

Innovation: The interplay between demand-side shock and supply-side environment

Ivalina Kalcheva, Ping McLemore, and Shagun Pant*

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Abstract

We provide empirical evidence that innovation is a result of both supply-side and demand-side factors. We find that positive shocks to product demand trigger innovation as firms strive to keep their competitive advantage; and that a firm's innovation response to this shock is dependent upon the quality of that firm's supply-side innovation environment. To do this we (i) exploit a shift in product demand generated by Medicare approvals for reimbursement coverage of medical devices and (ii) construct indexes that proxy for the quality of the supply-side innovation environment based on venture capital availability, number of research universities, as well as National Institute of Health (NIH) grants. Employing a triple-difference approach, we show empirically that innovation is significantly greater for firms that experience a positive shock to demand due to the Medicare approvals, when they are exposed to a more favorable supply-side innovation environment. This finding implies that both the demand-side trigger for innovation and the supply-side innovation environment are crucial for innovation to take place.

Keywords: innovation, demand, environment, medical device industry;

JEL classification codes: G24, M13, O3

*The contact author is Ping McLemore from the Federal Reserve Bank of Richmond and can be reached at ping.mclemore@rich.frb.org. Ivalina Kalcheva is from University of California, Riverside, School of Business Administration, The A. Gary Anderson Graduate School of Management, Finance Area, and can be reached at ivalina.kalcheva@ucr.edu. Shagun Pant is from University of Iowa, Department of Finance, and can be reached at shagun-pant@uiowa.edu. The authors thank Julian Atanassov, Alexander Butler, Peter Chung, Matthias Feldues, Henry Friedman, Yawen Jiao, Andrew Karolyi, Kai Li, Yun Liu, Michelle Lowry, Ryan McLemore, Nada Mora, Gordon Phillips, Richard Saito, Giorgo Sertsios, Rick Smith, and Pavel Teterin, as well as seminar participants at the 2015 Citrus Finance Conference, 2016 Eastern Finance Association Annual Meeting, 2016 Midwest Finance Association Annual Meeting, the Federal Reserve Bank of Richmond, and the Seventh Annual Meeting of the Academy of Behavioral Finance & Economics. The views expressed herein are those of the authors and do not necessarily reflect the position of the Federal Reserve Bank of Richmond or the Federal Reserve System. All errors are our own.

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Abstract

We provide empirical evidence that innovation is a result of both supply-side and demand-side factors. We find that positive shocks to product demand trigger innovation as firms strive to keep their competitive advantage; and that a firm's innovation response to this shock is dependent upon the quality of that firm's supply-side innovation environment. To do this we (i) exploit a shift in product demand generated by Medicare approvals for reimbursement coverage of medical devices and (ii) construct indexes that proxy for the quality of the supply-side innovation environment based on venture capital availability, number of research universities, as well as National Institute of Health (NIH) grants. Employing a triple-difference approach, we show empirically that innovation is significantly greater for firms that experience a positive shock to demand due to the Medicare approvals, when they are exposed to a more favorable supply-side innovation environment. This finding implies that both the demand-side trigger for innovation and the supply-side innovation environment are crucial for innovation to take place.

1 Introduction

The idea that innovation plays a crucial part in economic growth dates back to Schumpeter, who states that “earning out innovations is the only function which is fundamental in history” (Schumpeter, 1939, p.100). Innovation is a slow and gradual process, a result of a nexus of different factors.¹ Through the years, two separate strands of academic literature have evolved that concern innovation – one focused on supply-side factors and the other one on demand-side factors. Moreover, innovation policy and academic research have been largely focused on the supply side, i.e., factors that affect firm’s capabilities to innovate.² To date, the consensus among empirical researchers is that supply-side factors are critical for innovation to occur and that demand-side factors (and for that matter the market as a whole) are simply complements (di Stefano et al., 2012). Notably, little integration has occurred between the aforementioned two strands of literature and the interplay between the demand-driven and supply-side factors for stimulating innovation has been largely ignored in the empirical literature.³ Our paper makes two contributions to this field of research. First, we empirically show that a shift in demand is in fact critical for innovation to take place by taking advantage of a quasi-natural experiment. We also show that the interplay between demand-side factors and supply-side factors is paramount for innovation to materialize and thus innovation happens primarily when a need and a means to satisfy that need are simultaneously recognized.

We examine the interplay between a demand-driven lever for innovation and the quality of an organization’s supply-side innovation environmental factors in a natural experiment setting in the medical device industry. We find that firms that are affected by the demand-driven shock and have access to a more favorable supply-side innovation environment factors respond with higher levels of innovation. We utilize events where some medical devices receive Medicare national coverage reimbursement approvals (the treatment group) and some do not (the control group).⁴ With the reimbursement approvals, a large portion of the cost to the consumer for these

¹Shane and Ulrich (2004) and Chemmanur and Fulghieri (2014) provide an insightful overview of papers examining innovation and offer suggestions for future research.

²One exception is Adner and Levinthal (2001) who present a demand-based model of technology evolution that is focused on the interaction between technology development and the demand environment in which the technology is ultimately evaluated. They use simulations to suggest that demand heterogeneity is an important concern as firms move from product to process innovation.

³Zmud (1984), utilizing survey data, does not find evidence that innovation is most likely to occur when a need and a means to resolve that need are simultaneously recognized

⁴Phillips and Sertsios (2016) also exploit the event of Medicare national coverage reimbursement approvals of medical devices but study the differences in external financing sensitivities to investment opportunities for public versus private firms.

devices is covered through Medicare. As a result, the Medicare national reimbursement approval represents a positive exogenous shock to the demand for the device receiving the approval in all states in the United States. The increase in demand for a particular device is a potential trigger for innovation. Medical device firms operate in an industry that is characterized by high levels of competition and extensive patenting. As a result, firms need to innovate in response to the positive shock to demand if they are to keep their competitive edge. Notably, the exogenous shock to product demand represents a shift in the demand curve, which helps us analyze the effect of an increase in demand on innovation (Mowery and Rosenberg, 1979; Dosi, 1982).

To construct our tests, we need appropriate measures for both the quality of the supply-side innovation environment and innovation itself. We measure the quality of an organization's supply-side innovation environment by constructing two indexes based on three factors at the state level – venture capital (VC) availability, number of research universities, and National Institute of Health (NIH) grants.⁵

We also need a measure of innovation. Schumpeter defines innovation as “any ‘doing things differently’ in the realm of economic life” (Schumpeter, 1939, p.80). Innovation is a multifaceted concept and measuring it is a daunting task for any empirical research. Successful innovation occurs when new products or processes are introduced to the market.⁶ Nonetheless, traditional measures for innovation such as patents do not capture successful product innovation. Not everything that is patented will eventually turn into successful innovation and ultimately affect economic growth. “There are around 1.5 million patents in effect and in force in this country, and of those, maybe 3,000 are commercially viable” (Richard Maulsby, Director of Public Affairs, U.S. Patent & Trademark Office).⁷ That is, 99% of all patents are unsuccessful, which means that most of the patents are not commercialized (Greenhalgh and Rogers, 2010).^{8,9} A growing body of literature uses drug approvals or clinical trials as measures of innovation.¹⁰

⁵We focus on privately held medical device firms for which a major financing source is venture capital.

⁶“Innovation occurs at the point of bringing to the [...] market new products and processes arising from applications of both existing and new knowledge” (Greenhalgh and Rogers, 2010, p.3).

⁷This is quoted in Karen E. Klein, Smart Answers, “Avoiding the Inventor’s Lament,” *Business Week*, November 9, 2005.

⁸Under federal statute, any person who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent” (U.S. Code, Title 35, Part II, Chapter 10).

⁹More information on patent success rates can be found at:
http://www.inventionstatistics.com/Innovation_Risk_Taking_Inventors.html.

¹⁰Acemoglu and Linn (2004) measure innovation using the FDA approval of new drugs in the U.S., Lichtenberg (2015) measures pharmaceutical innovation as the number of registered drugs in Canada, and Finkelstein (2004) defines the number of clinical trials for new vaccines as innovation. Subsequent papers using this type of data include Yin (2008), Yin (2009), Kyle and McGahan (2012), Blume-Kohout and Sood (2013), Sampat and Williams (2015), Budish et al. (2015), Dubois et al. (2015), and Williams (2015).

We measure innovation as the number of filings for pre-market approvals (PMAs) and 510(k) clearances that medical device firms are required to file with the Food and Drug Administration (FDA) before the device can be sold on the market in the U.S. The main advantage of our measure of innovation is that it captures the output stage of the innovation process and, thus, is a measure of successful product innovation.

We employ a triple-difference regression model to study the relation between our innovation measure, the demand shock, and an organization's supply-side innovation environment.¹¹ The triple-difference model compares the difference in innovation between the device categories that are affected by the demand shock and those that are not, before and after the shock, across states with a more or less favorable innovation environment.¹² The parameter of interest of the triple-difference model is the interaction term of the following three dummy variables that capture the three layers of difference: (1) treatment versus control group; (2) before versus after the shock; and (3) a more versus a less favorable innovation environment.

Our tests address whether an organization's supply-side innovation environment is a critical component in nurturing innovation conditional on a positive demand-driven shock for innovation. We find that indeed both the supply-side innovation environment and the demand-driven shock are essential ingredients for firms to effectively innovate. In response to the increase in demand for medical devices, we observe more innovation in the treatment group that has access to a better innovation environment. This finding implies that innovation takes place in the presence of both an increase in the market demand for innovation and a nurturing environment to innovate. Our results are robust to a series of sensitivity tests, which include but are not restricted to various empirical specifications, the inclusion of different control variables, and various ways of constructing the measure for innovation.

Our study contributes to the literature on innovation by showing that innovation is stimulated by a demand-side trigger in the presence of a favorable supply-side environment by taking advantage of a natural experiment. Unlike prior studies that have primarily examined the supply-side factors for innovation in isolation, we show empirically that the interaction of

¹¹Butler and Cornaggia (2011) use a triple-difference approach to examine the effect of access to bank deposits on productivity. They exploit an exogenous shift in demand for U.S. corn and examine county-level productivity responses in the presence of varying levels of access to finance as measured by bank deposits.

¹²Medical device categories receive Medicare reimbursement on different dates. Thus, it is not likely that our tests are affected by contemporaneous changes in economy-wide factors.

the demand and supply sides makes innovation possible.¹³ Our study also relates to the strand of literature on public policy towards innovation. There is considerable evidence that innovation affects economic growth and researchers have looked at factors that impact innovation such as talent, federal programs, and research universities (Zucker et al., 2002; Iansiti, 2000). We show that in order to stimulate innovation, a mix of factors rather than a single one is needed.

As has been said, our findings have important policy implications; namely, regulators should focus on both the supply-side and the demand-side policies to encourage innovation. On the supply-side, regulators take initiatives to alleviate financial constraints, such as catering to venture capitalists and providing grants. The demand-side deserves equal attention. Regulators should acknowledge that customer demand is the ultimate driver for innovation. Innovation primarily exists due to market demand, and cannot occur without a high-quality external environment that nurtures innovative activities. The roles played by both sides are necessary and crucial.

2 Related Literature, Hypothesis, and Institutional Details

The debate of whether supply-side or demand-side factors induce innovation started in the Seventies (di Stefano et al., 2012). By the Eighties the consensus among empirical researchers was that supply-side factors were the main drivers of innovation and that demand played only a complementary role (*Ibid.*). Di Stefano et al. (2012) provide an extensive review of the most influential articles, based on bibliometrics, that have dealt with the aforementioned topic and conclude that demand is an important source of innovation. For example, there is some evidence that firms direct their R&D efforts, and ultimately innovation, towards the most profitable and largest markets (Schmookler, 1962; Schmookler, 1966; and Acemoglu and Linn, 2004). Another strand of literature reports a strong positive relationship between innovation (more patents for energy saving technology) and energy prices (Newell et al., 1999; Popp, 2002). Yet

¹³For example, using a sample of 170 firms in Silicon Valley and a survey approach, Hellmann and Puri (2000) demonstrate the importance of VC for innovative companies. Kortum and Lerner (2000) show that a dollar of VC is three times better at stimulating innovation than a dollar of corporate R&D. Further, a recent strand of papers uses banking deregulation to explore the link between bank credit supply and innovation. Yet, the empirical results are mixed. Chava et al. (2013) show contrasting effects of intrastate deregulation and interstate deregulation. They find that intrastate deregulation decreases innovation by young and private firms, and that interstate deregulation increases innovative activities of these firms. Hombert and Matray (2016) provide consistent evidence that intrastate banking deregulation has an adverse effect on innovation of small, young, and opaque firms. Yet, Cornaggia et al. (2015) find that the interstate banking deregulation in the 1990s caused increases in innovative activities of external-finance-dependent private firms.

another strand of literature indicates that consumers are a crucial source of ideas (Adner and Levinthal, 2001; von Hippel, 1986). To our knowledge, Zmud (1984) is the only study to look at whether innovation is most likely to occur when a need and a means to resolve that need are simultaneously recognized. Zmud (1984) utilizes survey data to study the question but does not provide conclusive evidence. We believe that so far in the literature there is no empirical evidence that the interplay between demand and supply factors is important for innovation. To provide empirical evidence on this unexplored issue, we propose and test the following main hypothesis:

H1: *A positive demand-side shock triggers higher levels of innovation mainly in the presence of a favorable innovation environment.*

To test this hypothesis, we use an exogenous positive shock to product demand and study the differential effect of the shock on the level of innovation for a treatment group versus a control group. This hypothesis implies that as compared to the control group, the treatment group innovates more after the shock conditional on a more favorable innovation environment. Specifically, to explore our main hypothesis we (i) take advantage of a natural experiment setting in the medical device industry; (ii) consider the Medicare approval coverage as an exogenous shock to demand for product innovation in the industry; (iii) use the number of FDA filings as a proxy for innovation; and (iv) construct two indexes to proxy for the quality of the external environment to foster innovation. Next we discuss each of these points in turn.

2.1 The Medical Device Industry

The medical device industry is one of the largest industries in healthcare. It includes manufacturers of electromedical and electrotherapeutic apparatuses, such as magnetic resonance imaging equipment, medical ultrasound equipment, pacemakers, hearing aids, electrocardiographs, and electromedical endoscopic equipment.¹⁴ The industry also manufactures irradiation apparatuses and tubes for applications, such as medical diagnostic, medical therapeutic, industrial, research, and scientific evaluation.

¹⁴IBISWorld Database provides a good overview at the industry level. Some of the statistics in this subsection are taken from the IBISWorld Medical Device Manufacturing in the US Report dated October 2015. See <http://www.ibisworld.com/industry/default.aspx?indid=764>, accessed November 10, 2015.

An important characteristic of the medical device industry is that no one firm dominates the market and thus traditionally this industry has had a low level of industry concentration (Holtzman, 2012).¹⁵ The majority of the medical device companies in the U.S. are small and medium-sized enterprises.¹⁶ More than 80% of medical device companies have fewer than 50 employees, and many (notably innovative start-up companies) have little to no sales revenue. Compared to other U.S. industries, small firms in the medical device industry are particularly important in the development of new or improved products, processes, or technologies.¹⁷ Small companies in the industry thrive on specialization, innovation, and new technologies. Such an industry profile defines the medical device sector as highly competitive. To remain competitive, companies must protect and enforce their intellectual property rights through extensive patenting which creates barriers to entry for potential competitors in the product market.

In this paper, we focus on innovation by private medical device companies for the following reasons: First, the external environment plays an important role for these small, privately held companies. Private companies in the medical device industry are primarily venture-backed and hence are sensitive to the availability of VC.¹⁸ These firms also have the opportunity to draw on innovative research being conducted at research universities that are located in their area. Second, there have been approximately 20,000 unique firms in the medical device industry over the last 30 years, of which almost 17,000 were privately held at the time innovation occurred.¹⁹ Also, acquisitions have been the main exit path for private medical device companies. Since private device companies are usually acquired, they do not go public. The major industry players mostly procure new technologies and gain market share by acquiring small and innovative companies instead of investing in their own in-house research and development and, thus, private

¹⁵The concentration ratio in the medical device category has increased in the recent years. In 1995 the ratio of revenues made up by the ten largest medical device companies was 45% (see Figures 6.25 and 6.26 on p.437 in Kruger and Kruger, 2012). Our main results are based on this period. In 2000 the ratio increased to 50%, in 2005 the ratio was 56% and by 2009 the ratio climbed to 62%.

¹⁶See <http://selectusa.commerce.gov/industry-snapshots/medical-device-industry-united-states>, accessed November 5, 2015.

¹⁷See page 17 in Chapter 2 of US-Congress, 1984.

¹⁸According to the 2012 Venture Capital Activity Report, medical device firms remain the preferred area for VC investing in healthcare. See <https://www.cbinsights.com/blog/medical-device-companies-healthcare-vc/> accessed August 2, 2016. About 28% of VC investing in terms of dollar value is in the healthcare industry, and about 42% of VC investing in terms of deal numbers is in the sector of medical devices and equipments.

¹⁹See footnote 14.

firms are key drivers of innovation.^{20,21}

2.2 Medicare National Coverage Reimbursement Approvals as Exogenous Shocks

In the U.S., Medicare coverage is a particularly important factor for product demand in the medical device industry because it directly affects the number of patients who have to pay for products and services as well as the amount that the providers will receive from Medicare reimbursement.²²

The nationwide determination of Medicare reimbursement for an item or service is called National Coverage Determination (NCD).²³ To improve the outcomes of the general health and safety of Medicare beneficiaries in the U.S., the Center for Medicare and Medicare Services (CMS) chooses to make national coverage decisions for items and services that are “reasonable and necessary” for the diagnosis or treatment of an illness or injury.²⁴ The NCDs fall into three categories: medical devices, laboratory/diagnostic tests, and medical procedures. In this paper we focus on the medical devices category.

Why is an NCD considered an exogenous shock to product demand and ultimately product innovation? First, NCDs are made through an evidence-based process, the majority of NCDs are requested internally by the CMS and the approval rate is about 60%.²⁵ Private medical device firms are typically not involved in NCD initiation.²⁶ Also, currently no clear understanding of what constitutes a good candidate for national coverage approval exists (Foote, 2002), which makes the outcome of an NCD request unpredictable.

²⁰See footnote 14.

²¹A significant body of empirical evidence also shows that young, private firms are generally the key drivers of groundbreaking innovation (Chava et al., 2013; Acs and Audretsch, 1987; Acs and Audretsch, 1988; Acs and Audretsch, 1993; Zucker et al., 1998; Kortum and Lerner, 2000; Samila and Sorenson, 2010; and Darby and Zucker, 2003).

²²See footnote 14.

²³In the absence of an NCD, an item or service may be covered at the discretion of the Medicare contractors based on a Local Coverage Determination.

²⁴As of 2012, in the U.S., there are almost 50 million Medicare beneficiaries, representing 16% of the total U.S. population. More details on Medicare and historical details about the CMS can be found in Appendix A.

²⁵Neumann et al. (2005) find that determinations by the CMS are generally consistent with the strength of evidence that establishes the safety, efficacy, and clinical benefit of a medical service or product. On the flip side, Foote (2002) notes that what constitutes a good candidate for national coverage approval is unclear.

²⁶Phillips and Sertsios (2016) note that “large public companies may lobby for the approval of NCD decisions raising concerns about the exogeneity of NCD approvals on those large firms’ external financing transactions.” They exclude 54 public firms with more than \$300 million in sales to address this concern. Our sample consists of small private companies and hence this is not a concern for our study.

Second, medical devices with an NCD approval become more affordable to Medicare patients because a patient is only responsible for a small deductible and a 20% co-payment of a medical device. Notably, an NCD approval for a given device is not limited to a particular firm, it applies to the device itself. Thus, the demand for these devices after the NCD approval is expected to increase. The expected increase in demand for approved and related devices creates opportunities for firms to innovate. We argue that an NCD approval is a positive shock to the investment opportunities of all firms operating in the product category, and ultimately innovation, as we now illustrate.

Naturally, firms already producing the device at the time of approval can simply increase production given the expected increase in demand for their devices.²⁷ However, in order to remain competitive these firms can also introduce new or modified devices to the market. Other firms, which are specialized in the same product line but do not produce the approved device at the time of approval, are likely to have the technology and expertise to take advantage of the improved investment opportunities and develop the approved device. Given the high level of competition in the industry and to avoid patent infringement, the best strategy for these firms is to innovate by introducing a new device or modify an existing device in some respects (e.g., more accurate, faster). Some other firms operating in the same category may produce devices related to the device that received an NCD approval. The increased demand for a device with an NCD approval may also increase the demand for related devices in the same category. For example, an NCD approval of a pacemaker can increase the demand for (i) cardiovascular prosthetic devices such as pacemaker chargers or pacemaker service tools; (ii) cardiovascular surgical devices such as cardiovascular surgical instruments or an intraluminal artery stripper; (iii) cardiovascular therapeutic devices such as embolectomy catheter, septostomy catheter or external cardiac compressor; and (iv) cardiovascular diagnostic devices such as noninvasive blood pressure measurement systems or arrhythmia detectors and alarms.²⁸ Therefore, an NCD approval of a device is a positive shock to the investment opportunities for all firms operating in the same product category, which in turn creates innovation opportunities. In this study, we do not need to identify which private firms produce the approved device, but only need to identify whether the firm is in the product category that has an approval.

²⁷The production of a device may simply increase (without any innovation) when the Medicare reimbursement of the device is approved. This works against us finding an effect of the NCD shock on innovation.

²⁸Cardiovascular devices are classified by the FDA and fall in one of the following subcategories: diagnostic, monitoring, prosthetic, surgical, and therapeutic cardiovascular devices (for more details see “Cardiovascular devices” in the Code of Federal Regulations Title 21, Chapter I, Subchapter H, Part 870).

2.3 FDA Filings as Innovation Proxy

The U.S. Patent and Trademark Office (PTO) approves patents that protect a company's inventions. The medical device industry relies on patents to protect their intellectual property and uses them as barriers to market entry by competitors (Ackerly et al., 2009), but before a new product can be marketed, it has to be approved by the FDA. The FDA has two review processes: pre-market approval (PMA) and 510(k) clearances. Medical devices are classified into high-, medium-, and low-risk categories. High-risk medical devices need to file for PMA, while the medium-risk medical devices need to file for 510(k) clearance. Low-risk devices, such as a tongue depressor, are usually exempt from the FDA reviews. Our main proxy for innovation is the number of total FDA filings, i.e., the total number of PMA and 510(k) filings (vs. approved PMA or cleared 510(k) filings).²⁹ These filings can be either for a new medical device or for a modification to an existing medical device.

Innovation is a cumulative process that builds upon existing knowledge, expertise, and products. It is a multifaceted concept and inherently difficult to quantify and measure. Greenhalgh and Rogers (2010) argue that successful innovation is achieved only at the commercialization stage when the product is just about to be introduced into the marketplace. By measuring product innovation with the number of FDA filings (510(k) and PMA) in a medical device category, we capture exactly the time when the product is ready for introduction into the marketplace.

Previous studies measure innovation using R&D expenditures and patents. R&D is technically an input to the innovation process and a patent serves as an intellectual property right. Thus, R&D expenditures and patents are measures of an early stage of innovation. More importantly, patents might never be commercialized and R&D expenditures might never turn into anything more than an innovative idea. As noted earlier, 99% of all patents are unsuccessful, i.e., most of the patents are not commercialized.³⁰ Similar criticism holds for using R&D expenditures as a measure of innovation in that expenses incurred might never turn into actual innovation. Therefore, the number of FDA filings is an all-encompassing measure that captures successful product innovation and can be considered as the output of the innovative

²⁹Our results are robust when we use the approved filings to construct the proxy for innovation.

³⁰See Footnote 8.

process.³¹

2.4 Innovation Environment Indexes

A handful of papers discuss the importance of external factors for successful development of a new product. For example, Weiss and Birnbaum (1989) provide a conceptual essay from the strategic point of view, where they argue that successful implementation of a firm’s technology strategy requires an understanding of both the external environment and the firm’s capability.³²

Our paper contributes to this literature by formally studying whether the quality of the external environment is critical for product innovation to take place. To do this we construct indexes that capture the characteristics of a firm’s external environment that nurture innovation. The indexes are based on VC availability (given that VC is the major funding source for the small private companies in our sample), National Institute of Health (NIH) grants, and availability of research universities. The importance of funding availability for innovation is well known and documented and thus VC availability and government sponsored funding such as NIH grants are critical (Chemmanur and Fulghieri, 2014). Empirical evidence from firm surveys confirms the importance of university research and public grants for corporate innovation (Mansfield, 1995, 1997; Cohen et al., 2002; Zucker et al., 2002; Mowery and Shane, 2002; Colyvas et al., 2002; Owen-Smith et al., 2002; and Hall et al., 2003.); and more so, for firms in science-based industries like biopharmaceuticals (Hall et al., 2001; Cockburn and Henderson, 2001; Mohnen and Hoareau, 2003; Belderbos et al., 2004; and Veugelers and Cassiman, 2005).

³¹An additional issue with using R&D expenditures is a lack of data availability. Our firms are small private firms that do not have to conform to the SEC disclosure rules of FASB guidelines for R&D reporting. The SEC (since 1972) and the FASB (since 1974) have required publicly traded firms to report all “material” R&D expenditure in the year in which the R&D expenses are incurred (Bound et al., 1984). The private companies in our sample do not have to conform to this rule, thus, preventing us from conducting meaningful statistical tests and inferences (Hirschey et al., 2012).

³²Gjerde et al. (2002) show theoretically that external factors such as a high degree of customer price sensitivity and a fast-moving exogenous technology frontier encourage innovation. Zirger and Maidique (1990) examine over 330 new products in the electronics industry and show that the following key factors affect product outcome: the quality of the R&D organization, the technical performance of the product, the product’s value to the customer, the synergy of the new product with the firm’s existing competences, and management support during the product development and introduction processes. They also show that the competence of the marketing and manufacturing organizations and market factors, such as the competitiveness and the size and rate of growth of the target market are also important but less significant.

3 Methodology and Data

In this section, we present the methodology for conducting our empirical test, the data and the construction of the variables used in our regression analysis. Detailed variable descriptions are provided in Appendix B.

3.1 Methodology

Our basic multivariate regression approach is a triple-difference model:

$$\begin{aligned}
 (\textit{Number of FDA Filings})_{k,i,t} = & \\
 = & \beta_1(\textit{Shock Time Dummy})_{k,t} \times (\textit{NCD Category Dummy})_k \times (\textit{IE Dummy})_{i,t} \\
 + & \beta_2(\textit{Shock Time Dummy})_{k,t} \times (\textit{NCD Category Dummy})_k \\
 + & \beta_3(\textit{Shock Time Dummy})_{k,t} \times (\textit{IE Dummy})_{i,t} & (1) \\
 + & \beta_4(\textit{NCD Category Dummy})_k \times (\textit{IE Dummy})_{i,t} \\
 + & \beta_5(\textit{Shock Time Dummy})_{k,t} + \beta_6(\textit{NCD Category Dummy})_k + \beta_7(\textit{IE Dummy})_{i,t} \\
 + & \textit{Constant} + \textit{Controls} + \varepsilon_{k,i,t},
 \end{aligned}$$

where subscripts k , i , and t denote medical device category, state, and year, respectively. We use annual data at the state level for each medical device category. We report robust t -statistics and cluster errors at the device category level.

The dependent variable, $(\textit{Number of FDA Filings})_{k,i,t}$, counts the number of FDA filings (510(k) and PMA filings) by medical device category k in state i and in year t , to capture innovation at the category-state-year level. $(\textit{Shock Time Dummy})_{k,t}$, takes a value of one if it is after an NCD and takes a value of zero if it is before. The second dummy variable, $(\textit{NCD Category Dummy})_k$, takes a value of one for a medical device category in the treatment group that experience the NCD shock and zero for the control group. The third dummy variable, $(\textit{IE Dummy})_{i,t}$, takes a value of one if the innovation environment index of state i in year t is above the average index across all states in year t and zero otherwise. The triple-difference regression model Eq.(1) includes interactions between these dummy variables – three difference-in-difference (DiD) terms and one difference-in-difference-in-difference (DiDiD) term. $(\textit{Shock Time Dummy})_{k,t} \times (\textit{NCD Category Dummy})_k$

represents the impact of the demand-side shock on innovations between treatment and control groups. $(Shock\ Time\ Dummy)_{k,t} \times (IE\ Dummy)_{i,t}$ compares the impact of the supply-side environment on innovation before and after the shock to product demand. The interaction term, $(NCD\ Category\ Dummy)_k \times (IE\ Dummy)_{i,t}$, compares the impact of the supply-side innovation environment between treatment and control groups.

The triple-difference term, $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (IE\ Dummy)_{i,t}$, is the main focus of our analysis. The parameter estimate associated with this triple-difference term, β_1 , captures the innovation response for a medical device category with an NCD approval (relative to a medical device category without an NCD approval) after the national coverage approvals (relative to the pre-approval period) across varying levels of the quality of a state's innovation environment. In other words, the triple-difference term captures three layers of difference and for ease of reference, we now provide an illustration of each layer. The first layer is the difference in the amount of innovation between states with more and less favorable supply-side environment:³³

$$Di = Innovation^{Better\ IE} - Innovation^{Worse\ IE}. \quad (2)$$

We expect to find that there is more innovation in states with better environment. The second difference, DiD , is the difference of Di , as just defined, between after and before the positive shock to product demand:

$$DiD = Di^{After\ Shock} - Di^{Before\ Shock}. \quad (3)$$

We expect to find that there is more innovation after the shock in states with better environment. The third difference is between the DiD for the treatment and the control groups:

$$DiDiD = DiD^{Treatment} - DiD^{Control}. \quad (4)$$

Thus, the triple-difference model in Eq.(1) tests whether firms innovate more in better supply-side innovation environments in the presence of a demand-side shock. We expect that innovation environment plays an important role in terms of nurturing innovation. Our hypothesis, **H1**, predicts β_1 to be positive and significant. The interpretation is that there is more innovation

³³Note that one can order the layers differently. For example, the first difference can be the difference in innovation from after to before the shock or treatment group versus control group.

in states with more favorable innovation environment (a supply-side factor) and in medical device categories that experience the positive shock to product demand (a demand-side factor). Ultimately, this finding will provide empirical evidence that the interplay between demand-side and supply-side factors is important for innovation to take place.

The regression model in Eq.(1) also includes the following control variables: the log of per capita GDP, unemployment rate and log of population. We collect these variables from the website of the Federal Reserve Bank of St. Louis.³⁴ These three variables are at the state level and are time-varying; thus, including them in the regression model controls for the macroeconomic conditions at the state-year level.

3.2 Variable Construction

3.2.1 *Number of FDA Filings*

The FDA website provides information on all companies that have filed with the FDA to introduce or modify a medical device for use in the U.S.³⁵ The FDA received the authority to regulate the introduction, manufacture, and use of medical devices in the U.S. in 1976 when President Gerald R. Ford signed the Medical Device Amendments into law. Since the quality of FDA filings data is poor before 1986, we use data after 1986 to construct our test sample.³⁶ The sample period of our study is 1987–2014.

There are 238,422 FDA filings (510(k) and PMA filings) by 20,354 firms from 1987 to 2014. Approximately 88% of the total filings are 510(k) filings, and the rest are PMAs. About 98% of the 510(k) filings and 63% of the PMA filings are approved by the FDA. Our sample includes only U.S. private medical device firms. Since a PMA filing is an onerous and exhaustive procedure that requires years of extensive investigation and clinical trials to demonstrate a device’s safety and effectiveness, most PMAs are filed by large public firms. Thus, PMA filings account for only about 1% in our sample, and 510(k) filings account for about 99%. The FDA ensures that the new product’s safety and effectiveness match the safety and effectiveness profile of an existing device. More importantly, given that the medical device industry is characterized by high levels of competition, extensive patenting and an litigious patent environment, the new

³⁴<https://www.stlouisfed.org/>.

³⁵<http://www.fda.gov/MedicalDevices/default.htm>.

³⁶There are several missing values for the number of filings for each medical device category before 1985. The recorded number of FDA filings increases by four times from 1985 to 1986 implying data recording errors.

device has to improve upon the old device without patent infringement.³⁷ FDA filings are not required for firms that continue to produce their existing devices.³⁸ Therefore, a firm will file 510(k) or PMA only when it has a new or an improved device that differs from the existing ones.

An NCD approval is an exogenous shock at the medical device category level. As a result we measure innovation at the device category level. When a device (i.e., an artificial heart) receives an NCD, all the firms (including firms which produce or have the resources to produce artificial hearts, and firms which produce other devices or parts related to artificial hearts) in the Cardiovascular category are affected by such a shock. We aggregate the number of FDA filings made by medical device firms at the category level for each state and year to get a proxy for innovation for a particular medical device category. Medical devices are classified into 19 categories by the FDA. These categories are: Anesthesiology, General Hospital, General and Plastic Surgery, Immunology, Ophthalmic, Radiology, Cardiovascular, Gastroenterology Urology, Microbiology, Orthopedic, Clinical Chemistry, Neurology, Pathology, Toxicology, Dental, Hematology, Obstetrics Gynecology, Physical Medicine, and Ear, Nose and Throat.

3.2.2 Shock Time Dummy and NCD Category Dummy

We hand-collect the NCD approval data from the Centers for Medicare and Medicaid Services (CMS) website.³⁹ After downloading all NCDs from the CMS website, we manually check whether an NCD is for a medical device. For each NCD for a medical device, we read the documentation and identify (i) whether it is an approval, rejection, or no action; and (ii) whether it is an original approval or an extension of a previous approval. We are interested in new approvals and do not consider extensions in terms of time or coverage. Additionally, we require a minimum of five years of data before and after an NCD. Thus, for an NCD to qualify

³⁷A Premarket Notification, 510(k), is a premarketing submission made to the FDA to demonstrate that the device to be marketed is safe and effective by proving substantial equivalence to a legally marketed device (predicate device) that is not subject to Premarket Approval (PMA). Submitters must compare their 510(k) device to a similar legally marketed U.S. device(s). A device recently cleared under 510(k) is usually used as a predicate device. However, any legally U.S. marketed device may be used as a predicate (see “How to find and effectively use predicate devices.” Fda.Gov. U.S. Food and Drug Administration, 21 Aug. 2014. Web. 24 Jun 2015).

³⁸The 510(k) clearance is a demonstration of equivalent safety and efficacy to the FDA, rather than a comparison of an older device to newer patent claims.

³⁹<https://www.cms.gov/>.

as an exogenous shock in our study it must be a new approval and must have data available for a minimum of five years before and after an event.

Four medical device categories receive qualifying NCD approvals during our sample period and constitute the treatment group. The four medical device categories in the treatment group receive a total of seven qualifying NCDs during our sample period. Table 1 reports the number of FDA filings for each medical device category in the treatment group before and after an NCD. The Cardiovascular medical-device category received its first NCD in 1993. This category has 1,578 FDA filings before 1993 and 3,662 FDA filings after. The Gastroenterology Urology category received its first NCD in 1994, second in 2001, and third in 2002. The Gastroenterology Urology category has 1,377 FDA filings before 1994 and 1,765 filings after. Firms in this category submitted a total of 825 filings after 2002. The first NCD for the Neurology category is in 1995 and second in 2003. There are 1,299 filings before 1995, and 966 filings after 2003. The Orthopedic category received its NCD in 1996. The number of FDA filings, made by private orthopedic device firms, is 1,634 before 1996, and 4,176 after.

There are 15 medical device categories that do not receive a qualifying NCD approval in the sample period, and we use these categories as candidates for the control group. The control group is constructed in two different ways. We first include all 15 medical device categories as a control for our treatment group, and then create a one-to-one matched control group. For each category in the treatment group, the matched category is determined as the category that has a similar market share prior to the event. We use a proxy for market share to match the treatment group with an appropriate control. More precisely, we match on the number of medical device firms in the category over a three-year window $(-7, -6, -5)$ four years prior to the event year.⁴⁰ For each pair of treatment and control category, the dummy variable, $(Shock\ Time\ Dummy)_{k,t}$, takes a value of one if it is after the treatment category receives an NCD and takes a value of zero if it is before.

3.2.3 *IE Dummy*

We construct two dichotomous innovation environment variables, *IE1 Dummy* and *IE2 Dummy*, to gauge how conducive a state's environment is to foster innovation. *IE1 Dummy* is constructed based on the following three dimensions which aim to capture the quality of the innovation environment: (i) the number of Healthcare related VC firms available in

⁴⁰Our results are robust to alternative matching criteria.

a state collected from Thomson One;^{41,42} (ii) the number of grants from the National Institutes of Health (NIH) in a state;⁴³ and (iii) the number of universities in a state that are classified as research universities by the Carnegie Classification of Institutions of Higher Education.⁴⁴ We first construct three dummy variables to represent these three dimensions. *VC Number Dummy* takes a value of one if the number of VC firms in state i year t is above the average number of VC firms across all states in year t . Similarly, *NIH Dummy* takes a value of one if the number of NIH grants in state i year t is above the average number of NIH grants across all states in year t . *CC Dummy* takes a value of one for state i in year t if the number of research universities in this state is above the average number of research universities across all states in year t . The sum of these three dummy variables is the first innovation environment index (*IE1*). *IE1 Dummy* takes a value of one if the innovation environment index of state i in year t is above the average index across all states in year t . The second innovation environment index (*IE2*) is similarly constructed with the exception that instead of the number of VC firms (the number of NIH grants) we use the dollar amount of VC invested (the dollar amount of NIH grants). *IE2 Dummy* is constructed using *IE2* in the same way as we construct *IE1 Dummy*. Thus, the dummy variable, $(IE\ Dummy)_{i,t}$, in Eq.(1) is one of our two variables, $(IE1\ Dummy)_{i,t}$ or $(IE2\ Dummy)_{i,t}$, and proxies for the quality of the innovation environment at the state-year level. We expect that firms located in states with more favorable innovation environments will innovate more after the positive shocks to product demand.⁴⁵

Table 2 reports the correlation between the components that comprise in each index. Panel A (B) shows the correlations of the components used to construct *IE1* (*IE2*). We observe the association between the components that construct the indexes is low, which indicates that these components represent different aspects of the innovation environment (the correlations are between 0.18 and 0.59). Panel C shows that the correlation between (*IE1 Dummy*) and

⁴¹The results also hold when we define the VC dummy based on the average number of VC firms across all industries (as opposed to only Healthcare).

⁴²The data source for the VC data is Thomson One (formerly known as VentureXpert and as Venture Economics before that). Thomson One is offered by Thomson Financial, a unit of Thomson Reuters. From Thomson One we collect company and VC information. Company information includes company name, location, industry, business description, date founded, and current status (e.g., went public, bankrupt). VC information includes VC firm name, VC type, date founded, investment round, and investment amount.

⁴³<https://www.nih.gov/>.

⁴⁴<http://carnegieclassifications.iu.edu/>. Research universities include those classified as either “R1: Doctoral Universities - Highest Research Activity” or “R2: Doctoral Universities - Higher Research Activity”.

⁴⁵Although the results are robust when we use the indexes themselves, versus creating dummy variables based on them, the interpretation is more straightforward using the dummy variables. Therefore, we report results using *IE1 Dummy* and *IE2 Dummy* instead of the *IE1* and *IE2*.

(*IE2 Dummy*) is 0.63, which suggests that each variable by itself also represents different aspects of the environment.

4 Empirical Results

In this section, we first provide univariate evidence on the relation between innovation and the organization's environment, and then show the results from estimating the triple-difference regression model in Eq.(1). At the end of the section we explore the effect of each component that comprises our indexes on innovation.

4.1 Univariate Results

Table 3 reports the mean number of PMA and 510(k) filings across category-state-year observations for the treatment and control groups, during the pre- and post-NCD periods, for states with more or less favorable innovation environments. Panels A and B report summary statistics for the case when the quality of the innovation environment is measured by *IE1 Dummy* and *IE2 Dummy*, respectively.

Table 3, Panel A, Columns (1) and (2) show that for a category in the treatment group, before NCD approvals, the number of annual average FDA filings is 8.64 in a favorable innovation environment and 1.43 in an unfavorable innovation environment. More important, the difference in means per Eq.(2), reported in Column (3), is positive and significant (7.21 with t -statistic = 15.40) showing that there is more innovation in states that have a more favorable innovation environment. Namely, all numbers reported in Column (3) in Panels A and B of Table 3 are positive and statistically significant. Taken together these results indicate that there is more innovation in states that have a favorable innovation environment.

Column (4) in Table 3 shows the second difference per Eq.(3), i.e., the difference in the average number of PMA and 510(k) filings between states with more or less favorable innovation environments from before to after the event. Notably, all differences in means in Column (4) are negative and significant for both the treatment and control groups, but more so for the control group. At first glance, this is unexpected because we predict that the NCD shock will have a positive effect on innovation. However, this result emphasizes that having a control group is critical in drawing any statistical inferences. In this case, the negative and significant second

difference in means reported in Column (4) shows that there is a general downward trend in innovation on average but less so for the treatment group. The general downward trend in innovation as measured by the number of FDA filings could be a result of stringent regulation through time due to greater complexity of the medical devices;⁴⁶ it could also be the case that the bar for innovation in the medical device industry has risen through time.⁴⁷ In any case, the fact that we have a treatment and a benchmark group controls for any general trends that affect the whole industry. More important, our results document that the downward trend is stronger in states with less favorable environments for innovation. This is consistent with our hypothesis that firms innovate more in more favorable innovation environments. Column (5) formally confirms the statement that the treatment group innovates more after the shock in better environments as evident by the positive and significant third-difference in means per Eq.(4). In the next subsection we perform multivariate tests and formally evaluate the economic significance of our results.

4.2 Regression Results

In this section, we test the triple-difference model (Eq.1) using panel data with category-state-year level observations. The dummy variable, $(NCD\ Category\ Dummy)_k$, in the triple-difference model takes a value of one if a medical device category is in the treatment group and zero if in the control group. The four categories that receive NCDs in our sample period constitute the treatment group. We define the control group in two different ways and report results for both cases. First, we include all medical device categories without NCDs in our sample period in the control group. Second, we identify a matching device category for each treatment category and use the matching category to construct the control group. Table 4 reports results when all medical device categories without NCDs are in the control group, and Table 5 reports results using the one-to-one matched sample.

In Table 4, we define the event period as 1993–1996 and study the difference in product innovation before 1993 versus after 1996. We do that because the four categories in the treatment

⁴⁶See “Do the FDA’s regulations governing medical devices need to be overhauled?,” *The Wall Street Journal*, by Thomas M. Burton, March 23, 2015.

⁴⁷For example, the newest medical device approved by FDA is Abbott Laboratories’ absorbable heart stent called Absorb, “a device cardiologists say represents a significant advance in treatment of coronary artery disease.” “It is a very different technology,” said Gregg Stone, director of cardiovascular research and education at New York-Presbyterian Hospital and a leader of Abbott-sponsored studies that led to approval of the device. “It allows the artery to reacquire its normal shape. It allows the vessel to grow.” *The Wall Street Journal*, “FDA Approves Abbott’s Absorbable Heart Stent,” by Ron Winslow, July 5, 2016.

group received their first NCDs in 1993, 1994, 1995, and 1996, respectively. Thus, the dummy variable, $(Shock\ Time\ Dummy)_{k,t}$, takes a value of zero before 1993 and one after 1996. Columns (1) and (2) report results when the proxy for the quality of the innovation environment is measured by $IE1\ Dummy$ and, Columns (3) and (4) report results when the quality of the innovation environment is measured by $IE2\ Dummy$. Columns (2) and (4) replicate Columns (1) and (3), but include state and year fixed effects. In all models we include state-level time-varying macroeconomic control variables. See Appendix B for detailed variable definitions. The errors are robust and clustered at the device category level.

In all four regression models in Table 4, the coefficient associated with the triple interaction term, $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (IE\ Dummy)_{i,t}$, is positive and significant (t -statistics are 1.98 and 2.06). The parameter estimate for the triple-difference term is 3.86 in Columns (1) and (2) when we use $IE1\ Dummy$ to proxy for the quality of the environment, and 3.58 in Columns (3) and (4) when we use $IE2\ Dummy$ as the proxy. The coefficients on the control variables are as expected. The results show that innovation is positively related to $\log(GDP\ per\ Capita)$ and $\log(Population)$ and negatively related to $Unemployment\ Rate$. These results imply that firms in device categories that experience an increase in product demand are able to respond with more innovation when the environment is more favorable for innovation on the first place.

We now assess the economic significance of our results based on the regression model estimates in Column (1) of Table 4. If we set $(IE\ Dummy)_{i,t}$ to zero while fixing the values of both $(Shock\ Time\ Dummy)_{k,t}$ and $(NCD\ Category\ Dummy)_k$ at one, we obtain a value of -3.22 for the dependent variable, $(Number\ of\ FDA\ Filings)_{k,i,t}$. If we set $(IE\ Dummy)_{i,t}$ to one while still holding the values of both the $(Shock\ Time\ Dummy)_{k,t}$ and $(NCD\ Category\ Dummy)_k$ at one, then the dependent variable is 4.47. The dummy variable, $(IE\ Dummy)_{i,t}$, being zero indicates that the quality of the environment to foster innovation in state i in year t is below the average across all states in year t , and $(IE\ Dummy)_{i,t}$ being one indicates an above average innovation environment. Thus, if state i improves its environment to nurture innovation in year t , i.e., $(IE\ Dummy)_{i,t}$ increases from zero to one, then the number of FDA filings in category k will increase by about eight in state i in year t .⁴⁸ Our results suggest that on average, if a state improves the innovation environment there is an economically

⁴⁸It is estimated as $4.47 - (-3.22) = 7.69$. We have 16,455 FDA filings in total in our sample for 19 categories, 50 states, and 28 years. Thus, on average, there are $16,455/19/50/28 = 0.6$ filings at the category-state-year level.

meaningful, almost eightfold increase in product innovation.

Altogether, the results shows that medical device firms that operate in states with a better innovation environment are more likely to innovate in response to the shift in demand than those firms that operate in states with a poor innovation environment. Although all medical device firms might want to increase their innovation in response to the shift in demand for product innovation, our results imply that firms operating in more nurturing innovation environments are better able to take these opportunities and introduce new or modified products to the market.

Table 5 reports regression results using the one-to-one matched sample, where a matching category is identified for each treatment category. We use a proxy for market share to match the treatment group with an appropriate control as explained in Section 3. For example, Cardiovascular device category received its first NCD in 1993 during our sample period and thus the $(Shock\ Time\ Dummy)_{k,t}$ takes a value of one after 1993 and zero before 1993 for both Cardiovascular and its matched category. The test sample for Table 5 includes four treatment categories and four corresponding matched control categories. In Columns (1) and (2) the $IE\ Dummy$ is $IE1\ Dummy$, and is $IE2\ Dummy$ in Columns (3) and (4). Columns (2) and (4) replicate Columns (1) and (3), but include state and year fixed effects. All models include state-level time-varying control variables. Errors are robust and clustered at the device category level.

We find that the coefficient estimate for the triple-difference variable, $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (IE\ Dummy)_{i,t}$, is positive and significant for all four regression specifications. The coefficient on the triple interaction term is 6.64 in the first two columns and 7.27 in the last two columns, with t -statistics around 3.00. These findings provide further evidence that even after controlling for the market share of the device categories, the quality of the environment to foster innovation is an essential condition for innovation to occur when innovative opportunities arise.

Tables 4 and 5 use only the first NCD events for each medical device category in the treatment group. The four medical device categories in the treatment group receive a total of seven NCDs during our sample period (see Panel A of Table 1). Next, we replicate the tests in Table 5 using all seven NCDs and report the results in Table 6. In this case, the sample includes seven treatment categories and seven corresponding matched categories. Table 6 shows that the coefficient estimate for the triple-difference term is positive and significant for all four

model specifications. The parameter of interest, β_1 in Eq.(1), has point estimates of 4.43 and 4.72 with t -statistics ranging from 3.21 to 3.51. These findings provide strong evidence that firms operating in better innovation environments are more able to take advantage of the new innovative opportunities.

In sum, the empirical results provide strong evidence that support our hypothesis that both the demand-side (positive shocks in demand for new products) and the supply-side (nurturing innovation environment), as well as the interplay between them are essential conditions for fostering innovation.

4.3 The Relative Importance of Each Index Component

We examine the relative importance of the components that comprise index $IE1$ and index $IE2$, and report the results in Tables 7 and 8, respectively. Recall that $IE1$ is constructed for each state using the number of VC firms, the number of NIH grants, and the Carnegie research classification dummy, while $IE2$ is constructed using the dollar amount invested by VC firms, the dollar amount of NIH grants, and the Carnegie research classification dummy. Column (1) of Table 7 includes the $(VC\ Number\ Dummy)_{i,t}$ and the $(NIH\ Number\ Dummy)_{i,t}$, as well as the appropriate second difference terms and the corresponding triple-difference terms. The coefficient on both triple terms in Column (1) are positive and significant indicating that both VC availability and NIH grants are important for innovation.

Column (2) of Table 7 includes the $(VC\ Number\ Dummy)_{i,t}$ and the $(CC\ Number\ Dummy)_{i,t}$, as well as the appropriate second difference terms and the corresponding triple-difference terms. The triple-difference term associated with $(VC\ Number\ Dummy)_{i,t}$ is positive and significant (t -statistic = 3.57) while the triple-difference term associated with $(CC\ Number\ Dummy)_{i,t}$ is not significant (t -statistic = 1.50). These results imply that VC availability is relatively more important for innovation than being close to a research university.

Column (3) of Table 7 includes the $(NIH\ Number\ Dummy)_{i,t}$ and the $(CC\ Number\ Dummy)_{i,t}$, as well as the appropriate second difference terms and the corresponding triple terms. The significant and positive coefficient on $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (NIH\ number\ dummy)_{i,t}$ and the insignificant coefficient on $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (CC\ dummy)_{i,t}$ show that NIH grants are relatively more important for innovation than the proximity to a research university. We acknowledge, however, that a research university has a greater chance of being granted an NIH grant.

Column (4) of Table 7 reports results of a horserace of all index constituents, i.e., the $(VC\ Number\ Dummy)_{i,t}$, the $(NIH\ Number\ Dummy)_{i,t}$ and the $(CC\ Number\ Dummy)_{i,t}$. The results reported in the last column show that the coefficients on $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (VC\ number\ dummy)_{i,t}$ and $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (NIH\ number\ dummy)_{i,t}$ are significant, while the coefficient on $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (CC\ dummy)_{i,t}$ is not significant. This finding suggests that the number of VC firms and the number of NIH grants are relatively more important components of the innovation environment compared to the number of research universities.

Table 8 is constructed following the format of Table 7. Focusing our attention on Column (4) we see that the coefficients on $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (VC\ amount\ dummy)_{i,t}$ and $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (CC\ dummy)_{i,t}$ are significant, but not the coefficient on $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (NIH\ amount\ dummy)_{i,t}$. This finding suggests that the amount of VC dollars invested and the number of research universities are relatively more important components of the innovation environment than the amount of dollars of NIH funding.

Across Tables 7 and 8 we see that each component is important in defining the quality of the environment to foster innovation. Nonetheless, VC availability (both number of VCs as well as VC dollars invested) is by far the most important component. In short, we find that each component contributes to innovation.

5 Robustness Tests

At this point, our measure for innovation is the number of 510(k) and PMA filings. We now test whether our results hold if we measure innovation only by 510(k) filings and by approved 510(k) and PMA filings.⁴⁹ Table 9 shows the results. Columns (1) and (2) use $(IE1\ Dummy)_{i,t}$ and Columns (3) and (4) uses $(IE2\ Dummy)_{i,t}$ as a proxy for the quality of the environment for fostering innovation. Columns (1) and (3) use 510(k) filings and Columns (2) and (4) use only approved filings (510(k) and PMA). The coefficients associated with the triple-difference term are positive and significant in all regression specifications confirming our main result that

⁴⁹ The medical device industry is characterized by small, private firms and thus the PMA filings comprise only about 1% of our sample. For this reason, restricting our sample to only PMA filings or approved PMA filings does not allow us to perform any meaningful statistical analysis.

innovation is greater for the treatment group after the demand shock in states that have better innovation environments.

Next, we restrict the pre-event period to the same length as the post-event period and also vary the pre-event and post-event window from three years before and after the event to seven years before and after. The results are reported in Table 10. Specifically, Table 10 replicates the regression model in Columns (2) and (4) of Table 9 where the proxy for innovation is the approved FDA filings. Columns (1) through (5) of Table 10 report results when the proxy for the quality of the environment to nurture innovation is $(IE1\ Dummy)_{i,t}$, and the pre-event and post-event window is varied from three to seven years before and after the event. The coefficient on the triple-difference term, $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (IE\ Dummy)_{i,t}$, is positive but insignificant in Columns (1) and (2) when the event window is three and four years before and after the NCD events. Notably, the coefficients on the triple-difference term in Columns (3), (4) and (5), when the event-window is five, six, and seven years before and after the NCDs events are positive and significant at the 10% level with corresponding p -values of 0.08 (t -statistic = 1.75), 0.07 (t -statistic = 1.79), and 0.06 (t -statistic = 1.86), respectively. We observe a similar pattern in Columns (6) through (10) where $IE2$ proxies for the quality of the environment to nurture innovation – the significance of the triple-difference term decreases as we shorten the test window to five years or less, the coefficient is still positive. Overall, these results show that it takes time for innovation to take place. According to Fargen et al. (2013), “It has been estimated that the time from concept to market for medical devices is 3-7 years, although no concrete data could be identified in the literature regarding time or cost.” It should be noted that time to market also depends on complexity and technological invention.

Next, we construct the dummy variable, $(IE\ Dummy)_{i,t}$, based on either $IE1$ or $IE2$, in different ways and find that our results are robust to all the transformations being tested. First, the dummy variable, $(IE\ Dummy)_{i,t}$, takes a value of one in state i in year t if it is more than the median across states in year t , and takes a value of zero otherwise. Then, $(IE\ Dummy)_{i,t}$ takes a value of one in the top quintile of the sample across states in year t , and takes a value of zero if it is in the bottom quintile. The results of these two tests are not reported for brevity, but are available upon request.

6 Conclusion

Traditionally, research and policies have been primarily concerned with factors on the supply side, such as access to financing, types of financing, publicly funded research programs, organization design, and the amount invested in Research and Development (R&D). However, focusing on supply-side policies alone is not sufficient for utilization of innovation. Demand-driven policies foster innovation by directly increasing the demand for the consumption of innovation (Edler and Yeow, 2016). Demand-driven policies could include government incentives either to the firm or the end user (Edler and Georghiou, 2007; Edler and Yeow, 2016). Innovation is presumably dependent upon a mixture of supply-side factors, pertaining to firms that strive to achieve and keep their competitive advantage, and demand-side factors, pertaining to market end users that creates innovative opportunities for firms (Coombs et al., 1987; Martin, 1994). We provide empirical evidence that focusing on supply-side policies alone is not sufficient for utilization of innovation and that both demand- and supply-side factors are crucial ingredients for the innovation process.

An advantage of our study is that we are able to precisely observe a shift in product demand which is an arrival of new investment opportunities from the firm’s perspective. We identify a set of shocks that increase the demand for a product ultimately innovation. Conditional on these positive shifts, we explore the role of the firm’s environment in fostering innovation and conclude that it is essential for firms to appropriately respond to and take advantage of the positive shift in demand for innovation. The main contribution of our paper is that we empirically show that there is a crucial mix of ingredients that are needed for innovation to occur – innovation is stimulated in the presence of positive shocks to product demand primarily when the environment is conducive for innovation.

We study the link between the environment and innovation for private firms in the medical device industry. The experiment exploits Medicare national coverage reimbursement approvals of medical devices. The national approvals represent positive exogenous shocks to the demand for the devices that receive the approvals. This exogenous shock allows us to examine the change in innovation as a function of varying levels of quality of the environment to nurture innovation. We find that firms operating in more favorable innovation environments are more able to take advantage of the increase in product demand by increasing innovation.

Our measure of innovation is the number of FDA filings (both 510(k) and PMA) in a medical device category. This measure captures successful product innovation. We employ

a difference-in-difference-in-difference testing approach where our control group is comprised of medical device categories that do not receive Medicare national coverage reimbursement approval during our sample period. We find that private medical device firms in states with better innovation environments have significantly more FDA filings in response to a positive shock to demand for new products. This result, being robust to different regression specifications and control variables, supports our argument that both the demand and supply sides of innovation play essential roles in stimulating and nurturing innovative activities.

Appendix A

Medicare

The following information regarding Medicare is from <https://www.medicare.gov/> and Phillips and Sertsios (2016). Medicare is composed of four parts: Part A to D. The program started in 1965 and offered only Part A. Part A covers hospital and inpatient services. Part B covers outpatient services, which include durable medical device expenses. Part C allows individuals to receive Medicare benefits through a private plan. Part D, which entered into effect in 2006, provides prescription drug coverage. Medicare pays for services by reimbursing health providers. Typically, Medicare sets the prospective payment amounts that health providers will receive for services provided to Medicare enrollees in advance. After service is provided, Medicare pays the health providers the predetermined rates minus the beneficiaries' cost-sharing liabilities. The cost-sharing liabilities of Medicare Part B consist of a small deductible and a 20% co-payment. About 50% of Medicare beneficiaries complement their coverage with other insurances, such as Medigap or health insurance programs provided by their employers. Medicare provides nearly universal public health insurance for people 65 years or older and covers about 97% of the elderly population in the U.S. In 2010, the program spending was \$524 billion, which represents approximately 20% of total health expenditures and 3.5% of the U.S. Gross Domestic Product.

CMS Coverage Decisions

Neumann et al. (2005) provide a historical overview of the CMS coverage decisions. Here we summarize the most important facts. Social Security Amendments, Sec. 1862[a][1], 1965, established broad categories of Medicare coverage for hospital and physician services but prohibited payment for expenses incurred for “items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Neumann et al., 2005). “Reasonable and necessary” intends to reflect the prevailing views of the physician community. In the 1960s, most coverage decisions had been made by Medicare’s local contractors – the state- or region-wide health insurers (carriers and fiscal intermediaries) who pay claims for the program (p.244, *Ibid.*). Consequently, complaints about opaqueness of the coverage process grew and, in 1989, the Health Care Financing Administration (HCFA) (now the CMS) published a proposed regulation stating that

for purposes of coverage, a technology would have to be accepted by the medical community, be safe, effective, non-investigational, and appropriate (*Ibid.*, p.244). In the late 1990s, the CMS established the Medicare Coverage Advisory Committee (MCAC) to provide external assistance in judging whether evidence existed to establish the safety, efficacy, and clinical benefit of a medical service or product for NCDs (*Ibid.*). The MCAC only offers advice; the CMS retains control over final decisions; and only those NCDs deemed in need of additional expertise go to MCAC (p.244, *Ibid.*). The CMS relies on its own medical experts and occasionally requests a formal health technology assessment from the Agency for Healthcare Research and Quality (*Ibid.*).

Appendix B

Variable Definitions

- *Number of FDA Filings* - the number of FDA filings in category k , state i , and year t .
- *NCD Category Dummy* - takes a value of one if a medical device category is in the treatment group and zero if it is in the control group.
- *Shock Time Dummy* - takes a value of zero if it is before an NCD event and one if after.
- *VC Number Dummy* - takes a value of one if the number of healthcare VC firms in state i year t is above the average number of healthcare VC firms across all states in year t .
- *VC Amount Dummy* - takes a value of one if the dollar amount of healthcare related VC invested in state i year t is above the average dollar amount of healthcare related VC invested across all states in year t .
- *NIH Number Dummy* - takes a value of one if the number of NIH grants in state i year t is above the average number of NIH grants across all states in year t .
- *NIH Amount Dummy* - takes a value of one if the dollar amount of NIH funding in state i year t is above the average dollar amount of NIH grant across all states in year t .
- *CC Dummy* - takes a value of one if the number of research universities in state i in year t is above the average number of research universities across all states in year t . Research

universities refer to those classified as either “R1: Doctoral Universities - Highest Research Activity” or “R2: Doctoral Universities - Higher Research Activity” by the Carnegie Classification of Institutions of Higher Education.

- *IE1* index and *IE1 Dummy* - *IE1* is the sum of *VC Number Dummy*, *NIH Number Dummy*, and *CC Cummy*. *IE1 Dummy* takes a value of one if *IE1* of state *i* in year *t* is above the average index across all states in year *t*.
- *IE2* index and *IE2 Dummy* - *IE2* is the sum of *VC Amount Dummy*, *NIH Amount Dummy*, and *CC Dummy*. *IE2 Dummy* takes a value of one if *IE2* of state *i* in year *t* is above the average index across all states in year *t*.
- $\log(\text{GDP per capita})$ - the logarithmic transformation of the state-level GDP per capita in year *t*.
- *Unemploymentrate* - state-level unemployment rate in year *t*.
- $\log(\text{Population})$ - the logarithmic transformation of state-level population in millions.

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Table 1. Number of FDA Filings Before and After NCDs.

This table reports the year of the first National Coverage Determination (NCD) approval and the year of any subsequent new NCD approvals (i.e., not extensions of previous NCDs in terms of time or coverage) in the sample period 1987–2014. The table also reports the total number of FDA filings, i.e., total number of 510(k) and PMA filings that are not necessarily approved, from the beginning of our sample period to the NCD year and the number of FDA filings after the NCD year until the end of the sample period.

| | Cardiovascular | Gastroenterology Urology | | | Neurology | | Orthopedic |
|----------------------------------|----------------|-----------------------------|-------|-------|-----------|-------|------------|
| Year of NCD | 1993 | 1994 | 2001 | 2002 | 1995 | 2003 | 1996 |
| Number of FDA Filings before NCD | 1,578 | 1,377 | 2,251 | 2,363 | 1,299 | 2,356 | 1,634 |
| Number of FDA Filings after NCD | 3,662 | 1,765 | 922 | 825 | 1,975 | 966 | 4,176 |

Table 2. Correlations of the Components Used to Construct the Two Innovation Environment Indexes (*IE1* and *IE2*).

This table shows the association between the components of the two innovation environment indexes. Panel A reports the association between the components of the first index (*IE1*) and Panel B reports the association between the components of the second index (*IE2*). *IE1* is constructed based on (i) the number of VC firms located in a state, (ii) the number of grants from the National Institutes of Health (NIH) in a state, and (iii) the number of universities in a state that are classified as research universities by the Carnegie Classification of Institutions of Higher Education. We first construct three dummy variables to represent these three dimensions. *VC Number Dummy* takes a value of one if the number of VC firms in state *i* in year *t* is above the average number of VC firms across all states in year *t*. *NIH Dummy* takes a value of one if the number of NIH grants in state *i* in year *t* is above the average number of NIH grants across all states in year *t*. *CC Dummy* takes the value of one if the number of research universities in state *i* in year *t* is above the average number of research universities across all states in year *t*. Research universities refer to those classified as either “R1: Doctoral Universities - Highest Research Activity” or “R2: Doctoral Universities - Higher Research Activity” by the Carnegie Classification of Institutions of Higher Education. Next we define the innovation environment index as the sum of the three dummy variables. *IE1 Dummy* takes a value of one if the innovation environment index of state *i* in year *t* is above the average index across all states in year *t*. *IE2 Dummy* is constructed in a similar way with the difference being that instead of the number of VC firms located in a state we use the dollar amount of VC invested in a state, and instead of the number of NIH grants we use the amount of the grant in dollars. For detailed variable definitions see Appendix B.

| Panel A: Correlations of the components used to construct <i>IE1</i> | | | |
|----------------------------------------------------------------------|------------------------|-------------------------|-----------------|
| | <i>VC Number Dummy</i> | <i>NIH Number Dummy</i> | <i>CC Dummy</i> |
| <i>VC Number Dummy</i> | 1 | 0.35 | 0.29 |
| <i>NIH Number Dummy</i> | 0.35 | 1 | 0.59 |
| <i>CC Dummy</i> | 0.29 | 0.59 | 1 |

| Panel B: Correlations of the components used to construct <i>IE2</i> | | | |
|----------------------------------------------------------------------|------------------------|-------------------------|-----------------|
| | <i>VC Amount Dummy</i> | <i>NIH Amount Dummy</i> | <i>CC Dummy</i> |
| <i>VC Amount Dummy</i> | 1 | 0.31 | 0.18 |
| <i>NIH Amount Dummy</i> | 0.31 | 1 | 0.47 |
| <i>CC Dummy</i> | 0.18 | 0.47 | 1 |

| Panel C: Correlation between <i>IE1 Dummy</i> and <i>IE2 Dummy</i> | | |
|--------------------------------------------------------------------|------------------|------------------|
| | <i>IE1 Dummy</i> | <i>IE2 Dummy</i> |
| <i>IE1 Dummy</i> | 1 | 0.63 |
| <i>IE2 Dummy</i> | 0.63 | 1 |

Table 3. Univariate Evidence on the Relation Between Innovation, Demand Shocks and Environment.

This table reports the average number of PMA and 510(k) filings across 22,800 category-state-year observations for the treatment and control groups during the pre- and post-event periods for states with more or less favorable environments for fostering innovation. The four categories that received their first NCDs in our sample period construct the treatment group and medical device categories without NCDs in our sample period construct the control group. The four categories in the treatment group received their first NCD in 1993, 1994, 1995, and 1996, respectively. We define the event period as 1993–1996 and study the difference in innovation before 1993 versus after 1996. Panel A and Panel B report the summary statistics for the case when the proxy for the quality of the environment for nurturing innovation is *IE1 Dummy* and *IE2 Dummy*, respectively. *t*-statistics are in parentheses. For detailed variable definitions see Appendix B.

| | | (1) | (2) | (3) | (4) | (5) |
|--------------------------------------------------------------|-----------------------------------|-----------------------------|----------------------------|-----------------|----------------------------|------------------------------------|
| | | Better IE (IE dummy = 1) | Worse IE (IE dummy = 0) | 1st Diff | 2nd Diff (Diff-in-Diff) | 3rd Diff (Diff-in-Diff-in-Diff) |
| Panel A: The innovation environment is proxied by <i>IE1</i> | | | | | | |
| Treatment Group (NCD category dummy = 1) | Pre-event (shock time dummy = 0) | 8.64 | 1.43 | 7.21 (15.40) | | |
| | Post-event (shock time dummy = 1) | 7.33 | 1.17 | 6.16 (28.42) | -1.05 (-2.04) | |
| Control Group (NCD category dummy = 0) | Pre-event (shock time dummy = 0) | 9.44 | 1.15 | 8.29 (28.54) | | |
| | Post-event (shock time dummy = 1) | 3.95 | 0.58 | 3.37 (40.10) | -4.92 (-16.27) | 3.87 (6.47) |
| Panel B: The innovation environment is proxied by <i>IE2</i> | | | | | | |
| Treatment Group (NCD category dummy = 1) | Pre-event (shock time dummy = 0) | 9.76 | 2.19 | 7.57 (13.05) | | |
| | Post-event (shock time dummy = 1) | 7.65 | 1.80 | 5.85 (22.72) | -1.72 (-2.71) | |
| Control Group (NCD category dummy = 0) | Pre-event (shock time dummy = 0) | 11.05 | 1.96 | 9.09 (25.48) | | |
| | Post-event (shock time dummy = 1) | 4.60 | 0.81 | 3.79 (39.15) | -5.30 (-14.34) | 3.58 (4.87) |

**Table 4. Triple-Difference Regression Model:
All Non-NCD Medical Categories in the Control Group, First NCDs.**

This table reports regression results of four specifications of the triple-difference model (Eq.1). The dependent variable, $(Number\ of\ FDA\ Filings)_{i,t,k}$, counts the number of FDA filings by category k in state i and in year t . The dependent variable captures innovation at the category-state-year level. $(NCD\ Category\ Dummy)_k$ takes a value of one if a medical device category is in the treatment group and zero if in the control group. The four categories that received NCDs in our sample period construct the treatment group, and we include all medical device categories without NCDs in our sample period in the control group. The four categories in the treatment group received their first NCD in 1993, 1994, 1995, and 1996, respectively. We define the event period as 1993–1996 and study the difference in innovation before 1993 versus after 1996. $(Shock\ Time\ Dummy)_{k,t}$ takes a value of zero before 1993 and one after 1996. In Columns (1) and (2) the $(IE\ Dummy)_{i,t}$ is $(IE1\ Dummy)_{i,t}$, while in Columns (3) and (4) it is $(IE2\ Dummy)_{i,t}$. Columns (2) and (4) replicate Columns (1) and (3), but include state and year fixed effects. In all models we include state-level $log(GDP\ per\ Capita)$, $Unemployment\ Rate$, and $log(Population)$ as time-varying control variables. Errors are robust and clustered at the device category level. For detailed variable definitions see Appendix B. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) |
|-------------------------------------------------------------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (IE\ Dummy)$ | 3.86 (2.06) | 3.86 (2.06) | 3.58 (1.98) | 3.58 (1.98) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | 0.32 (1.76) | 0.32 (1.75) | 0.76 (1.83) | 0.76 (1.83) |
| $(Shock\ Time\ Dummy) \times (IE\ Dummy)$ | -4.80 (-5.79) | -4.91 (-5.79) | -5.04 (-5.45) | -5.12 (-5.39) |
| $(NCD\ Category\ Dummy) \times (IE\ Dummy)$ | -1.08 (-0.67) | -1.08 (-0.66) | -1.52 (-0.69) | -1.52 (-0.69) |
| $(Shock\ Time\ Dummy)$ | -2.65 (-5.89) | -1.86 (-3.38) | -3.26 (-6.40) | -2.89 (-4.61) |
| $(NCD\ Category\ Dummy)$ | 0.28 (1.16) | 0.28 (1.15) | 0.23 (0.61) | 0.23 (0.61) |
| $(IE\ Dummy)$ | 4.90 (4.60) | 3.87 (4.36) | 5.62 (4.23) | 3.36 (3.72) |
| $log(GDP\ per\ Capita)$ | 3.13 (4.94) | 1.88 (3.56) | 3.26 (5.27) | 2.22 (3.88) |
| $Unemployment\ Rate$ | -0.83 (-3.38) | -1.41 (-3.29) | -1.08 (-4.00) | -1.57 (-3.58) |
| $log(Population)$ | 1.88 (6.48) | 1.91 (3.37) | 1.96 (6.85) | 1.58 (2.90) |
| State FE | No | Yes | No | Yes |
| Year FE | No | Yes | No | Yes |
| Adj R^2 | 0.2078 | 0.4177 | 0.2049 | 0.4115 |
| Number of Observations | 22, 800 | 22, 800 | 22, 800 | 22, 800 |

**Table 5. Triple-Difference Regression Model:
One-to-One Matched Sample, First NCDs.**

This table reports regression results of four specifications of the triple-difference model (Eq.1). The dependent variable, $(Number\ of\ FDA\ Filings)_{i,t,k}$, counts the number of FDA filings by category k in state i and in year t . The dependent variable captures innovation at the category-state-year level. $(NCD\ Category\ Dummy)_k$ takes a value of one if a medical device category is in the treatment group and zero if in the control group. The four categories that received NCDs in our sample period construct the treatment group. We create a matched control group. For each category in the treatment group, the matched category is determined as the category that has a similar market share prior to the event. For each pair of treatment and control categories, the dummy variable, $(Shock\ Time\ Dummy)_{k,t}$, takes a value of one if it is after an NCD and takes a value of zero if it is before. In Columns (1) and (2) the $(IE\ Dummy)_{i,t}$ is $(IE1\ Dummy)_{i,t}$, while in Columns (3) and (4) it is $(IE2\ Dummy)_{i,t}$. Columns (2) and (4) replicate Columns (1) and (3), but include state and year fixed effects. In all models we include state-level $\log(GDP\ per\ Capita)$, $Unemployment\ Rate$, and $\log(Population)$ as time-varying control variables. For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) |
|-----------------------------------------------------------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times IE\ Dummy$ | 6.64 (3.01) | 6.64 (3.00) | 7.27 (3.09) | 7.27 (3.07) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | 0.41 (1.25) | 0.41 (1.24) | 1.15 (1.89) | 1.15 (1.90) |
| $(Shock\ Time\ Dummy) \times IE\ Dummy$ | -7.61 (-4.48) | -7.72 (-4.50) | -8.37 (-4.63) | -8.24 (-4.31) |
| $(NCD\ Category\ Dummy) \times IE\ Dummy$ | -7.86 (-3.01) | -7.86 (-2.99) | -9.95 (-3.25) | -9.95 (-3.21) |
| $(Shock\ Time\ Dummy)$ | -2.88 (-6.84) | 1.78 (0.79) | -3.87 (-6.20) | 0.83 (0.37) |
| $(NCD\ Category\ Dummy)$ | -0.60 (-1.65) | -0.60 (-1.83) | -1.18 (-1.93) | -1.18 (-1.97) |
| $(IE\ Dummy)$ | 9.98 (4.02) | 7.72 (3.59) | 11.96 (4.80) | 7.96 (4.05) |
| $\log(GDP\ per\ Capita)$ | 3.79 (5.22) | 2.68 (2.34) | 4.01 (5.26) | 2.95 (2.60) |
| $Unemployment\ Rate$ | -0.21 (-0.40) | -1.19 (-1.40) | -0.68 (-1.14) | -1.35 (-1.54) |
| $\log(Population)$ | 2.90 (8.46) | 3.83 (5.72) | 3.05 (8.08) | 3.44 (5.06) |
| State FE | No | Yes | No | Yes |
| Year FE | No | Yes | No | Yes |
| Adj R^2 | 0.2845 | 0.5648 | 0.2896 | 0.5649 |
| Number of Observations | 10,800 | 10,800 | 10,800 | 10,800 |

**Table 6. Triple-Difference Regression Model:
All NCDs.**

This table reports regression results of four specifications of the triple-difference model (Eq.1). The dependent variable, $(Number\ of\ FDA\ Filings)_{i,t,k}$, counts the number of FDA filings by category k in state i and in year t . The dependent variable captures innovation at the category-state-year level. $(NCD\ Category\ Dummy)_k$ takes a value of one if a medical device category is in the treatment group and zero if in the control group. The four categories that comprise the treatment group received a total of seven NCDs in our sample period. In the current table we use all seven NCDs received by these categories to construct the treatment group. We create a one-to-one matched control group. For each category in the treatment group, the matched category is determined as the category that has a similar market share prior to the event. For each pair of treatment and control categories, the dummy variable, $(Shock\ Time\ Dummy)_{k,t}$, takes a value of one if it is after an NCD and takes a value of zero if it is before. In Columns (1) and (2) the $(IE\ Dummy)_{i,t}$ is $IE1$, while in Columns (3) and (4) it is $IE2$. Columns (2) and (4) replicate Columns (1) and (3), but include state and year fixed effects. In all models we include state-level $\log(GDP\ per\ Capita)$, $Unemployment\ Rate$, and $\log(Population)$ as time-varying control variables. For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) |
|-------------------------------------------------------------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (IE\ Dummy)$ | 4.43 (3.22) | 4.43 (3.21) | 4.72 (3.51) | 4.72 (3.50) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | 0.10 (0.47) | 0.10 (0.43) | 0.63 (1.64) | 0.63 (1.62) |
| $(Shock\ Time\ Dummy) \times (IE\ Dummy)$ | -5.53 (-5.48) | -5.55 (-5.45) | -5.91 (-5.34) | -5.65 (-5.23) |
| $(NCD\ Category\ Dummy) \times (IE\ Dummy)$ | -5.58 (-3.49) | -5.58 (-3.49) | -7.00 (-3.41) | -7.00 (-3.40) |
| $(Shock\ Time\ Dummy)$ | -1.12 (-2.59) | 1.83 (3.13) | -1.89 (-3.91) | 1.17 (1.88) |
| $(NCD\ Category\ Dummy)$ | -0.23 (-0.77) | -0.23 (-1.16) | -0.65 (-1.46) | -0.65 (-2.15) |
| $(IE\ Dummy)$ | 7.99 (5.68) | 5.63 (4.62) | 9.15 (5.17) | 4.91 (3.20) |
| $\log(GDP\ per\ Capita)$ | 1.56 (2.21) | 3.16 (4.07) | 1.82 (2.75) | 3.53 (4.29) |
| $Unemployment\ Rate$ | 0.95 (2.47) | -0.86 (-1.46) | 0.56 (1.32) | -0.95 (-1.54) |
| $\log(Population)$ | 2.37 (8.86) | 3.68 (6.46) | 2.61 (9.93) | 3.51 (7.05) |
| State FE | No | Yes | No | Yes |
| Year FE | No | Yes | No | Yes |
| Adj R^2 | 0.258 | 0.5342 | 0.2598 | 0.5334 |
| Number of Observations | 18,900 | 18,900 | 18,900 | 18,900 |

Table 7. The Relative Importance of Each Component in $IE1$: Horse Race of Components.

This table reports regression results of four specifications of the triple-difference model (Eq.1). The dependent variable, $(Number\ of\ FDA\ Filings)_{i,t,k}$, counts the number of FDA filings by category k in state i and in year t . The dependent variable captures innovation at the category-state-year level. The base regression model is similar to the one reported in Column (2) of Table 4. In this table, instead of using $(IE1\ Dummy)_{i,t}$ as a measure of the quality of the environment to foster innovation, we use its components $(VC\ Number\ Dummy)_{i,t}$, $(NIH\ Number\ Dummy)_{i,t}$, and $(CC\ Dummy)_{i,t}$. For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) |
|----------------------------------------------------------------------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (VC\ Number\ Dummy)$ | 2.21 (3.21) | 2.53 (3.57) | | 2.03 (3.52) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (NIH\ Number\ Dummy)$ | 2.77 (1.89) | | 2.39 (2.32) | 1.91 (1.98) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (CC\ Dummy)$ | | 2.52 (1.50) | 1.77 (1.23) | 1.51 (1.05) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | 0.12 (0.76) | 0.09 (0.37) | -0.05 (-0.29) | -0.11 (-0.54) |
| $(Shock\ Time\ Dummy) \times (VC\ Number\ Dummy)$ | -5.29 (-8.48) | -5.55 (-8.01) | | -5.07 (-8.60) |
| $(Shock\ Time\ Dummy) \times (NIH\ Number\ Dummy)$ | -2.93 (-4.38) | | -2.81 (-4.35) | -2.06 (-3.55) |
| $(Shock\ Time\ Dummy) \times (CC\ Dummy)$ | | -2.68 (-4.55) | -2.16 (-4.51) | -1.48 (-3.32) |
| $(NCD\ Category\ Dummy) \times (VC\ Number\ Dummy)$ | 0.10 (0.06) | 0.14 (0.08) | | 0.20 (0.12) |
| $(NCD\ Category\ Dummy) \times (NIH\ Number\ Dummy)$ | -0.89 (-0.70) | | -0.28 (-0.23) | -0.31 (-0.31) |
| $(NCD\ Category\ Dummy) \times (CC\ Dummy)$ | | -1.21 (-1.12) | -1.03 (-1.35) | -1.04 (-1.51) |
| $(Shock\ Time\ Dummy)$ | -2.42 (-3.86) | -2.06 (-3.65) | -2.32 (-4.00) | -1.99 (-3.59) |
| $(NCD\ Category\ Dummy)$ | 0.25 (2.00) | 0.38 (2.09) | 0.42 (2.54) | 0.41 (2.61) |
| $(VC\ Number\ Dummy)$ | 4.05 (6.07) | 3.95 (5.77) | | 3.86 (6.10) |
| $(NIH\ Number\ Dummy)$ | 2.49 (3.15) | | 2.56 (3.17) | 1.84 (2.64) |
| $(CC\ Dummy)$ | | 1.13 (2.48) | 0.73 (1.91) | 0.64 (1.76) |
| $\log(GDP\ per\ Capita)$ | 3.25 (4.50) | 2.71 (4.66) | 2.97 (4.66) | 2.87 (4.68) |
| $Unemployment\ Rate$ | -0.95 (-2.49) | -1.38 (-3.11) | -1.26 (-3.07) | -1.13 (-2.79) |
| $\log(Population)$ | 1.83 (3.28) | 1.73 (3.27) | 2.31 (3.95) | 1.73 (3.28) |
| State FE | Yes | Yes | Yes | Yes |
| Year FE | Yes | Yes | Yes | Yes |
| Adj R^2 | 0.4271 | 0.4255 | 0.4164 | 0.4281 |
| Number of Observations | 22,800 | 22,800 | 22,800 | 22,800 |

Table 8. The Relative Importance of Each Component in $IE2$: Horse Race of Components.

This table reports regression results of four specifications of the triple-difference model (Eq.1). The dependent variable, $(Number\ of\ FDA\ Filings)_{i,t,k}$, counts the number of FDA filings by category k in state i and in year t . The dependent variable captures innovation at the category-state-year level. The base regression model is similar to the one reported in Column (4) of Table 4. In this table, instead of using $(IE2\ Dummy)_{i,t}$ as a measure of the quality of the environment to foster innovation, we use its components $(VC\ Amount\ Dummy)_{i,t}$, $(NIH\ Amount\ Dummy)_{i,t}$, and $(CC\ Dummy)_{i,t}$. For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) |
|----------------------------------------------------------------------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (VC\ Amount\ Dummy)$ | 3.29 (4.53) | 3.96 (4.84) | | 3.07 (4.33) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (NIH\ Amount\ Dummy)$ | 2.81 (1.54) | | 2.09 (1.57) | 1.70 (1.21) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) \times (CC\ Dummy)$ | | 2.79 (1.62) | 2.27 (2.04) | 2.16 (1.96) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | 0.26 (0.98) | 0.11 (0.53) | -0.13 (-0.48) | -0.16 (-0.59) |
| $(Shock\ Time\ Dummy) \times (VC\ Amount\ Dummy)$ | -5.05 (-4.62) | -5.30 (-4.86) | | -4.74 (-4.51) |
| $(Shock\ Time\ Dummy) \times (NIH\ Amount\ Dummy)$ | -2.87 (-5.32) | | -2.14 (-4.05) | -1.57 (-3.24) |
| $(Shock\ Time\ Dummy) \times (CC\ Dummy)$ | | -3.37 (-5.25) | -2.80 (-4.28) | -2.60 (-4.13) |
| $(NCD\ Category\ Dummy) \times (VC\ Amount\ Dummy)$ | -1.72 (-0.92) | -1.57 (-0.76) | | -1.59 (-0.87) |
| $(NCD\ Category\ Dummy) \times (NIH\ Amount\ Dummy)$ | -0.55 (-0.35) | | -0.02 (-0.02) | 0.10 (0.07) |
| $(NCD\ Category\ Dummy) \times (CC\ Dummy)$ | | -1.05 (-0.90) | -1.17 (-1.47) | -1.11 (-1.45) |
| $(Shock\ Time\ Dummy)$ | -3.72 (-4.85) | -2.71 (-4.32) | -2.42 (-3.92) | -2.59 (-4.12) |
| $(NCD\ Category\ Dummy)$ | 0.25 (0.71) | 0.44 (1.83) | 0.39 (1.44) | 0.43 (1.59) |
| $(VC\ Amount\ Dummy)$ | 3.09 (2.80) | 2.99 (2.72) | | 2.84 (2.68) |
| $(NIH\ Amount\ Dummy)$ | 1.82 (3.70) | | 1.32 (2.44) | 0.64 (1.34) |
| $(CC\ Dummy)$ | | 1.02 (2.30) | 0.64 (1.53) | 0.47 (1.21) |
| $\log(GDP\ per\ Capita)$ | 4.04 (4.71) | 3.28 (4.68) | 2.81 (4.63) | 3.20 (4.69) |
| $Unemployment\ Rate$ | -0.84 (-2.08) | -1.42 (-3.10) | -1.33 (-2.90) | -1.21 (-2.64) |
| $\log(Population)$ | 1.95 (2.92) | 2.29 (3.58) | 1.78 (2.79) | 1.89 (2.75) |
| State FE | Yes | Yes | Yes | Yes |
| Year FE | Yes | Yes | Yes | Yes |
| Adj R^2 | 0.4142 | 0.4162 | 0.4153 | 0.4187 |
| Number of Observations | 22,800 | 22,800 | 22,800 | 22,800 |

Table 9. Robustness Tests.

This table reports robustness tests based on the regression models in Columns (2) and (4) of Table 4. In the current table Columns (1) and (2) use $(IE1\ Dummy)_{i,t}$ and Columns (3) and (4) use $(IE2\ Dummy)_{i,t}$ as a proxy for the quality of the environment for fostering innovation. Columns (1) and (3) use only 510(k) filings as a proxy for innovation and Columns (2) and (4) use only approved FDA filings, i.e, cleared 510(k) filings and approved PMAs. For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) |
|--------------------------------------------------------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) * (IE\ Dummy)$ | 3.75 (2.00) | 3.96 (2.04) | 3.44 (1.88) | 3.59 (1.97) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | 0.28 (1.55) | 0.38 (1.70) | 0.72 (1.72) | 0.85 (1.77) |
| $(Shock\ Time\ Dummy) \times (IE\ Dummy)$ | -4.87 (-5.78) | -4.77 (-5.99) | -5.06 (-5.36) | -4.94 (-5.74) |
| $(NCD\ Category\ Dummy) \times (IE\ Dummy)$ | -1.05 (-0.65) | -1.29 (-0.82) | -1.49 (-0.69) | -1.63 (-0.75) |
| $(Shock\ Time\ Dummy)$ | -1.91 (-3.38) | -1.78 (-3.57) | -2.93 (-4.58) | -2.78 (-4.84) |
| $(NCD\ Category\ Dummy)$ | 0.29 (1.21) | 0.18 (0.81) | 0.24 (0.66) | 0.09 (0.27) |
| $(IE\ Dummy)$ | 3.85 (4.40) | 3.77 (4.46) | 3.33 (3.71) | 3.24 (3.86) |
| $\log(GDP\ per\ Capita)$ | 1.87 (3.42) | 1.80 (3.74) | 2.20 (3.77) | 2.13 (3.98) |
| $Unemployment\ Rate$ | -1.39 (-3.28) | -1.44 (-3.35) | -1.56 (-3.57) | -1.60 (-3.62) |
| $\log(Population)$ | 1.90 (3.39) | 1.84 (3.29) | 1.57 (2.92) | 1.52 (2.82) |
| State FE | Yes | Yes | Yes | Yes |
| Year FE | Yes | Yes | Yes | Yes |
| Adj R^2 | 0.4110 | 0.4163 | 0.4047 | 0.4102 |
| Number of Observations | 22,800 | 22,800 | 22,800 | 22,800 |

Table 10. Short-Term Tests.

This table reports regression results of the triple-difference model (Eq.1) using event windows of varying lengths. The table replicates the regression model in Columns (2) and (4) of Table 4. Columns (1) through (5) report results when the proxy for the quality of the environment to nurture innovation is $(IE1 Dummy)_{i,t}$ and the pre-event and post-event window varies from three years before and after the event to seven years before and after the event. Similarly, Columns (6) through (10) report results when the proxy for the quality of the environment to nurture innovation is $(IE2 Dummy)_{i,t}$, and the pre-event and post-event window varies from three years before and after the event to seven years before and after the event. For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. t -statistics are in parentheses.

| | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) | (10) |
|--------------------------------------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy) * (IE\ Dummy)$ | 1.72 (0.96) | 2.85 (1.59) | 3.10 (1.75) | 3.04 (1.79) | 3.25 (1.86) | 1.23 (0.74) | 2.38 (1.44) | 2.42 (1.45) | 2.30 (1.46) | 2.59 (1.71) |
| $(Shock\ Time\ Dummy) \times (NCD\ Category\ Dummy)$ | -0.20 (-1.25) | -0.02 (-0.16) | 0.08 (0.63) | 0.10 (0.63) | 0.17 (1.16) | 0.07 (0.29) | 0.37 (1.33) | 0.54 (1.81) | 0.58 (1.82) | 0.66 (1.89) |
| $(Shock\ Time\ Dummy) \times (IE\ Dummy)$ | -2.87 (-4.13) | -3.89 (-4.36) | -3.94 (-5.08) | -3.80 (-5.45) | -3.90 (-5.63) | -3.00 (-2.70) | -4.07 (-3.36) | -4.20 (-4.41) | -3.81 (-4.85) | -3.86 (-5.15) |
| $(NCD\ Category\ Dummy) \times (IE\ Dummy)$ | -0.79 (-0.52) | -1.61 (-0.95) | -1.63 (-0.99) | -1.29 (-0.82) | -1.29 (-0.82) | -1.30 (-0.58) | -2.10 (-0.89) | -2.00 (-0.87) | -1.63 (-0.75) | -1.63 (-0.75) |
| $(Shock\ Time\ Dummy)$ | -0.91 (-1.52) | -1.10 (-2.33) | -1.55 (-2.68) | -1.89 (-3.38) | -2.31 (-4.44) | -1.44 (-2.13) | -1.91 (-3.52) | -2.41 (-4.29) | -2.48 (-4.87) | -2.93 (-6.14) |
| $(NCD\ Category\ Dummy)$ | 0.36 (1.37) | 0.21 (0.79) | 0.18 (0.71) | 0.18 (0.81) | 0.18 (0.81) | 0.35 (1.05) | 0.11 (0.31) | 0.07 (0.18) | 0.09 (0.27) | 0.09 (0.27) |
| $(IE\ Dummy)$ | 2.13 (3.06) | 3.03 (3.88) | 3.24 (4.25) | 2.76 (3.79) | 2.89 (3.93) | 1.78 (2.04) | 2.53 (2.58) | 2.68 (3.09) | 2.21 (3.11) | 2.32 (3.23) |
| $\log(GDP\ per\ Capita)$ | 0.22 (0.14) | -1.49 (-1.35) | 1.37 (0.86) | 2.83 (1.71) | 3.19 (2.21) | 1.62 (0.87) | 0.20 (0.18) | 2.59 (1.73) | 3.21 (2.06) | 3.68 (2.81) |
| $Unemployment\ Rate$ | -0.97 (-0.81) | -3.12 (-1.88) | -2.13 (-2.37) | -1.28 (-1.98) | -1.25 (-2.04) | -0.19 (-0.15) | -2.42 (-1.48) | -2.00 (-2.24) | -1.32 (-2.10) | -1.31 (-2.19) |
| $\log(Population)$ | 3.66 (3.51) | 3.52 (2.86) | 2.54 (1.98) | 2.53 (2.23) | 2.40 (2.26) | 3.23 (2.51) | 2.85 (2.27) | 1.97 (1.51) | 1.80 (1.59) | 1.70 (1.61) |
| State FE | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Year FE | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Adj R^2 | 0.4621 | 0.4380 | 0.4422 | 0.4470 | 0.4426 | 0.4607 | 0.4354 | 0.4397 | 0.4436 | 0.4386 |
| Number of Observation | 5,700 | 7,600 | 9,500 | 11,400 | 12,350 | 5,700 | 7,600 | 9,500 | 11,400 | 12,350 |