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Experts provide much-needed policy analysis for clinical integration of next generation sequencing

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As genetic sequencing technologies continue to evolve rapidly, becoming part of clinical care, there is a critical need to establish appropriate policies and regulatory frameworks to address potential challenges, legal and ethical experts have said. A special policy issue of the *Journal of Law, Medicine & Ethics* published online today and edited by experts with the Center for Medical Ethics and Health Policy at Baylor College of Medicine gives policy makers the tools to jumpstart this process.

Experts with the Center for Medical Ethics and Health Policy at Baylor were tapped to serve as editors of this special issue of the journal, which addressed a variety of topics including U.S. Food and Drug Administration regulation, reimbursement, intellectual property issues, and proprietary databases. They did so with the help of a $1.6 million National Human Genome Research Institute grant to Dr. Amy McGuire, director of the Center and a leading expert on legal and ethical issues in genetics. The grant allowed experts to study how the evolution of the next generation sequencing industry impacts these major policy areas.

Next generation sequencing technologies allow clinicians and scientists to determine the precise order of nucleotides – or building blocks—in a DNA sequence.

"This special issue of the journal represents the most comprehensive analysis to date of legal and policy issues associated with the clinical

integration of next generation sequencing," said McGuire.

In an introductory commentary included in the issue, authors McGuire, Dr. David Kaufman, director of research at the Genetics and Public Policy Center at Johns Hopkins University in Washington, D.C., and Dr. Margaret Curnutte, a post-doctoral fellow in the Center for Medical Ethics and Health Policy at Baylor, highlight the priority areas of policy uncertainty.

"Next generation sequencing is potentially transformative for genetic testing applications because it allows clinicians to look broadly across the genome to identify a wide range of genetic changes that are, or may in the future be, clinically significant, as well as to more precisely diagnose and treat disease," the authors noted in the introduction. "The potential expansion of clinical utility and the decreasing costs have brought next generation sequencing methods to the cusp of mainstream clinical diagnostic testing."

There are a host of policy challenges facing clinical integration that must be addressed before genomic sequencing is available for routine clinical use. Though many companies and laboratories involved in clinical sequencing are working to address these issues, there continues to be much variability in analysis – which is why the journal's editors called on McGuire and her team to coordinate the current issue's special focus.

"We believe that a more coordinated approach to policy development is needed since this technology presents several challenges that lie outside existing regulatory frameworks," the authors noted.

Reports in the current issue authored by leading experts on each subject were designed to provide policy makers with the most comprehensive background to address policy making decisions.

The highlighted articles included in the journal provide in-depth reports on some of the most pressing issues:

- Regulation of clinical genetic testing by the Center for Medicare and Medicaid Services through its Clinical Laboratory Improvement Amendments, state law, and the FDA, by legal experts Gail Javitt, of the Johns Hopkins Berman Institute of Bioethics and counsel at Sidley Austin LLP, and Katherine Carner, associate with Allen Boone Humphries Robinson LLP.

  Comprehensive review of the coverage and reimbursement environment confronting clinical next generation sequencing authored by Dr. Patricia Deverka, an adjunct associate professor at the University of North Carolina at Chapel Hill School of Pharmacy, and Jennifer Dreyfus, principal of Dreyfus Consulting, LLC.

- Examination of current case law related to the patenting of human genes by Dr. Robert Cook-Deegan, of the Sanford School of Public Policy at Duke University and Dr. Subhashini Chandrasekharan of the Global Health Institute also at Duke University.
- Discussion of the legality of proprietary databases held as trade secrets by Dr. Barbara Evans, director of the Center for Biotechnology & Law at the University of Houston Law Center.

"There is an immediate need for critical thought about what the highest policy priorities surrounding clinical next generation sequencing are and how we may begin to address them," the introduction authors said. "To develop policy priorities for clinical NGS in the absence of robust clinical data, we suggest input and deliberation from a broad array of stakeholders including NGS technology and informatics companies, clinical laboratories, health care professionals, insurers, regulatory and

public health agencies, health economists and patient groups."

It is our hope that the scholarship in this issue will begin to generate such conversations, and provide policy makers with access to sound policy options based on wide-ranging expert opinions and rigorous research, they said.

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