NBER INNOVATION POLICY WORKING GROUP
RESEARCH GRANT PROPOSAL

Regulating Innovation with Uncertain Quality:
Medical Device Access and Risk

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Motivation and Objectives

Innovative new products are brought to the market because their creators and buyers believe they provide new value, but there is always some risk that a new product may not work as intended. This is why most products go through pre-market testing. But how much testing is enough? This tension exists in areas as diverse as finance, health care, and manufactured goods. The goal of this project is to provide a general framework for measuring this tradeoff between access and risk, and then exploit cross-country regulatory differences and unusually detailed data to quantify the tradeoff for a large set of medical devices.

The medical device context provides the data and variation necessary to quantify these forces, but it is also a context where this tension has become an increasingly important topic of policy debate worldwide. In the US, the FDA has faced attacks from both sides, with some claiming that a slower, tougher approval process is crippling innovation; and others claiming that the approval process is too lax, allowing too many dangerous devices into the market.[1] As rising incomes in the developing world lead to both greater incidence of "western" diseases and greater ability to afford the most advanced technologies, the debate on how to regulate medical devices has taken on global significance, drawing the interest of the UN and WHO.[2]

Prior Research and Anticipated Contribution

Despite the importance of the access/risk tradeoff in general (and in the medical device context in particular), empirical inquiry has been limited by two major difficulties: (1) assembling data that can quantify both the returns and also the risks of increased access; (2) finding "experimental" variation in access that can identify the tradeoff between these competing forces. In this study we address the second challenge by exploiting the fact that the EU approval process is both faster and less costly than the US process for many types of devices, and this difference is due largely to historical political processes. This allows us to compare a newly constructed detailed data set on a broad set of cardiovascular devices available in the US versus the EU from 2004-2013 to measure the access/risk tradeoff and inform optimal regulatory policy.

Our work builds on prior empirical research on optimal entry regulation (Timmins 2002; Miravete, Seim, and Thurk 2013) and consumer learning (Roberts and Urban 1988; Erdem and Keane 1996; Ackerberg 2003; Crawford and Shum 2005; Ching 2010), and to our knowledge one of the first to combine these two. This combination is essential in allowing us to address the policy question at the heart of this paper. And because it relies on established models and data that is relatively easily available, we hope provides an approach that future researchers might find useful in the area of entry regulation via product approval/certification processes.

[1] "Medical Treatment, Out of Reach," The New York Times, February 2, 2011. "In Medicine, New Isn't Always Improved," The New York Times, June 25, 2011.

[2] "UN: Western Diseases a Growing Burden on Developing World," The Wall Street Journal, May 14, 2010. "Global Forum to Improve Developing Country Access to Medical Devices," press release, WHO, September 9, 2010.

Data and Methodology

Data on the quantity of each product used in each country allows us to calculate a *probability of recall* that accounts for the intensity of use of each product. This is important because by their nature unanticipated risks are more likely to be realized the more intensely a product is used. Thus it is possible that the aggregate similarities in recalls between the US and EU conflate differences in intensity of use and risk across the two environments. Combining the recall and quantity data will allow us to tease apart these effects.

The quantity data will also play a key role in measuring the benefits of increased access to innovative new products. In a previous study, Grennan (2012), the co-investigator has shown how the quantity and price data can be used to produce welfare estimates for the use of a given medical device, using established methods for the empirical analysis of new goods (Bresnahan and Gordon 1996). While this approach to quantifying the benefits of access is different from many of the commonly used measures for medical products (e.g. Cutler et. al. 2006; Duggan and Garthwaite 2010), we argue that it does have the benefit of potentially capturing difficult-to-measure impacts of devices on health-related productivity as in Garthwaite (2011) and other quality of life and value related factors emphasized by Fuchs (2010).

The detailed quantity and price data that make this study possible have already been purchase from Millennium Research Group, a leading medical device market research firm. Since 2004 their MarketTrack survey of hospitals has collected monthly price and quantity data on over 40 different device categories from over 500 hospitals across the US and EU.

Intended Scholarly and Social Benefits

We expect this research to have an impact in both academic and policy communities. For the academic community, we expect our research to inform how scholars think about innovation by highlighting the tension between the upside of access and downside of risk. By providing a framework for both thinking about and measuring this tradeoff, we hope that this work will encourage future research in other contexts where this tension is a major issue, such as financial innovation. In order to achieve this impact, we will present the research widely at seminars in conferences; publish at least one academic paper in a top economics journal; and include findings in our teaching of undergraduate, MBA, and Ph.D. students interested in innovation and health care.

Further, the quantitative findings regarding the access/risk tradeoff in medical devices will be directly relevant to policy discussions regarding the FDA and EU regulatory approaches. Our hope is that our research because a key reference in these debates and helps to inform international policy as medical device regulation becomes increasingly important worldwide.

BUDGET

Summary of Funds Requested ($US)

Research assistant compensation	20,000
TOTAL	20,000

Budget Justification

Research assistant compensation, $20,000
To assist in collecting data on outcomes related to device risk across products in our data, data on clinical trials, and basic statistical analysis we plan to employ one undergraduate student for the spring and summer of 2014 and two graduate students for summer 2014. This grant would help greatly in covering these costs.