

REGULATING INTERMEDIATE TECHNOLOGIES

Rachel E. Sachs*

Over the last several years, scholars studying health innovation policy have carefully considered the ways in which administrative agencies do and should regulate different types of technologies to encourage their development and dissemination. Scholars have examined a range of legal incentives, including patents, Food and Drug Administration (FDA) exclusivity periods, taxes, grants, health insurance reimbursement, and other tools to promote socially valuable innovations that our current system has structurally disfavored. This research has considered broad categories of technologies, including drugs, devices, and diagnostics.

However, this research has neglected the temporal dimension of the issue. Specifically, a large set of innovations in the life sciences may be considered to be intermediate innovations. Scientists continue to improve these technologies over time, even as the initial products are made available to patients. Yet the relevant innovation policy levers are not set up to consider whether intermediate technologies ought to be regulated differently than technologies which are further along in the development process.

Whether our existing regulatory frameworks are cognizant of an innovation's stage of development matters. In many cases, if the regulatory structure is not appropriately calibrated, the technology will be frozen in time such that future development does not occur. The essential concern is that if the regulation around the intermediate technology is not appropriately calibrated, the later-stage technology will not be developed at all. This failure would be harmful for public health and for societal welfare. Policy levers which may facially appear to be targeted at early-stage technologies are not driven by this policy question, and lack a fit with this type of consideration.

This Article articulates the problem of regulating intermediate technologies in the life sciences and considers how existing laws might be altered to accommodate the situation. It chiefly argues that some of the FDA's existing regulatory approaches around devices or biologic products are already capable of addressing the problem (even if they were designed for other purposes), and others can be altered to do so. Other solutions may lie in the realm of reimbursement, in which the stage of a technology could play into the payments made by insurers for that technology.

* Associate Professor, Washington University in St. Louis School of Law.