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Symposium: Proceedings of "The Genomics Revolution? Science, Law and Policy"

Introduction

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Symposium: Proceedings of "The Genomics Revolution? Science, Law and Policy"

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INTRODUCTION

Completion of a map of the human genome in 2003,[1] the coupling of biology and information technology ("bioinformatics"),[2] and the pace of advancement of this and related fields have given rise to expectations that a "genomics revolution" will transform the practice of medicine.[3] Some of the greatest expectations are placed in the fields of population health, including database compilation;[4] the use of pharmacogenomics and pharmacogenetics to genetically profile responses to drugs;[5] haplotype mapping, meaning identification of linkages between genetic variants and populations;[6] and individualized medicine based upon genetic profiling.[7]

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1. HGP was driven to completion years ahead of schedule through competition between industry and government-led teams that ultimately joined forces to declare a joint victory. *See generally* 291 Science 1145 (Feb. 16, 2001) (issue entitled "The Human Genome"); 409 Nature 745 (Feb. 15, 2001) (issue dedicated to the release of a draft map of the human genome). Information about the Human Genome Project may be obtained from the National Human Genome Research Institute (NHGRI), available at www.nhgri.nih.gov.

2. *See generally* Essentials of Genomics and Bioinformatics (C.W. Sensen ed., 2005).

3. *See generally* James D. Watson, DNA: The Secret of Life (Alfred A. Knopf ed., 2003); The Genomic Revolution: Unveiling the Unity of Life (Michael Yudell & Robert DeSalle eds., 2002) (concluding, "The knowledge gained [from HGP] could cure cancer, prevent heart disease, and feed millions. At the same time, its improper use can discriminate, stigmatize, and cheapen life through frivolous enhancement technologies."); Allen Guttmacher & Francis Collins, *Welcome to the Genomic Era*, 349 New Eng. J. Med. 996–98 (2004), *available at* www.nejm.org; *Climbing the Helical Staircase: A Survey of Biotechnology*, The Economist, Mar. 29, 2003, at 1–24.

4. *See generally* Symposium, *Regulation of Biobanks*, 33 J.L.Med. & Ethics 1–188 (Mark Rothstein & Bartha Knoppers eds., 2005).

5. Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles*, 43 Jurimetrics J. 1 (2002).

6. *See generally* HapMap Homepage, International HapMap Project, www.hapmap.org; National Genome Research Institute Homepage, www.genome.gov.

7. *See generally* Watson, *supra* note 3; Guttmacher & Collins, *supra* note 3; Noah, *supra* note 5.

To contribute to prospective discussion of the impact of genomics on health care and society, the Pennington Biomedical Research Center, LSU; the Paul M. Hebert Law Center, LSU; and the University of Montréal's Centre for Public Law Research collaborated to host a live symposium on February 4-6, 2004, with the mission of assessing the scientific expectations and social implications being placed on the genomics revolution.[8] This symposium, *The Genomics Revolution? Science, Law and Policy*, was organized into three sessions centered on case study applications of genomics. Each case study opened with presentations to explain and address science expectations, and those presentations were followed by panel presentations and discussions of associated law and policy issues.

The first session focused on the topic of population health. The objective was to probe the extent to which genomics will introduce meaningful risk predictions for common diseases in the context of health populations. Discussion focused on three common diseases: heart disease, diabetes, and obesity.

The second session addressed pharmacogenomics. This discussion centered on whether pharmacogenomics will deliver tangible health care returns, when, for whom, and at what costs.

The third session was on haplotype mapping. The central question was, "Where will haplotype mapping take us?"

The live symposium succeeded in generating engaging presentations and interactive discussion drawn from the varied disciplines of science, medicine, and law-policy. We, the conference Co-Chairs and the *Louisiana Law Review*, are delighted to publish this special proceedings symposium with contributions drawn from presentation transcripts. The symposium begins with overview presentations by Dr. Michael McGinnis and Professor Bartha Knoppers. In *Population Health and the Influence of Medical and Scientific Advances*, Dr. McGinnis explains that the application of genomic technologies to medical care has the potential to lessen our dependence on "halfway technologies"—treatments that turn diseases into chronic conditions rather than

8. These published proceedings do not necessarily reflect changes made thereafter, though most of the contributors have periodically updated their pieces during the production process.

eliminating them—and thereby both improve human health and reduce costs.[9]

Professor Knoppers explains how four phenomena—reductionism, overgeneralization, exceptionalism, and commercialization—are affecting how population health, pharmacogenomics, and the haplotype map will be received.[10] She concludes in *Overview of Law and Policy Challenges* that, "if we stop equating tissues with humans and genes with persons, . . . we might have some possibility in the next decade of having a more international approach, more harmonization and, thus, true collaboration."[11]

The case study on population health is addressed through presentations by Dr. Paula Yoon, Professor Michael Malinowski, Robert Wells, and Professor Hank Greely. In *Risk Prediction for Common Diseases*, Dr. Yoon explains that scale matters in the conversion of new science tools and processes into disease treatment and prevention.[12] In her words, "We need large-scale, population-based collaborative research because, when you start looking at multiple genes and multiple environmental factors to stratify risks, you need big numbers to find meaningful associations."[13]

Professor Malinowski builds upon the premise that biobanking, the organized collection of DNA and accompanying medical information from human populations,[14] is necessary to meet the pressing needs of the genomics research community. In *Taking Genomics to the BioBank: Access to Human Biological Samples and Medical Information*, he encourages drawing from biotechnology technology transfer and development experience to

9. J. Michael McGinnis, *Population Health and the Influence of Medical and Scientific Advances*, 66 La. L. Rev. (Special Issue) 9, 19-20, (2005).

10. Bartha Maria Knoppers, *Overview of Law and Policy Challenges*, 66 La. L. Rev. (Special Issue) 21 (2005).

11. *Id.* at 30-31.

12. Paula W. Yoon, *Risk Prediction for Common Diseases,* 66 La. L. Rev. (Special Issue) 33 (2005).

13. *Id.* at 40.

14. For an excellent, timely treatment of biobanking, see *Symposium:Biobanks*, *supra* note 4, at 1–188.

frame and address questions, and to move science, medicine, and biobanking forward in a responsible manner.[15]

In *Intellectual Property/Ownership Issues*, Robert Wells addresses the challenge of finding a balance in intellectual property policy between the often conflicting goals of providing commercial incentives and maximizing the research community's access to the means to expeditiously advance the medical application of genomics.[16] He proposes a thoughtful technology transfer and development approach that "would bring some of the interested players to the table and try to create the kind of framework that at least allows basic research to go forward and researchers to feel like they are not going to get a cease and desist order from a patent-holder somewhere trying to block their work."[17]

Professor Greely addresses the social, ethical, and legal issues generally applicable to biobanking, and then the special problems that arise from biobanking in particular populations. In *Population Participation and Other Factors that Impact the Compilation and the Utility of Resulting Databases*, he emphasizes that "We are the people, we are the generation that has both the opportunity and the duty to create some settled expectations, some rules, some guidelines, some standards, about how people in biobanks and populations in biobanks should be treated."[18]

Pharmacogenomics,[19] the topic of the second case study, is addressed through presentations by Dr. Janet Woodcock, Dr. Jeffrey Moe, and Professor Mark Rothstein. Dr. Woodcock addresses existing and developing public policy around the science of pharmacogenomics and how the field will be integrated into new drug development, and she does so with the intention of broadening discussion beyond the scientific community and the Food and Drug Administration. In *FDA Policy on*

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15. Michael J. Malinowski, *Taking Genomics to the Biobank: Access to Human Biological Samples and Medical Information*, 66 La. L. Rev. (Special Issue) 43 (2005).

16. Robert Wells, *Intellectual Property/Ownership Issues*, 66 La. L. Rev. (Special Issue) 69 (2005).

17. *Id.* at 77.

18. Henry T. Greely, *Population Participation and Other Factors that Impact the Compilation and the Utility of Resulting Databases*, 66 La. L. Rev. (Special Issue) 79, 90 (2005).

19. *See supra* note 5 and accompanying text.

Pharmacogenomic Data in Drug Development, she concludes that "Pharmacogenomics will introduce deeper understanding [in drug development], but most likely with high clinical complexity."[20]

Dr. Moe and Professor Rothstein both look beyond drug development to the market and law-policy implications of folding medicinal products created through pharmacogenomics into health care systems. In *Commercialization Considerations for Individualized Diagnostic and Drug Therapies Resulting from Pharmacogenomics*, Dr. Moe identifies specific challenges to commercializing pharmacogenomics. He concludes that, "With all these commercialization challenges in mind, my own judgment is that pharmacogenomics will most likely exacerbate the current challenges we face in health care rather than solve them."[21] His reasoning is that "We are struggling, and many times failing, to practice the current standard of care based on population-level understanding, much less attempting to take the standard of care to a higher level of individualization."[22]

Professor Rothstein addresses liability issues from the perspectives of drug manufacturers and health care providers. He concludes that it "remains to be seen whether personal injury lawsuits based on alleged failure to properly prescribe, dose, dispense, and administer medications will increase as a result of the growing availability of pharmacogenomic-based drugs,"[23] and that "these could well be a significant increase in the potential liability of pharmacists and nurses as well as physicians."[24] He closes by emphasizing the importance of not "allow[ing] liability concerns to paralyze either drug development or the clinical introduction of safer and more effective pharmacogenomic medications."[25]

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20. Janet Woodcock, *FDA Policy on Pharmacogenomic Data in Drug Development*, 66 La. L. Rev. (Special Issue) 91, 102 (2005).

21. Jeffrey L. Moe, *Commercialization Considerations for Individualized Diagnostic and Drug Therapies Resulting from Pharmacogenomics*, 66 La. L. Rev. (Special Issue) 103, 115 (2005).

22. *Id.*

23. Mark A. Rothstein, *Liability Issues in Pharmacogenomics*, 66 La. L. Rev. (Special Issue) 117, 123 (2005).

24. *Id.*

25. *Id.* at 124.

Haplotype mapping is the subject of the third case study. In their presentations, Professors Clayton and Ossorio explain the ethical, legal, social, and political implications already identified in the context of the HapMap project and illustrate that, regardless of the validity of the underlying scientific premises, the effort has already generated valuable returns. In *Implications for Existing Law/Regulations*, Professor Clayton draws from her experience as Co-Chair, with Professor Knoppers, of the HapMap Ethics Committee, and emphasizes that "HapMap is a step. It is a hypothesis."[26] She shares her hope that, in the process of taking that step and testing the hypothesis, "we have managed to learn some things about how better to proceed in a way that creates trust with people who are going to be involved in genetic epidemiology research as research participants."[27]

In *Race, Genetic Variation, and the Haplotype Mapping Project*, Professor Ossorio explains the selection of HapMap participants in some detail, and she raises probing questions about the potential impact of the project and similar genetic studies on contemporary and future notions of race.[28] Her discussion forces thoughtful reflection on how race has been defined thus far, and potential harms and benefits of looking at racial and ethnic differences in the context of contemporary genetic science.

As a collective whole, we hope that this multidisciplinary symposium makes a significant contribution to the law literature and, more importantly, to the law and policy that will shape the future of science, medicine, and society. Our sincere appreciation to each of the conference faculty for the collegiality, talent, and many individual efforts that made this symposium possible.

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26. Ellen Wright Clayton, *Implications for Existing Law/Regulations*, 66 La. L. Rev. (Special Issue) 125, 129 (2005).

27. *Id.* at 129.

28. Pilar N. Ossorio, *Race, Genetic Variation and the Haplotype Mapping Project*, 66 La. L. Rev. (Special Issue) 131 (2005).