decade in the genetic and genomic era, by highlighting a few events that have occurred since the Symposium on March 20, 2009. Francis Collins, M.D., Ph.D, the leader of the International Human Genome Project and the National Human Genome Research Institute, was officially sworn in as the sixteenth director of the National Institutes of Health (NIH) on August 17, 2009.45 Dr. Collins was nominated by President Barack Obama on July 8, 2009 and was unanimously confirmed by the U.S. Senate on August 7, 2009.46 Dr. Collins brings his perspective as a physician-geneticist to this role as the leader of the largest biomedical enterprise in the world, with a budget of more than thirty billion dollars.47 He has presented a research agenda for NIH to the scientific community that includes the development of technologies in areas such as DNA sequencing, nanotechnology, proteomics, metabolomics, small-molecule screening, RNA interference, imaging, and computational biology.48

In November of 2009, deCODE genetics declared chapter 11 bankruptcy in the United States.49 On January 5, 2010, GenomeWeb

44. Carl N. Edwards, In Search of Legal Scholarship: Strategies for the Integration of Science into the Practice of Law, 8 S. CAL. INTERDISC. L.J. 1, 36 (1998).
46. Id.
announced that deCODE genetics had received notification from the Nasdaq Stock Market that the firm’s common stock would be suspended from trading as of the open of business on January 6, 2010.50

A research team led by Sarah Tishkoff of the University of Pennsylvania and Carlos D. Bustamante of Cornell University published a study in the Proceedings of the National Academy of Sciences (PNAS) which suggests that care should be taken when conducting pharmacogenetic research within the racial population group described as “African American.”51 Their research findings highlight the genetic diversity that exists within individuals who self-identify as African American. They state: “That some individuals who self-identify as African American show almost no West African ancestry and others show almost complete West African ancestry has implications for pharmacogenomics studies and assessment of disease risk.”52

In 2009 the New Yorker published an article “Brain Gain”53 reporting the underground growth of the use of drugs described as ‘neuroenhancers,’ a type of cognitive enhancement that is increasingly being used on college campuses.

Unlike many hypothetical scenarios that bioethicists worry about—human clones, “designer babies”—cognitive enhancement is already in full swing. Even if today’s smart drugs aren’t as powerful as such drugs may someday be, there are plenty of questions that need to be asked about them. . . . Could enhancing one kind of thinking exact a toll on others? All these questions need proper scientific answers, but for now much of the discussion is taking place furtively, among the increasing number of Americans who are performing daily experiments on their own brains.54

The article provided a glimpse of this new world of “enhancement drugs” used to maintain a competitive edge. Researchers are seeking to keep pace with the growth of the off-label use of these drugs and are conducting studies to explore their medical implications.55

The Symposium highlighted some of the issues and challenges that will face society in the age of genetic and genomic science. Going forward, I

52. Id.
53. Margaret Talbot, Brain Gain: The Underground World of “Neuroenhancing” Drugs, NEW YORKER, Apr. 27, 2009, at 32.
54. Id. at 37.
55. See, e.g., Nora D. Volkow et al., Effects of Modafinil on Dopamine and Dopamine Transporters in the Male Human Brain: Clinical Implications, 301 JAMA 1148, 1148-54 (2009).
believe an important challenge for the legal profession is to train a cadre of lawyers knowledgeable of science and genomics to play an important role in the translation of the technological and scientific discoveries into benefits for society.