Global Spillovers of U.S. Medical Technology Regulation

Parker Rogers[1] and Fernando Stipanicic[2]

Abstract

When a single country is a dominant buyer and innovator in a global industry, its domestic rules can serve as de facto global regulation. Firms seeking access to that market reorient their innovation, redesign products, and shift R&D to comply, shaping which technologies are developed and diffuse worldwide. Medical technologies are a canonical setting: the United States is the world's largest buyer and a leading producer of medical devices, and the U.S. Food and Drug Administration (FDA) regulates entry. We study how major changes in U.S. medical device regulation propagate globally, reshaping innovation, trade, high-skill labor, and the global availability of new technologies.

The FDA classifies devices into three risk classes and periodically down-classifies mature device types, easing premarket requirements for some technologies but not others. We exploit these shifts, combine them with global data on patents, FDA registrations, trade, and inventor locations, and apply a matching procedure comparing reclassified device types to similar non-reclassified technologies. This design identifies the causal impact of U.S. regulation on innovation, trade, inventor mobility, and production worldwide.

When the FDA loosens regulation, patenting rises sharply in both U.S. and foreign jurisdictions. U.S. patent filings increase by about 250%, while filings in major foreign jurisdictions (Canada, China, Europe, Australia, Korea, and Japan) increase by roughly 300–450%. Patenting by inventors in each jurisdiction rises by 70–275% (about 200% for U.S.-based inventors). Reclassifications also trigger substantial inventor mobility, with foreign inventor inflows into the U.S. rising by roughly 150%.

Global production and trade reorganize in tandem. In HS10 product codes linked to deregulated device types, U.S. export values rise by about 40% and import values by roughly 75%. Patenting responses are larger for inventors in foreign countries with stronger bilateral trade ties to the United States, with a roughly log-linear relationship between patenting responses and trade intensity. On the production side, the likelihood that U.S. firms outsource manufacturing to foreign producers rises by 9 percentage points and contracting to domestic third-party manufacturers by 15.7 points. Foreign manufacturers are 15.7 points more likely to enter the U.S. market after deregulation, and importer registrations rise by 9.7 points, consistent with expanded trade channels into the U.S. market.

Finally, we examine safety outcomes. Serious and total adverse events reported to the FDA from foreign sources and involving devices made by firms registered in reclassified device types decline in economically meaningful magnitudes after deregulation, though imprecisely estimated. We find no evidence that deregulation worsens safety; instead, the pattern is more

[1] Kelley School of Business, Indiana University
[2] Department of Economics, University of Oslo

consistent with easing U.S. regulation in mature device types expanding the global availability of high-quality technologies than with triggering a race to the bottom. Taken together, our findings show that regulatory reforms in a single large market reshape domestic innovation and production, reallocate inventive effort across countries, reorganize global value chains, and shape the availability of technologies worldwide without detectable deterioration in measured safety, making regulatory design in large economies a powerful lever of global innovation policy.

Acknowledgements: Rogers gratefully acknowledges support from the National Institute on Aging (T32-AG000186). Rogers and Stipanicic declare no conflicts of interest.