Regulating the Diagnosis of Disease

Maya Durvasula
Stanford University; Stanford Law School

Uncertainty in the incidence of disease complicates nearly all facets of healthcare markets. While some diagnoses—such as a broken hip—provide little scope for interpretation, many diseases require a decision-maker to take a set of measurements and render a judgment. At what point does blood pressure become “high”? At what bone density is a patient suffering from osteoporosis? At what score on a mental health questionnaire does a patient become a candidate for medication? Increasingly, these decisions are guided by diagnostic technologies—such as screening devices, genetic tests, algorithms—that tie specific diagnoses to therapeutic products. This Article investigates an incentive problem at the heart of this market. Firms marketing products that treat disease frequently develop or acquire technologies that diagnose disease. That is, many firms that sell patients drugs also sell them diagnoses.

This Article examines the legal and medical implications of this market-shaping power—a firm’s ability to define the extent and scope of its own market—for over-, under-, and mis-diagnosis of disease. I use a simple model of the economics of diagnosis to identify conditions that give rise to these distortions and to characterize their empirical signatures. I map elements of this framework to detailed case studies drawn from across disease markets, which suggest these problems exist at a quantitatively important scale in practice. Although these distortions are welfare-reducing, I argue that existing modes of liability and regulation offer little recourse—a challenge that reflects, more generally, the limitations of standard tools to police markets for innovation---before sketching a path forward.