Bringing High-Risk Medical Devices to Market: Approval Times, Panel Heterogeneity and Entry Order

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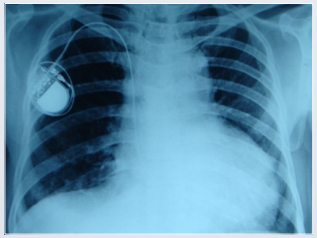
Abstract

Regulation of medical products is a public health and safety issue with substantial economic implications. This project presents the first empirical model of approval regulation for new medical devices. Using a unique dataset of all high-risk device approvals since 1970, I explore the evolution of the FDA's high-risk device regulatory process as well as differences across specialty areas and disease groups. I document several new facts about the regulation of high-risk medical devices: For novel devices, approval times have mostly decreased over recent decades. However, I identify substantial heterogeneity across regulatory categories. For example, while average review times have fallen for novel cardiovascular devices over the past two decades, they have increased for new radiological devices. Next, I develop an empirical model that predicts approval times for devices in different product categories and in different years. I use this model to show that approval times are decreasing in market entry order. That is, the earliest entrants in a product category can expect significantly longer review times than "me too" market entrants. This entry order gradient is precisely the opposite of what has been documented in the market for new pharmaceuticals. As such, the burden of significantly longer regulatory times poses relative disincentives for medical device innovators to pursue novel innovation vs. follow-on innovation.



Motivation and Objectives

Background:

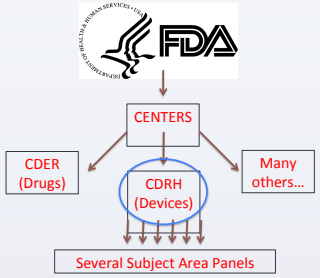
- US market for medical devices is over $100 billion annually and growing
- In the US, disproportionate spending in the Medicare population, where incentives for use and technology adoption are major drivers of health care spending growth
- Innovators and manufacturers frustrated with long U.S. review times: regulatory process is seen as slow, risk-averse, and expensive

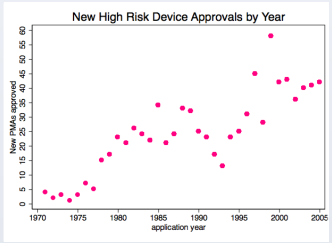
Project Aims:

- Document heterogeneities in review times across the CDRH's (specialty-specific) device review committees
- Perform first study of the relationship between market entry strategy/entry order on review in a medical device setting
- In a pharmaceutical setting, first drug in a therapeutic category faces shorter review times; results preview: in device setting, the opposite

The Regulatory Process and Data

The FDA's Center for Devices and Radiological Health approves and regulates medical devices:



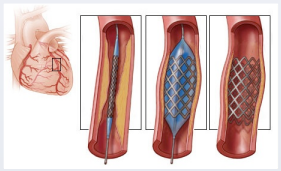


Devices are categorized by the risk they pose to users:

① **Class I:** simplest and subject to least oversight and regulation (stethoscopes, tongue depressors)
② **Class II:** intermediate risk, reviewed using so-called 510(k) premarket notification process (contact lens solutions, hearing aids)
③ **Class III:** devices of the highest risk, which support or sustain human life and/or are implantable; subjected to the strictest of testing standards (pacemakers, stents, heart valves, silicone breast implants)

⇒ premarket approval (PMA) process

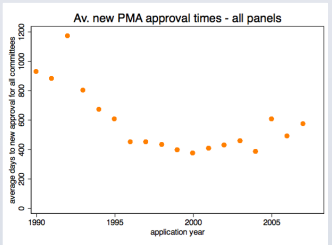
This project focuses on the approval regulation of Class III devices: Class III devices include a number of implantable life-sustaining devices, as well as radiation-emitting devices such as large scanners.



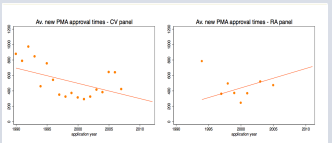
- I use a unique data set of all new high-risk medical device approvals by the FDA (> 4 decades of historical data)
- Data include application dates, approval dates, applicant firm, product codes (i.e. type of device), the committee reviewing the product as well as information about whether the product is a new device or a modification of an existing product

Facts about Review Times and Incentives for Innovation

Review times for new high-risk devices have mostly decreased over recent decades:



But this trend masks significant heterogeneity across different categories of products:



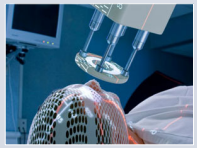
In the Pharmaceutical Industry, empirical research has documented *first mover advantage* for new drugs in a therapeutic category, but for devices, the regulatory statute is quite different:

- Drugs: rigorous, data requirements are substantial and long-standing
- Devices: less established data requirements, significantly more regulatory uncertainty

Uncertainty about FDA data requirements for a new type of device leads to first mover disadvantage in an economic model of competitive strategy under uncertainty:

Two primary late mover advantages in market for medical devices:

① Ability to free ride on first-mover investments (here, establishment of data requirements)
② Resolution of technological and market uncertainty



Empirical Model

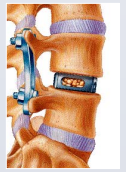
I build an empirical model of entry order and approval regulation and show that the most innovative medical devices experience far longer approval times than follow-on innovations:

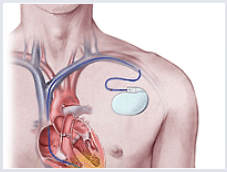
Dependent variable = Additional Months to PMA approval				
First Device in Category	11.2***	7.1***	6.0***	5.9**
Advisory Committee FEs	x	x	x	x
Product Code FEs	x	x	x	x
Year FEs		x	x	x
Applicant FEs			x	x
Decision Code FEs				x
N	494	494	494	494
R^2	0.5175	0.5966	0.6502	0.6510

* p<0.05, ** p<0.01, *** p<0.001

Conclusions

- I document several facts about patterns of new product entry and approval times in the market for new high-risk medical devices.
- An economic model of entry order under uncertainty leads to the hypothesis that there may be first mover disadvantages in entering a new medical device product market.
- I find empirical evidence for this hypothesis by analyzing a unique data set of high-risk medical device approvals in the United States.
- Even my most conservative estimates indicate that the first device in a product category spends nearly six additional months getting approved than follow-on devices.
- This suggests that medical device innovators are often incentivized to create follow-on products, rather than totally novel new devices.





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