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Innovation under Regulatory Uncertainty: Evidence from Medical Technology

Ariel Dora Stern*

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Abstract

This paper explores how the regulatory approval process affects innovation incentives in medical technologies. Prior studies have found early mover regulatory advantages for drugs. I find the opposite for medical devices, where pioneer entrants spend 34 percent (7.2 months) longer than follow-on entrants in regulatory approval. Back-of-the-envelope calculations suggest that the cost of a delay of this length is upwards of 7 percent of the total cost of bringing a new high-risk device to market. Considering potential explanations, I find that approval times are largely unrelated to technological novelty, but are meaningfully reduced by the publication of objective regulatory guidelines. Finally, I consider how the regulatory process affects small firms' market entry patterns and find that small firms are less likely to be pioneers in new device markets, a fact consistent with relatively higher costs of doing so for more financially constrained firms.

Keywords: Regulation; Innovation; FDA; Medical Devices

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