# IMPROVING LIFE SCIENCES REGULATION: SOLUTIONS TO THE CURRENT IMPASSE

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*Scientific and technological innovations continue to advance at a faster pace than the law. While recent legislative efforts have focused on increasing funding for the approval of certain life sciences innovations and scientific research, significant improvements remain outstanding. This Article provides a structural solution that would improve the regulation of life sciences innovations that are used in the practice of medicine.*

*This Article challenges the prevailing scholarly and federal employee view that that the FDA has exclusive jurisdiction over life sciences innovations as many current (and forthcoming) medical innovations do not squarely fit within the categories of products regulated by the FDA. Instead, these innovations are hybrids of state and federal jurisdiction. As such, federal jurisdiction exists to the extent that these medical innovations use drugs, biologics, or medical devices, but state jurisdiction exists to the extent that these medical innovations are procedures as states regulate the practice of medicine.*

*This Article argues that the regulation of numerous current and forthcoming life sciences innovations requires the recognition of a state-federal partnership not only because both federal and state jurisdiction already co-exist but also because shared governance would improve the transparency and quality of regulation. A state-federal partnership already exists in health care: Medicaid. Similarly, many federal agencies have programs in which they cooperate with states in regulation, often through programs that involve waivers or an "opt-in" structure. In areas of shared jurisdiction and regulatory gaps, waivers often provide a cooperative solution for shared governance. A waiver-based solution to the regulation of the life sciences would: 1. reduce the reliance upon an* ad hoc *system of regulating life sciences innovations that do not fall within the categories of products traditionally regulated by the FDA, 2. curtail the significance of the FDA's resource shortage, 3. reduce the federal usurpation of state jurisdiction, and 4. remove ethical decision-making from the purview of the FDA.*

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