Regulating Health Technologies in a Post-FDA World

Rachel Sachs
Washington University in St. Louis School of Law

For over sixty years, the Food & Drug Administration (FDA) has had the authority to review the safety and efficacy of new prescription drugs before they enter the United States market. In the wake of recent legal and political events, this Article explores a no-longer hypothetical question: what would happen to the regulation of prescription drugs and other healthcare technologies in a world without the FDA? Who – if anyone – could determine whether or not they are safe and effective for patients? This Article examines not only critical actions that FDA takes to ensure the safety and efficacy of new healthcare technologies (particularly prescription drugs), but also the reasons why we have an FDA in the first place and the theories motivating those actions. Analyzing both FDA's functions and also its animating goals helps to identify other institutional actors and legal tools, including intellectual property law and insurance reimbursement, which may pick up the agency's mantle, however partially. Ultimately, the Article concludes that at present, no other institutional actor has the resources and institutional capabilities to fully replace FDA, and a post-FDA world would be harmful to patient safety, to innovation, and to the development of information about the safety and efficacy of new healthcare technologies. In a limited set of cases, however, there may be potential for different actors – other countries' pharmaceutical regulators, insurance companies, or independent non-profit entities – to serve as a partial substitute for FDA.