Algorithmic Medicine and the Lessons of Genomic Testing

Author : Nicolas Terry

Date : August 8, 2019

Sharona Hoffman, *What Genetic Testing Teaches About Predictive Health Analytics Regulation*, __ **N.C. L. Rev.** __ (forthcoming), available at SSRN.

Professor Sharona Hoffman is one of our most prominent health law scholars. She is particularly interested in the intricacies of health privacy and quality in the context of pervasive healthcare technologies such as electronic health records and big data. Her expertise extends to a deep understanding of the Genetic Information Nondiscrimination Act of 2008 (GINA) and the scope of the Americans with Disabilities Act (ADA). In her excellent article, *What Genetic Testing Teaches about Predictive Health Analytics Regulation*, Hoffman neatly combines these interests, providing a thoughtful critique of predictive health analytics founded on a detailed description of our legal and policy experiences with genetic testing. The comparison is particularly pertinent because, to an extent, algorithmic medicine is stepping into a space that many had hoped would by now be occupied by precision medicine.

Hoffman identifies the policy and regulatory issues raised by both genetic testing and what she labels as long-term predictive analytics as "clinical validity and accuracy, privacy and discrimination, and psychological harms." (P. 14.) At root, these raise the question of what Jessica Roberts and Elizabeth Weeks call "healthism," "[p]ermitting—and even *encouraging*—discriminatory treatment based on an individual's health status."

Hoffman's position is that, while we have taken a "relatively cautious approach to genetic testing," the approach to predictive health analytics has been "more cavalier." (P. 3.) To a large extent this is likely because the publicly-funded human genome project featured (as Hoffman notes) a concomitant Ethical, Legal and Social Implications Research Program (ELSI). In contrast (and at least in the U.S.), most predictive health analytics projects are in the hands of private actors such as Alphabet's Verily or IBM Watson (even if some of their products eventually may receive reimbursement from public funds). A lack of social inquiry or concern with regard to the latter also may be attributable to different media and public perceptions. Cracking our genetic code was big news, regularly reported on. In contrast, analysis of predictive health analytics, while of interest to economists is more likely to be subsumed under broader, frequently dystopian visions about the very future of mankind or at least its impact on employment.

Hoffman correctly views the risks such as breach of privacy or discrimination associated with health analytics as amplified by the inclusion of non-traditional data sources and the products such as health scores offered by businesses such as data-brokers. Those observations also inform the regulatory problems she identifies. For example, while GINA would regulate many of these activities if they involved genetic information the same cannot be said of predictive health analytics. Similarly, as Hoffman points out, other regulatory models struggle here. Thus, the HIPAA Privacy Rule falls down when data is in the hands of persons who are not covered entities or their business associates while the Food and Drug Administration's jurisdiction maps poorly to these products and the risks they pose (notwithstanding the agency's recent discussion paper on healthcare AI).

As a result and as Hoffman terms it, this "article is a call to action." (P. 32.) First, she argues that the scientific community must "carefully consider the benefits and risks of predictive health analytics and implement safeguards to address its hazards… and develop oversight mechanisms to safeguard the quality of predictive models." (P. 4.) Second:

> Data subjects should enjoy rights that give them a degree of control over their data including predicted health outcomes. They should have an expanded right to consent to disclosure of their health information a right to

> discover who has seen their health data and a right to sue for privacy breaches that harm them and for discrimination based on disease predictions.

(P. 4.) This second group of recommendations inevitably leads to a call for changes to the HIPAA rules and the ADA, the former extending the reach of "covered entity" and "health information." Here I part company somewhat, as I remain unconvinced that HIPAA can be usefully extended much beyond its current scope. I go further (accepting the inevitable accusation of political naïvety) arguing that when looking at regulatory options for healthcare AI we should go big or go home.

Hoffman's "call to action" deserves immediate attention. So far the public debate in the U.S. has been muted, limited to the technocratic musings of the Obama Administration's Artificial Intelligence Automation, and the Economy report to the more jingoistic proposals of the Trump Administration' Artificial Intelligence for the American People. Our friends in Europe seem be further along the regulatory path, benefiting from perceptive reports from both the House of Lords in the UK and the European Commission's Ethics Guidelines For Trustworthy AI.

Professor Hoffman is on solid ground in arguing that now is the time for action. As she argues, "many more minds must tackle the challenges of predictive health analytics and develop mechanisms to enhance the integrity and benefits of this technology." (P. 39.) To do otherwise would be "imprudent and could cost society dearly." (P. 39.) Highlighting those perils with her perceptive and apposite comparisons to the risks associated with genetic testing and the appropriate legal and policy steps that followed will be the lasting message of this excellent article.

Cite as: Nicolas Terry, *Algorithmic Medicine and the Lessons of Genomic Testing*, JOTWELL (August 8, 2019) (reviewing Sharona Hoffman, *What Genetic Testing Teaches About Predictive Health Analytics Regulation*, __ **N.C. L. Rev.** __ (forthcoming), available at SSRN), https://health.jotwell.com/algorithmic-medicine-and-the-lessons-of-genomic-testing/.