Research Policy 47 (2018) 440–461

Contents lists available at ScienceDirect

Research Policy

journal homepage: www.elsevier.com/locate/respol

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

Ivalina Kalcheva[a], Ping McLemore[b,*], Shagun Pant[c]

[a] University of California, Riverside, School of Business Administration, United States
[b] Federal Reserve Bank of Richmond, United States
[c] University of Iowa, Department of Finance, United States

ARTICLE INFO

JEL classification:
G24
M13
O3

Keywords:
Innovation
Demand
Supply-side environment
Medical device industry
Venture capital

ABSTRACT

We study the interaction between supply- and demand-side factors and its effect on innovation. Employing a quasi-natural experiment, we show that a shift in demand has an impact on innovation and this effect is conditional on an enabling supply-side environment. Specifically, we exploit a shift in product demand generated by Medicare approvals for reimbursement coverage of medical devices. Using a triple-difference approach, we find that innovation is significantly greater for medical device firms that experience a positive shock to demand due to the Medicare approvals when the firms are exposed to a more favorable supply-side environment. The highest level of innovation is accomplished when all three of our supply-side factors: venture capital (industry), universities (academia), and National Institutes of Health grants (government) are concentrated in one place. These findings show that (i) a positive interaction between supply- and demand-side factors fosters innovation, and (ii) the trilateral intersection of industry, academia, and government creates the highest level of innovation.

1. Introduction

The idea that innovation plays a crucial role 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. Through the years, two separate strands of academic literature have evolved that concern innovation – one studies the supply-side factors and the other investigates the demand-side factors (Shane and Ulrich, 2004; di Stefano et al., 2012; Chemmanur and Fulghieri, 2014). Notably, little integration has occurred between these two strands of literature and the interplay between the demand- and supply-side factors for stimulating innovation has been largely unexplored. On the empirical front, researchers who examine the effects of supply-side factors on innovation have controlled for potential market size but have not systematically explored the interaction effects between the demand- and supply-side factors (Toole, 2012; Blume-Kohout, 2012).[1] Our study fills this gap in the empirical literature. By taking advantage of a quasi-natural experiment, we simultaneously address the effect of both the supply- and demand-side factors on innovation. We find that a shift in demand has an impact on innovation and that this effect is conditional on an enabling supply-side environment. We contribute to this field of research by showing empirically that the interaction between a positive shift in demand and favorable supply-side factors leads to the highest level of innovation.

We examine the interaction between the supply- and demand-side factors on innovation in a quasi-natural experimental setting in the medical device industry. We utilize events where some medical devices

☆ The authors thank John Walsh (the editor) and two anonymous referees for their helpful comments and suggestions that greatly improved the paper. The authors also thank Julian Atanassov, Alexander Butler, Peter Chung, Matthias Feldues, Henry Friedman, Yawen Jiao, Andrew Karolyi, Kai Li, Yun Liu, Michelle Lowry, Clark Lundberg, Ryan McLemore, Nada Mora, Gordon Phillips, Richard Saito, Giorgo Sertsios, Rick Smith, Pavel Teterin, and Ying Xiao, 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, the Seventh Annual Meeting of the Academy of Behavioral Finance & Economics, 2016 California Corporate Finance Conference, and 2016 Financial Management Association Meeting. 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.

* Corresponding author.
E-mail addresses: ivalina.kalcheva@ucr.edu (I. Kalcheva), ping.mclemore@rich.frb.org (P. McLemore), shagun-pant@uiowa.edu (S. Pant).

[1] Adner and Levinthal (2001) 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. Zmud (1984) uses survey data and does not find evidence that innovation is most likely to occur when a need and a means to resolve that need are simultaneously recognized.

https://doi.org/10.1016/j.respol.2017.11.011
Received 13 September 2016; Received in revised form 20 November 2017; Accepted 25 November 2017
Available online 06 January 2018
0048-7333/ © 2017 Elsevier B.V. All rights reserved.

receive Medicare national coverage reimbursement approvals (the treatment group) and some do not (the control group).[2] With the reimbursement approvals, a large portion of the cost to the consumer for these 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).

Schumpeter (1939) 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 empirical research. We proxy for innovation with 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 U.S. market. Successful innovation occurs when new products or processes are introduced to the market. "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) Our measure of innovation captures the output stage of the innovation process and, thus, is a measure of product innovation.

Next, we identify, define, and measure the supply-side environment. Our sample consists of private firms, which are usually small relative to publicly traded firms, in the medical device industry. To construct a measure of the quality of the supply-side environment, we rely on input factors that are important for medical device firms. We take advantage of the fact that the quality of the supply-side factors is naturally geographically segmented at the state level and define the supply-side environment for firms in our sample at the state level. Specifically, we consider National Institutes of Health (NIH) grants, availability of venture capital (VC), number of research universities, R&D investments, and Small Business Innovation Research (SBIR) funding.

We employ a triple-difference regression model to study the relation between innovation, demand, and an organization's supply-side environment. 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 supply-side environment.[3] The parameter of interest of the triple-difference model is the interaction term of the following three variables, which captures the three layers of difference: (1) treatment versus control group; (2) before versus after the demand shock; and (3) a more versus a less favorable supply-side environment.

Our tests address the question of whether the interaction between the demand and the organization's supply-side environment is an important component in nurturing innovation. We find that, indeed, both the supply-side environment and the demand for innovation 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 supply-side 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, and various ways of constructing the measure for innovation, as well as the measure for the supply-side environment.

Our study 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). First, we show that an increase in demand through Medicare approval helps foster innovation in the medical device industry. This finding has implications for regulators to provide incentives (such as solar systems tax breaks, electric cars tax breaks, etc.) that lead to a positive shift in the demand curve. Second, we provide evidence that each of the supply-side factors: VC (industry financing), NIH (government involvement in programs that support research), and research universities (academia) are important for innovation. We further show that the intersection of these factors is vital for fostering innovation (e.g., the presence of research universities on its own is not as impactful as research universities combined with VC availability). The highest level of innovation is accomplished when all three supply-side factors are concentrated in one place. This finding speaks to the importance of the triple helix of university-industry-government (Etzkowitz and Leydesdorff, 2000).[4] While each factor is important on its own, the trilateral interrelation between academia, state, and industry creates the highest level of innovation. Third, we provide evidence that for private firms location (geographical proximity) matters. Firms in states that have access to all three supply-side factors are able to innovate and better respond to shifts in demand. Given this evidence, we contemplate that the formation of innovation clusters such as California, New Jersey, and Massachusetts is due to an intersection of factors: availability of financial resources (venture capital), government involvement, and university collaboration. Regulators may take initiatives to alleviate financial constraints, such as catering to venture capitalists and providing grants. Additionally, there is a need to establish and support the growth of research universities that train skilled labor, provide a platform to collaborate, and often serve as incubators for new firms.

The remainder of the paper is organized as follows. Section 2 presents the research design and provides institutional details. Section 3 describes the data, variable construction and methodology. Sections 4 and 5 present the main empirical findings and results of robustness tests, respectively. Section 6 concludes.

2. Institutional details and research design

The debate of whether supply-side or demand-side factors induce innovation started in the 1970s and by the 1980s the consensus among empirical researchers was that supply-side factors were the main drivers of innovation and that demand played only a complementary role (di Stefano et al., 2012). 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, toward the most profitable and largest markets (Schmookler, 1962, 1966; 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 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

[2] Phillips 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.

[3] Medical device categories receive Medicare approvals on different dates. This fact is advantageous for our study since it is less likely that our tests are affected by contemporaneous changes in economy-wide factors.

[4] This finding is supported by articles in the popular press. For example, "Silicon Valley is a unique amalgam of academia, private sector and US government research investment coupled with a population of (serial) entrepreneurs." in "Next Silicon Valleys: How did California get it so right?" by Neil Koenig 9 February 2014, BBC News. See: http://www.bbc.com/news/technology-26041341.

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 systematic 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 supply-side 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 supply-side 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 measures that proxy for the quality of the supply-side 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.[5] The industry also manufactures irradiation apparatuses and tubes for applications, such as medical diagnostic, medical therapeutic, industrial, research, and scientific evaluation.

An important characteristic of the medical device industry is that no single firm dominates the market and thus, traditionally, this industry has had a low level of industry concentration (Holtzman, 2012).[6] The majority of the medical device companies in the U.S. are small and medium-sized enterprises.[7] 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.[8] 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.

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. These statistics support prior research findings that young and private firms are generally the key drivers of groundbreaking innovation which ultimately leads to economic growth (Chava et al., 2013; Acs and Audretsch, 1987, 1988, 1993; Zucker et al., 1998; Kortum and Lerner, 2000; Samila and Sorenson, 2010; Darby and Zucker, 2003). Thus, our sample consists of private firms in the medical device industry. Our focus on privately-held firms, which are usually small, also helps with the research design as explained in Section 2.2.

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.[9]

The nationwide determination of Medicare reimbursement for an item or service is called National Coverage Determination (NCD).[10] 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.[11] The NCDs fall into three categories: medical devices, laboratory/diagnostic tests, and medical procedures. In this paper we focus on the medical devices category.

The Medicare National Coverage Process is a nine-month process. The first six months include: (1) preliminary discussion; (2) assignment to a benefit category; (3) generation of a National Coverage request; (4) review by the Centers for Medicare & Medicaid Services (CMS) staff; (5) external technology assessment and/or Medicare Coverage Advisory Committee recommendations; (6) CMS staff review of assessments and/or advisory information; and (7) posting a draft decision memorandum. The next three months of the NCD process includes a thirty-day public comment period on the Draft Decision Memorandum, followed by a sixty-day requirement to complete the Final Decision Memorandum and implementation instructions.[12]

In order to draw a valid statistical inference from a natural experiment, the shock must be exogenous (Meyer, 1995). 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%.[13] 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.

Second, private medical device firms are typically small and hence unlikely to be involved in NCD initiation. This fact is a distinct advantage of our sample of firms. On the other hand, public companies, which are typically large, may lobby for the Medicare national reimbursement approval decisions raising concerns about the exogeneity of the approval event. Additionally, the NCDs are a cleaner shock to private firms because the demand for their products is most likely limited to U.S. customers. On the flip side, the demand for products of large public firms is more global and can be affected by economic and regulatory changes in countries that they or their subsidiaries operate. In this sense, including large public firms in our sample will raise

[5] IBISWorld 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.

[6] The concentration ratio in the medical device category has increased in recent years. In 1995, the ratio of revenues made 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%.

[7] See http://selectusa.commerce.gov/industry-snapshots/medical-device-industry-united-states, accessed November 5, 2015.

[8] See page 17 in Chapter 2 of US-Congress (1984) “Federal policies and the medical devices industry,” U.S. Congress, Office of Technology Assessment.

[9] See footnote 5.

[10] In 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.

[11] As 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.

[12] See: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/8a.pdf, https://innovation.cms.gov/files/reports/innovators-guide-to-medicare.pdf.

[13] Neumann 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.

concerns of cross-country confounding factors that are hard to measure and control for. As such, the NCD would not be a clean shock to public firms.

Third, 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 is expected to increase after the NCD approval. 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 leads to 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.[14] 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 other 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.[15] 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, we need only to identify whether the firm is in the product category that has an approval.

2.3. FDA filings as an 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 must 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.[16] 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. A growing body of literature uses drug approvals or clinical trials as measures of innovation. 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, 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). The major advantage of these measures is that they quantify the output stage of the innovation process, i.e., product innovation. We acknowledge the possibility that they might not capture the successful diffusion of innovation (Rogers, 2003). We use an analogous measure for innovation and define 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 merit of our measure of innovation is that it captures the output stage of the innovation process and, thus, is a measure of product innovation.

Frequently-used indicators for innovation are based on either R&D expenditure or patents. Researchers have used a simple count of patents and quality-adjusted patents (patents adjusted for citation counts, family size, licensing, and subsequent use in products, etc.) as a measure of innovation (Trajtenberg, 1990; Albert et al., 1991; Harhoff et al., 1999, 2003; Hall et al., 2005; Moser et al., 2017). These measures are commonly used because these statistics are usually readily available, objective, and quantifiable.

R&D expenditure is technically an input to the innovation process and might never become anything more than an innovative idea. Thus, R&D expenditure is a measure of an early stage of innovation. An additional issue with using R&D expenditure in our study is a lack of data availability. Our firms are private firms that do not have to conform to the SEC disclosure rules of FASB guidelines for R&D reporting (Hirschey et al., 2012).[17]

A patent serves as an intellectual property right and might never be commercialized. Not everything that is patented will eventually turn into successful innovation and ultimately affect economic growth.[18] As such, a simple count of number of patents is unlikely to capture the qualitative aspect of innovative output. At the same time, a quality-adjusted measure of patents is not without concerns. The citing behavior of applicants, patent attorneys, and examiners can create noise and bias in citations (Alcácer and Gittelman, 2006; Alcácer et al.,2009). We cannot use patents as a measure for innovation in our study. Most medical devices have multiple patents and some patents are related to more than one device, which results in an imperfect match between the patent data and the device categories. Acemoglu and Linn (2004), who investigate the effect of (potential) market size on the entry of new drugs and pharmaceutical innovation, also discuss the problems of trying to look into patents. They note that the major issue is the imperfect match between the patent data and the FDA categories, bearing in mind the potential use of certain chemical structures in multiple drug lines. A similar problem

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

[15] Cardiovascular 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).

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

[17] 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).

[18] "There are around 1.5 million patents in effect and in force in this country, and of those, maybe 3000 are commercially viable" (Richard Maulsby, Director of Public Affairs, U.S. Patent & Trademark Office). This is quoted in Karen E. Klein, Smart Answers, "Avoiding the Inventor's Lament," *Business Week*, November 9, 2005. That is, 99% of all patents are unsuccessful, which means that most of the patents are not commercialized (Greenhalgh and Rogers, 2010).

exists in the case of using patents related to medical devices. Acemoglu and Linn (2004) acknowledge this issue and measure innovation using the FDA approval of new drugs in the U.S.

2.4. Supply-side environment

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 a successful implementation of a firm's technology strategy requires an understanding of both the external environment and the firm's capability.[19]

Our paper contributes to this literature by formally studying whether and how the quality of the supply-side environment is critical for product innovation to take place in the presence of a demand-side shock. In selecting the variables to measure the quality of the supply-side environment to nurture innovation, we focus on factors that are important for private medical device firms. Our main proxies are based on the following three dimensions: (i) private industry financing, (ii) government funding, and (iii) universities. These proxies are in line with the concept of the triple helix of university-industry-government relationships initiated in the 1990s by Etzkowitz (1993). Specifically, we use VC availability (given that VC is the major funding source for private companies), National Institute of Health (NIH) grants, and the availability of research universities. The importance of funding availability for innovation is well known and documented, 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; 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; Veugelers and Cassiman, 2005).

Private firms in the medical device industry are primarily venture-backed and hence sensitive to the availability of VC.[20] Furthermore, research universities are often incubators for small private medical device firms and thus the number of research universities is a factor that defines the quality of the supply-side environment. For example, Osseon Therapeutics, a firm in our sample that filed a 510(k) in the orthopedic medical category, is a spinoff of the University of North California. Another example is Voxello Company, a spinoff from the University of Iowa.[21] In fact, the University of Iowa has a program that brings together students from the colleges of law, medicine, engineering, and business to develop ideas for original medical devices.[22]

In order to vary the quality of the supply-side environment across firms we take advantage of the fact that the quality of supply-side factors is naturally geographically segmented at the state level. Private firms are typically small and rely heavily on their local environment.[23] We measure the supply-side environment at the state level, where states differ in the quality of the environment to foster innovation.[24] We take the geographical segmentation of the supply-side environment as given in order to study the innovation response of firms in the presence of a demand shock. We are unable to observe the formation and evolution of geographical clusters of innovation. For example, we cannot comment on why firms or VCs locate in certain states. Theoretically, the location of firms and VCs could be a result of a combination of one or more of the following factors: (i) social planning where things happen simultaneously; (ii) cost-benefit analysis that each firm or VC performs; and (iii) a game theoretic outcome where one firm moves first and the other firm follows. We acknowledge the possibility that VCs might have a preference to locate close to their portfolio companies and those companies might want to be close to their customers. In addition to the above variables, we also consider R&D intensity at the state level and Small Business Innovation Research (SBIR) funding as alternative supply-side factors.

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:

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

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. Errors are robust and clustered 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

[19] Gjerde 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.

[20] According 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 equipment.

[21] See https://now.uiowa.edu/2016/04/giving-voice-patients-who-cant-speak.

[22] See "Medicine's thorny problems tackled by multidisciplinary Iowa Medical Innovation Group" by Rebekah Tilley, August 15, 2016, https://research.uiowa.edu/impact/news.

[23] Defining the supply-side environment for a large firm is a daunting task. Large firms are not confined to a single state and often have a global presence. They have access to many sources of financing and human capital. Therefore, public firms, usually large, might have a different innovation response. In this paper we focus on private firms (typically small). The innovation response of public firms (typically large) to changes in supply and demand factors and their interaction is a good avenue for future research.

[24] We acknowledge the possibility that knowledge flows across states. This phenomenon, however, works against us finding evidence that the supply-side environment matters. Our results show that in spite of the possibility that knowledge flows across states, the state-level environment (the supply-side factor) is important for innovation to take place.

category k in state i and in year t, to capture innovation at the category-state-year level. $(Shock\ Time\ Dummy)_{k,t}$, takes a value of one if it is after an NCD and a value of zero if it is before. The second dummy variable, $(NCD\ Category\ Dummy)_k$, takes a value of one for a medical device category in the treatment group that experiences the NCD shock and zero for the control group. The third dummy variable, $(SE\ Dummy)_{i,t}$, takes a value of one if the supply-side environment index of state i in year t is classified as good 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. $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k$ represents the impact of the demand-side shock on innovations between treatment and control groups. $(Shock\ Time\ Dummy)_{k,t} \times (SE\ Dummy)_{i,t}$ compares the impact of the supply-side environment on innovation before and after the shock to product demand. The interaction term, $(NCD\ Category\ Dummy)_k \times (SE\ Dummy)_{i,t}$, compares the impact of the supply-side environment between treatment and control groups.

The triple-difference term, $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (SE\ Dummy)_{i,t}$, is the main focus of our analysis.[25] It captures how innovation is affected by the interaction of the demand-side shock and the quality of the supply-side environment. The parameter estimate associated with the triple-difference term, β_1, captures the innovation response for a medical device category subject to 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 supply-side 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 between the amount of innovation after and before the positive shock to product demand:[26]

$$\mathrm{Di} = \mathrm{Innovation}^{\text{After Shock}} - \mathrm{Innovation}^{\text{Before Shock}}. \quad (2)$$

The second difference, DiD, is the difference of Di, as just defined, between the treatment group and control group:

$$\mathrm{DiD} = \mathrm{Di}^{\text{Treatment}} - \mathrm{Di}^{\text{Control}}. \quad (3)$$

We expect to find a significant increase in the difference between the innovation by medical device categories subject to the positive shock to product demand (the treatment group) and those that do not experience the shock (the control group) from the pre-event to the post-event period.[27] The third difference is between the DiD for states with a more and less favorable supply-side environment:

$$\mathrm{DiDiD} = \mathrm{DiD}^{\text{Better SE}} - \mathrm{DiD}^{\text{Worse SE}}. \quad (4)$$

Thus, the triple-difference model in Eq. (1) tests whether firms innovate more in better supply-side environments in the presence of a demand-side shock. It is possible that at the national level, a trend in the supply-side may affect the trend on the demand-side. However, our study takes advantage of the variation in the supply-side environment at the state level. We test whether there is a change in the difference between the levels of innovation of the treatment and control groups from the pre-event to the post-event period, and whether this difference is conditional on the state-level supply-side environment. We expect that the environment plays an important role in terms of nurturing innovation. Our hypothesis, H1, predicts β_1 to be positive and significant. A positive β_1 implies that there is more innovation in states with a more favorable 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.

It has been shown that macroeconomic conditions are correlated with innovation (Fagerberg and Srholec, 2008; Fagerberg et al., 2010). We control for economic conditions with two variables: unemployment rate and GDP per capita. We expect to find that the unemployment rate is negatively related to innovation and that GDP per capita is positively related to innovation. In addition, we include state population to control for the size of state; we expect that more populated states have more innovation. Therefore, the regression model in Eq. (1) includes the following control variables: *Log(GDP per Capita)*, *Unemployment Rate/10* and *Log(Population/10,000)*. We collect these variables from the website of the Federal Reserve Bank of St. Louis.[28] 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.

Generally, there are differences in technological opportunities across industries (Klevorick et al., 1995). Presumably the medical device industry has its own trend during our sample period. Having both a benchmark and a treatment group, controls for a general time trend which is important to draw inferences. However, a bias could still arise from unobserved and uncontrolled differences in innovation potential between the two groups being compared. We include the number of firms in each category (k) in each year (t), *Log(1 + # of Firms in a Category)*, as a control variable in our regression specifications. In this way we control for differences in technological opportunities across categories (Klevorick et al., 1995; Astebro and Dahlin, 2005) and differences in market size, which is a demand-side factor across categories (Acemoglu and Linn, 2004). We expect to find that *Log(1 + # of Firms in a Category)* is positively related to innovation. An additional concern could be that states with a high number of medical device firms might drive some of our results. We add the number of firms in each state (i) in each year (t), *Log(1 + # of Firms in a State)*, as an additional control variable and report results in the robustness section.

3.2. Data and 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.[29] The FDA was authorized to regulate the introduction, manufacture, and use of medical devices in the U.S. in 1976 when the Medical Device Amendments was signed into law. We use FDA data after 1986 to construct our test sample because the quality of FDA filings data is poor before 1986.[30] 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 through 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, which requires years of

[25] Butler and Cornaggia (2011) use a triple-difference approach to exploit a 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.

[26] Note that one can order the layers differently. For example, the first difference can be the difference in innovation between states with more, or less favorable supply-side environment or between the treatment versus control group.

[27] The difference-in-difference method is superior compared to a single-difference approach, i.e., a single cross-sectional approach or a single time-series approach (Meyer, 1995). Specifically, the single cross-sectional estimator does not account for omitted common trends, and the single time-series estimator does not account for omitted cross-sectional differences. Moreover, "the great appeal of [difference-in-difference] estimation comes from its simplicity as well as its potential to circumvent many of the endogeneity problems that typically arise when making comparisons between heterogeneous [individual items]" (Bertrand et al., 2004).

[28] See https://www.stlouisfed.org/.

[29] See http://www.fda.gov/MedicalDevices/default.htm.

[30] There 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.

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% of fillings 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 important, given that the medical device industry is characterized by high levels of competition, extensive patenting, and a litigious patent environment the new device has to improve upon the old device without patent infringement.[31] FDA filings are not required for firms that continue to produce their existing devices.[32] Therefore, a firm will file a 510(k) or PMA only when it has a new or improved device that differs from 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, as well as 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.[33] After downloading all NCDs from the CMS website, we manually verify that the NCD is for a medical device. We read the documentation for each NCD for a medical device 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 available before and after an NCD in our sample period.

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 1578 FDA filings before 1993 and 3662 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 1377 FDA filings before 1994 and 1765 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 1299 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 1634 before 1996, and 4176 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.[34] 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 the treatment category receives an NCD and takes a value of zero if it is before.

3.2.3. SE Dummy

We construct different dichotomous supply-side measures based on VC availability, NIH funding, and existence of research universities to gauge how conducive a state's environment is to foster innovation. Specifically, our measures are constructed based on three dimensions which aim to capture the quality of the supply-side environment: (i) the number of (or amount invested by) Healthcare related VC firms in a state. The 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.[35] (ii) the number of grants (or amount invested) from the National Institutes of Health (NIH) in a state;[36] and (iii) the number of universities in a state that are classified as research universities by the Carnegie Classification of Institutions of Higher Education.[37]

We first construct the following dummy variables to represent these three dimensions. *VC Number Dummy* (*VC Amount 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 (dollar amount of VC invested) across all states in year t. Similarly, *NIH Number Dummy* (*NIH Amount 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 (the dollar amount 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.

Next, we create different supply-side environment proxies that aim to gauge the importance of different combinations of the aforementioned supply-side environment factors. Specifically, we construct two supply-side environment indexes for our main tests. The first index, denoted as *SE1*, is constructed using the *VC Number Dummy*, *NIH Number Dummy*, and *CC Dummy*, and the second index, denoted as *SE2* is constructed using the *VC Amount Dummy*, *NIH Amount Dummy*, and *CC Dummy*. We investigate the following nine different versions for *SE1*:

- $SE1 = 1$ if $VC\ Number\ Dummy + NIH\ Number\ Dummy + CC\ Dummy \geq 1$;
- $SE1 = 1$ if $VC\ Number\ Dummy = 1$;
- $SE1 = 1$ if $NIH\ Number\ Dummy = 1$;
- $SE1 = 1$ if $CC\ Dummy = 1$;

[31] A 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 device, legally marketed in the U.S., 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).

[32] The 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.

[33] See https://www.cms.gov/.

[34] Our results are robust to alternative matching criteria.

[35] The results also hold when we define VC availability based on VC firms across all industries (as opposed to only Healthcare).

[36] See https://www.nih.gov/.

[37] See http://carnegieclassifications.iu.edu/. Research universities include those classified as either "R1: Doctoral Universities – Highest Research Activity" or "R2: Doctoral Universities – Higher Research Activity".

Table 1
Number of FDA filings before and after NCDs.

	Cardiovascular	Gastroenterology Urology			Neurology		Orthopedic
Year of NCD	1993	1994	2001	2002	1995	2003	1996
Number of FDA filings before NCD	1578	1377	2251	2363	1299	2356	1634
Number of FDA filings after NCD	3662	1765	922	825	1975	966	4176

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.

- *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* ≥ 2;
- *SE1* = 1 if *VC Number Dummy* = 1 and *NIH Number Dummy* = 1;
- *SE1* = 1 if *NIH Number Dummy* = 1 and *CC Dummy* = 1;
- *SE1* = 1 if *VC Number Dummy* = 1 and *CC Dummy* = 1;
- *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3.

We construct the different versions for the *SE2* index in a similar fashion where *VC Number Dummy* and *NIH Number Dummy* are replaced with their dollar analogues, *VC Amount Dummy* and *NIH Amount Dummy*.

The first version of the supply-side index classifies a state that has any one of the three supply-side environment factors as a good state. This version is the least restrictive classification. Versions (2)–(4) specify exactly which factor must be present for a state to be classified as good. Version (5) classifies a state that has any two of the three supply-side environment factors as a good state. Versions (6)–(8) specify exactly which two factors must be present for a state to be classified as good. Finally, version (9) requires that all three factors must be present and thus is the most restrictive classification scheme. These nine versions of each index capture all possible combinations of the three factors, which enable us to study the importance of each of them individually as well as different combinations of them.

We expect that firms located in states with a more favorable supply-side environment will innovate more after the positive shocks to product demand. We also expect that when all three factors are present in a state, innovation is the highest. While each factor individually can contribute to a positive environment for innovation, a combination of factors can deliver the highest level of innovation.

Our main results are reported using all nine versions of each index for a total of 17 proxies (the case when *SE1* = 1 if *CC Dummy* = 1 is the same for both indexes) for the supply-side environment.[38] Thus, the dummy variable, $(SE\ Dummy)_{i,t}$, in Eq. (1) is one of the 17 index versions.

As a robustness test, we introduce two other alternative measures for the supply-side environment that capture the quality of the environment more broadly. Specifically, we use "R&D as a Percentage of Gross Domestic Product" and "Average Annual Federal Small Business Innovation Research Funding per $1 Million of Gross Domestic Product" as two other continuous measures of the supply-side factor. We obtain these variables from the Science and Engineering Indicators Tables published by the National Science Board on the National Science Foundation website.[39] "R&D as a Percentage of Gross Domestic Product" is available for the period 1991-2012, and is collected from Table 8.39. "Average Annual Federal Small Business Innovation Research Funding per $1 Million of Gross Domestic Product" is available for the period 1990-2012, and is collected from Table 8.54.

3.3. Sample distribution and summary statistics

Tables 2 and 3 provide detailed information on our sample distribution and summary statistics for all variables used in the regression models, respectively. Panel A of Table 2 reports the number of medical device firms by state. We observe a large variation across states. Almost 22% of all private medical device firms are located in California.[40] Massachusetts and New Jersey each host about 6% of the private medical device firms. At the other end of the sample distribution only a couple of private medical device firms are located in Alaska and Wyoming. Notably, there are medical device firms in all states.

Panel B of Table 2 shows the sample distribution of the number of states that have firms in a particular medical device category and the number of firms in each category. The number of states that have firms in a particular category ranges from 26 (Pathology, 463 firms) to 50 (general and Plastic Surgery, 8461 firms). Across medical device categories in the treatment group, Neurology is present in 48 states (higher end of the spectrum) and Orthopedic in 41 states (lower end of the spectrum). We observe that across medical device categories in the control group, Pathology is present in only 26 states while General & Plastic Surgery is present in all 50 states.

Table 3 reports summary statistics of the variables in our main regression sample. The average number of FDA filings in a year in a state is 2.23 with a minimum of zero and a maximum of 183. States with the highest number of annual filings are California, New Jersey, Massachusetts, and Florida. States with the lowest number of filings are South Dakota, West Virginia, Wyoming, and Alaska. The average of *VC Number Dummy*, is 0.16. The interpretation is that about 16% of the state-year-category observations have a value of one for *VC Number Dummy*. The same interpretation applies to the other constructed dummy variables, including *VC Amount Dummy*, *NIH Number Dummy*, *NIH Amount Dummy*, and *CC Dummy*.

The average *R&D per GDP* is 2.11, which means that, on average in a state, R&D accounts for about 2.11% of the state's GDP. The average of *SBIR/100* funding per one million dollars of GDP is 117 (1.17 × 100 = 117). The average of *Log*(*GDP per Capita*) is 10.28. The average *Unemployment Rate/10* is 5.7% (0.57 % ×10 = 5.7%). The average *Log(Population/10,000)* is 6.4. The average of *Log(1 + # of Firms in a Category)* is 4.22. The average of *Log(1 + # of Firms in a State)* is 2.62.

We also report the summary statistics for different versions of the two supply-side environment indexes. For example, the first version of *SE1* is *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* ≥ 1, and we find that *SE1* takes a value of either zero or one with a mean of 0.48. The interpretation is that about 48% of the state-year-category observations have a value of one for *SE1*. The same interpretation applies for the rest of the versions (please see Section 3.2.3 for a description of the different versions of *SE1* and *SE2*) and is not repeated here for brevity.

[38] The correlation among all 17 proxies ranges from 0.19 to 0.96. Specifically, the correlation between *SE*1 and *SE*2 when all three factors are present in a state is 0.56 indicating that each index by itself represents different aspects of the environment.

[39] The data is collected from https://www.nsf.gov/statistics/2016/nsb20161/#/data on March 15, 2017.

[40] Our results are robust to excluding California from the sample, see Table 7.

Table 2
Sample distribution.

Panel A: Sample distribution of number of firms by state

State	# of firms	%	State	# of firms	%
AK	2	0.00	MT	41	0.06
AL	238	0.36	NC	748	1.14
AR	39	0.06	ND	29	0.04
AZ	670	1.02	NE	146	0.22
CA	14,682	22.31	NH	517	0.79
CO	1480	2.25	NJ	4628	7.03
CT	1651	2.51	NM	95	0.14
DE	552	0.84	NV	272	0.41
FL	4169	6.33	NY	3605	5.48
GA	1080	1.64	OH	1648	2.50
HI	45	0.07	OK	181	0.28
IA	195	0.30	OR	678	1.03
ID	69	0.10	PA	2851	4.33
IL	3115	4.73	RI	216	0.33
IN	1682	2.56	SC	181	0.28
KS	310	0.47	SD	19	0.03
KY	129	0.20	TN	1286	1.95
LA	77	0.12	TX	3280	4.98
MA	4480	6.81	UT	755	1.15
MD	1670	2.54	VA	693	1.05
ME	226	0.34	VT	92	0.14
MI	1107	1.68	WA	1095	1.66
MN	2589	3.93	WI	1260	1.91
MO	1142	1.74	WV	11	0.02
MS	84	0.13	WY	4	0.01
Total				65,814	100

Panel B: Sample distribution of number of firms by device category

Device category	# of states	# of firms
Categories in the treatment group		
Cardiovascular	45	5297
Gastroenterology & urology	43	3227
Neurology	48	3324
Orthopedic	41	5936
Categories in the control group		
Anesthesiology	44	4103
Clinical chemistry	41	4972
Clinical toxicology	27	1243
Dental	45	5508
Ear, nose, & throat	43	1787
General & plastic surgery	50	8461
General hospital	46	6333
Hematology	31	1445
Immunology	32	1394
Microbiology	37	2308
Obstetrics & gynecology	44	2012
Ophthalmic	45	2683
Pathology	26	463
Physical medicine	37	589
Radiology	47	4729
Total		65,814

This table provides information on the sample distribution. Panels A and B show the sample distribution of the number of firms by state and by category, respectively.

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).

4.1. Univariate results

Table 4 reports the mean number of FDA (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 supply-side environments. Panels A and B report univariate results for the case when the quality of the supply-side environment is measured by $SE1 = 1$ if $VC\ Number\ Dummy + NIH\ Number\ Dummy + CC\ Dummy = 3$ and $SE2 = 1$ if $VC\ Amount\ Dummy + NIH\ Amount\ Dummy + CC\ Dummy = 3$, respectively.

Table 4, Panel A, Columns (1) and (2) show that the average of annual FDA filings is 15.51 before NCD approvals and is 10.64 after the approvals for the treatment group in a favorable supply-side

Table 3
Summary statistics.

Variable	Obs.	Mean	Median	St. Dev.	Min	Max	# of states SE = 1
Number of FDA Filings	22,800	2.23	0	6.42	0	183	
VC Number Dummy	22,800	0.16	0	0.37	0	1	
VC Amount Dummy	22,800	0.07	0	0.25	0	1	
NIH Number Dummy	22,800	0.34	0	0.47	0	1	
NIH Amount Dummy	22,800	0.33	0	0.47	0	1	
CC Dummy	22,800	0.37	0	0.48	0	1	
SE1 = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* ≥ 1	22,800	0.48	0	0.50	0	1	34
SE1 = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* ≥ 2	22,800	0.28	0	0.45	0	1	19
SE1 = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3	22,800	0.10	0	0.31	0	1	12
SE1 = 1 if *VC Number Dummy* = 1 and *NIH Number Dummy* = 1;	22,800	0.12	0	0.32	0	1	14
SE1 = 1 if *NIH Number Dummy* = 1 and *CC Dummy* = 1;	22,800	0.26	0	0.44	0	1	17
SE1 = 1 if *VC Number Dummy* = 1 and *CC Dummy* = 1;	22,800	0.11	0	0.32	0	1	14
SE2 = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* ≥ 1	22,800	0.48	0	0.50	0	1	34
SE2 = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* ≥ 2	22,800	0.25	0	0.43	0	1	17
SE2 = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3	22,800	0.05	0	0.21	0	1	6
SE2 = 1 if *VC Amount Dummy* = 1 and *NIH Amount Dummy* = 1;	22,800	0.06	0	0.24	0	1	7
SE2 = 1 if *NIH Amount Dummy* = 1 and *CC Dummy* = 1;	22,800	0.23	0	0.42	0	1	17
SE2 = 1 if *VC Amount Dummy* = 1 and *CC Dummy* = 1;	22,800	0.05	0	0.22	0	1	7
R&D per GDP (%)	16,853	2.11	1.80	1.47	0.23	8.55	
SBIR/100 ($)	18,050	1.17	0.75	1.18	0.01	7.67	
Log(*GDP per Capita*)	22,800	10.28	10.34	0.36	9.30	11.08	
Unemployment Rate/10 (%)	22,800	0.57	0.54	0.19	0.23	1.37	
Log(Population/10,000)	22,800	6.40	6.49	1.04	4.03	8.91	
Log(1 + # of Firms in a Category)	22,800	4.22	4.55	1.31	0	6.51	
Log(1 + # of Firms in a State)	22,800	2.62	2.83	1.63	0	6.81	

This table shows summary statistics of state-category-year variables. *Number of FDA Filings* is the number of FDA filings in category *k*, state *i*, and year *t*. *VC Number Dummy* (*VC Amount Dummy*) takes a value of one if the number (dollar amount) of healthcare VC firms in state *i* in year *t* is above the average number (dollar amount) of healthcare VC firms across all states in year *t*. *NIH Number Dummy* (*NIH Amount Dummy*) takes a value of one if the number (dollar amount) of NIH grants in state *i* in year *t* is above the average number (dollar amount) of NIH grants 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. The different versions of the supply-side environment index *SE*1 are based on *VC Number Dummy*, *NIH Number Dummy* and *CC Dummy*. The different versions of the supply-side environment index *SE*2 are based on *VC Amount Dummy*, *NIH Amount Dummy* and *CC Dummy*. *R&D per GDP* is R&D as a percentage of Gross Domestic Product in a state in a year. *SBIR*/100 is the average annual Federal Small Business Innovation Research Funding divided by 100 per $1 Million of Gross Domestic Product in a state. *Log*(*GDP per Capita*) is the logarithmic transformation of the state-level GDP per capita in year *t*. *Unemployment rate/10* is the state-level unemployment rate in year *t* divided by ten. *Log*(*Population*/10, 000) is the logarithmic transformation of state-level population divided by 10,000. *Log(1 + # of Firms in a Category)* is the logarithmic transformation of one plus number of private medical device firms in a category in a year in a state. *Log(1 + # of Firms in a State)* is the logarithmic transformation of one plus the number of private medical device firms in a state in a year. For detailed variable definitions see Appendix B.

Table 4
Univariate evidence on the relation between innovation, demand- and supply-side factors.

		(1) Pre-event (*Shock Time Dummy* = 0)	(2) Post-event (*Shock Time Dummy* = 1)	(3) 1st Diff	(4) 2nd Diff (Diff-in-Diff)	(5) 3rd Diff (Diff-in-Diff-in-Diff)
Panel A: The supply-side environment is proxied by *SE1* = *1* if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = *3*						
Better SE (*SE* = 1)	Treatment Group (*NCD Category Dummy* = 1)	15.51	10.64	−4.87		
				(−3.01)		
	Control Group (*NCD Category Dummy* = 0)	18.38	6.43	−11.95	7.08	
				(−13.74)	(3.76)	
Worse SE (*SE* = 0)	Treatment Group (*NCD Category Dummy* = 1)	2.51	1.91	−0.60		
				(−3.68)		
	Control Group (*NCD Category Dummy* = 0)	2.32	0.90	−1.42	0.82	6.25
				(−22.11)	(5.48)	(7.70)
Panel B: The supply-side environment is proxied by *SE2* = *1* if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = *3*						
Better SE (*SE* = 1)	Treatment Group (*NCD Category Dummy* = 1)	15.08	16.81	1.72		
				(0.70)		
	Control Group (*NCD Category Dummy* = 0)	17.82	10.54	−7.28	9.00	
				(−4.84)	(2.83)	
Worse SE (*SE* = 0)	Treatment Group (*NCD Category Dummy* = 1)	2.94	2.22	−0.71		
				(−3.85)		
	Control Group (*NCD Category Dummy* = 0)	2.85	1.08	−1.76	1.05	7.95
				(−22.49)	(5.85)	(7.21)

This table reports the average number of FDA 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 supply-side environment 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. Panels A and B report the summary statistics for the case when the proxy for the quality of the supply-side environment for nurturing innovation is *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 and *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3, respectively. *T*-statistics are in parentheses. For detailed variable definitions see Appendix B.

Table 5
Triple-difference regression model: All non-NCD medical device categories in the control group, first NCDs.

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Panel A: The supply-side environment is proxied by *SE1* based on *VC Number Dummy*, *NIH Number Dummy*, and *CC Dummy*									
Shock Time Dummy × NCD Category Dummy × SE Dummy	2.61	3.49	3.42	3.15	3.89	4.57	4.24	6.04	6.27
	(1.76)	(2.93)	(2.19)	(1.81)	(2.07)	(2.87)	(1.92)	(3.08)	(2.52)
Shock Time Dummy × NCD Category Dummy	−0.82	−0.10	−0.71	−0.71	−0.65	−0.06	−0.65	−0.18	−0.13
	(−2.66)	(−0.35)	(−4.95)	(−2.72)	(−4.39)	(−0.17)	(−3.09)	(−0.59)	(−0.41)
Shock Time Dummy × SE Dummy	−3.75	−5.31	−4.24	−3.68	−4.73	−8.95	−4.40	−7.72	−9.95
	(−5.75)	(−7.22)	(−5.24)	(−5.65)	(−5.80)	(−6.35)	(−5.51)	(−6.75)	(−6.35)
NCD Category Dummy × SE Dummy	−0.24	−0.25	−0.87	−1.16	−1.11	−1.49	−1.38	−3.08	−3.10
	(−0.18)	(−0.12)	(−0.57)	(−0.88)	(−0.69)	(−0.52)	(−0.76)	(−1.03)	(−0.82)
Shock Time Dummy	−2.18	−2.08	−1.95	−2.48	−1.91	−1.76	−2.38	−2.43	−2.31
	(−4.58)	(−4.55)	(−4.87)	(−5.37)	(−4.66)	(−4.53)	(−5.5)	(−5.05)	(−5.11)
NCD Category Dummy	−0.23	−0.30	−0.06	0.06	−0.03	−0.19	−0.01	−0.06	−0.12
	(−0.93)	(−1.32)	(−0.46)	(0.39)	(−0.21)	(−0.82)	(−0.06)	(−0.22)	(−0.44)
SE Dummy	1.87	6.88	3.64	2.52	4.73	11.48	4.29	9.95	12.53
	(3.05)	(6.5)	(3.89)	(3.60)	(4.53)	(5.76)	(4.09)	(5.98)	(5.66)
Log(GDP per Capita)	4.96	3.27	3.96	4.68	3.81	2.71	4.09	3.53	3.26
	(5.85)	(5.57)	(5.52)	(5.86)	(5.51)	(5.02)	(5.82)	(5.55)	(5.46)
Unemployment Rate/10	−0.34	−0.44	−0.33	−0.46	−0.44	−0.47	−0.52	−0.62	−0.68
	(−1.68)	(−1.92)	(−1.71)	(−2.13)	(−2.03)	(−2.13)	(−2.43)	(−2.75)	(−3.01)
Log(Population/10,000)	2.56	1.84	2.10	2.36	1.88	1.65	1.97	1.75	1.67
	(6.53)	(6.49)	(6.66)	(6.70)	(6.54)	(6.37)	(6.98)	(6.47)	(6.51)
Log(1 + # of Firms in a Category)	1.11	1.09	1.10	1.11	1.10	1.09	1.10	1.10	1.09
	(4.40)	(4.50)	(4.44)	(4.38)	(4.43)	(4.55)	(4.40)	(4.44)	(4.46)
Adj R^2	0.2393	0.2671	0.2409	0.2353	0.2472	0.2927	0.2422	0.2742	0.2871
Number of observations	22,800	22,800	22,800	22,800	22,800	22,800	22,800	22,800	22,800
Panel B: The supply-side environment is proxied by *SE2* based on *VC Amount Dummy*, *NIH Amount Dummy*, and *CC Dummy*									
Shock Time Dummy × NCD Category Dummy × SE Dummy	3.15	5.06	3.28		3.05	6.32	3.79	7.47	8.07
	(1.71)	(4.23)	(1.84)		(1.95)	(3.15)	(2.09)	(4.21)	(4.25)
Shock Time Dummy × NCD Category Dummy	−1.07	0.11	−0.64		−0.41	0.11	−0.43	0.10	0.09
	(−2.24)	(0.29)	(−2.82)		(−2.66)	(0.28)	(−2.89)	(0.24)	(0.23)
Shock Time Dummy × SE Dummy	−3.49	−3.00	−3.53		−4.04	−7.33	−3.94	−5.96	−5.44
	(−5.91)	(−4.13)	(−5.55)		(−5.53)	(−5.14)	(−5.51)	(−4.85)	(−4.60)
NCD Category Dummy × SE Dummy	−0.56	−2.01	−0.73		−1.57	−2.95	−1.57	−2.95	−2.95
	(−0.41)	(−0.85)	(−0.42)		(−0.90)	(−0.78)	(−0.90)	(−0.78)	(−0.78)
Shock Time Dummy	−2.49	−3.19	−2.55		−2.66	−2.91	−2.66	−3.28	−3.18
	(−5.08)	(−5.74)	(−5.01)		(−5.41)	(−5.66)	(−5.38)	(−5.69)	(−5.68)
NCD Category Dummy	−0.10	−0.21	−0.12		0.02	−0.22	0.02	−0.22	−0.22
	(−0.36)	(−0.62)	(−0.43)		(0.11)	(−0.64)	(0.11)	(−0.65)	(−0.65)
SE Dummy	1.24	6.62	2.54		3.66	11.36	3.74	11.54	11.59
	(2.55)	(4.56)	(3.53)		(3.82)	(4.80)	(3.91)	(4.83)	(4.84)
Log(GDP per Capita)	5.20	3.92	4.45		4.36	3.57	4.31	4.11	3.94
	(6.02)	(5.97)	(5.76)		(5.83)	(5.89)	(5.74)	(5.83)	(5.83)
Unemployment Rate/10	−0.45	−0.91	−0.38		−0.51	−0.92	−0.55	−1.10	−1.22
	(−2.13)	(−3.55)	(−1.91)		(−2.36)	(−3.66)	(−2.54)	(−4.16)	(−4.50)
Log(Population/10,000)	2.72	2.02	2.28		2.13	1.94	2.08	1.83	1.82
	(6.78)	(6.82)	(6.85)		(6.88)	(6.78)	(6.85)	(6.74)	(6.76)
Log(1 + # of Firms in a Category)	1.11	1.09	1.11		1.10	1.09	1.10	1.10	1.10
	(4.39)	(4.51)	(4.42)		(4.40)	(4.54)	(4.40)	(4.50)	(4.50)

(*continued on next page*)

Table 5 (*continued*)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Adj R^2	0.2389	0.2563	0.2351		0.2358	0.2717	0.2365	0.2843	0.2889
Number of observations	22,800	22,800	22,800		22,800	22,800	22,800	22,800	22,800

This table reports regression results 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. Panels A and B report results when the supply-side environment is proxied by *SE1* and *SE2*, respectively. Columns (1) through (9) report results for different versions of *SE1* and *SE2*. Column (1) of Panels A and B report results when *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* ≥ 1 and *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* ≥ 1. Columns (2), (3) and (4) of Panel A (Panel B) report results for when the supply-side environment is proxied by *VC Number Dummy*, *NIH Number Dummy* and *CC Dummy* (*VC Amount Dummy*, *NIH Amount Dummy*, and *CC Dummy*). Column (5) of Panels A and B report results when *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* ≥ 2 and *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* ≥ 2. Column (6) of Panels A and B report results when *SE1* = 1 if *VC Number Dummy* = 1 and *NIH Number Dummy* = 1 and *SE2* = 1 if *VC Amount Dummy* = 1 and *NIH Amount Dummy* = 1. Column (7) of Panels A and B report results when *SE1* = 1 if *NIH Number Dummy* = 1 and *CC Dummy* = 1; and *SE2* = 1 if *NIH Amount Dummy* = 1 and *CC Dummy* = 1. Column (8) of Panels A and B report results when *SE1* = 1 if *VC Number Dummy* = 1 and *CC Dummy* = 1 and *SE2* = 1 if *VC Amount Dummy* = 1 and *CC Dummy* = 1. Column (9) of Panels A and B report results when supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 and *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3. In all models we include state-level *Log(GDP per Capita)*, *Unemployment Rate/10*, and *Log(Population/10,000)*, as well as a category-level and *Log(1 + # of Firms in a Category)* 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.

environment. Correspondingly, the average of annual FDA filings is 18.38 (6.43) before (after) the shock for the control group in a favorable supply-side environment. The difference in means per Eq. (2), reported in Column (3), is negative and significant for both the treatment (−4.87 with *t*-statistic = −3.01) and control groups (−11.95 with *t*-statistic = −13.74). Because the first difference in means is more negative for the control group, the second difference per Eq. (3) reported in Column (4) is positive and significant (7.08 with *t*-statistic = 3.76). There are two points to take away from this result.

First, the negative and significant first difference in means reported in Column (3) shows a general downward trend in innovation but less so for the treatment group, which leads to a positive and significant second difference in means reported in Column (4). 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;[41] it could also be the case that the bar for innovation in the medical device industry has risen through time.[42] In any case, having a treatment and a benchmark group controls for any general parallel trends that affect the whole industry. Second, this result emphasizes that having a control group is critical in drawing any statistical inferences and speaks to the advantages of the difference-in-difference methodology.

Focusing now on the case when the supply-side environment is less favorable, we observe that the average annual number of FDA filings is much lower (ranges from 0.90 (post-event for the control group) to 2.51 (pre-event for the treatment group)) when compared to the filings for the more favorable supply-side environment. This finding is consistent with our hypothesis that firms innovate more in a more favorable supply-side environment. The first difference in means reported in Column (3), when the environment is unfavorable, is negative and significant for both the treatment (-0.60 with *t*-statistics = −3.68) and the control groups (−1.42 with *t*-statistics = −22.11) again showing a general downward trend in innovation over our sample period. The second difference is positive and significant (0.82 and *t*-statistic = 5.48). This finding shows that the treatment group experiences an increase in innovation relative to the control group.

The third difference in means per Eq. (4), reported in Column (5) of both Panels A and B is positive and significant which formally confirms the statement that the treatment group innovates more than the control group, after the shock, in a better supply-side environment. This univariate evidence provides preliminary support of our hypothesis that the interaction between the supply- and demand-side factors affect innovation. 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 first report regression results when we include all medical device categories without NCDs in the control group. Table 5 reports these results. In Table 5, we define the event period as 1993–1996 and study the difference in

[41] See "Do the FDA's regulations governing medical devices need to be overhauled?," *The Wall Street Journal*, by Thomas M. Burton, March 23, 2015.

[42] For 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.

Table 6
Triple-difference regression model: One-to-one matched sample, first NCDs, and all NCDs.

	(1)	(2)	(3)	(4)
Shock Time Dummy × NCD Category Dummy × SE Dummy	11.55	9.32	7.77	8.41
	(3.24)	(3.60)	(4.22)	(3.75)
Shock Time Dummy × NCD Category Dummy	0.13	0.53	0.67	0.93
	(0.40)	(1.50)	(1.54)	(1.76)
Shock Time Dummy × SE Dummy	−13.92	−6.31	−8.92	−6.71
	(−4.37)	(−3.15)	(−5.27)	(−4.50)
NCD Category Dummy × SE Dummy	−14.6	−14.96	−10.72	−13.89
	(−2.80)	(−2.81)	(−3.51)	(−4.53)
Shock Time Dummy	−2.57	−3.68	−1.62	−2.44
	(−16.01)	(−11.49)	(−3.17)	(−4.13)
NCD Category Dummy	0.26	−0.23	−0.45	−0.79
	(0.97)	(−1.11)	(−0.69)	(−1.02)
SE Dummy	20.89	21.07	15.41	20.02
	(4.84)	(4.65)	(5.83)	(7.54)
Log(GDP per Capita)	4.64	5.47	1.06	1.95
	(9.50)	(8.84)	(1.66)	(3.01)
Unemployment Rate/10	−0.17	−0.95	0.5	−0.17
	(−0.72)	(−2.95)	(1.35)	(−0.42)
Log(Population/10,000)	2.70	2.88	2.40	2.55
	(8.20)	(7.96)	(10.61)	(10.11)
Log(1 + # of Firms in a Category)	3.54	3.52	0.24	0.24
	(7.78)	(7.76)	(2.22)	(2.18)
Adj R^2	0.3669	0.3807	0.3042	0.3272
Number of observations	10,800	10,800	18,900	18,900

This table reports regression results of the triple-difference model (Eq. (1)). Columns (1) and (2) use a one-to-one matched sample. 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. The number of observations in Columns (1) and (2) is 10,800, calculated as eight categories (four in the treatment group and four in the control group) multiplied by 27 years and 50 state, i.e., $8 \times 27 \times 50 = 10,800$. Columns (3) and (4) report regression results when we use all seven NCDs received by the categories to construct the treatment group. We again construct a one-to-one matched sample. The number of observations in Columns (3) and (4) is 18,900, calculated as 14 categories (seven in the treatment group and seven in the control group) multiplied by 27 years and 50 states, i.e., $14 \times 27 \times 50 = 18,900$. The supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 in Columns (1) and (3) and by *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3 in Columns (2) and (4). 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. 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 all models we include state-level *Log*(*GDP per Capita*), *Unemployment Rate/10*, and *Log(Population/10,000)*, as well as a category-level and *Log(1 + # of Firms in a Category)* 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.

product innovation before 1993 versus after 1996, because the four categories in the treatment 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. In all models we include state-level time-varying macroeconomic control variables (*Log*(*GDP per Capita*), *Unemployment Rate/10*, and *Log (Population/10,000)*) and a category-level time-varying control variable (*Log(1 + # of Firms in a Category)*). See Appendix B for detailed variable definitions. The errors are robust and clustered at the device category level.

Panels A and B of Table 5 report results for all versions of *SE1* and *SE2*, respectively. Columns (1) through (9) report results from the least restrictive analogue, i.e., when any one of the factors is present in a state, to the most restrictive analogue, i.e., when all three factors are present simultaneously in a state.

There are two points to take away from Table 5. First, the coefficient associated with the triple-difference term, *Shock Time Dummy* × *NCD Category Dummy* × *SE Dummy*, is positive and significant in both Panels A and B regardless of the particular versions of *SE1* and *SE2* used to gauge the quality of the supply-side environment. The coefficients range from 2.61 (Column (1), Panel A) to 8.07 (Column (9), Panel B) with *t*-statistics ranging from 1.71 (Column (1), Panel B) to 4.25 (Column (9), Panel B). These multivariate regression results support our hypothesis that after the demand-side shock the treatment group innovates more relative to the control group when the supply-side environment is more favorable.

Second, while our results are robust to different variations of *SE1* and *SE2*, the intersection of all three supply-side environment dimensions leads to the highest level of innovation. In Column (1) of Table 5, where any one factor is present in a state, the coefficient of the triple-difference term is 2.61 using *SE1* (Panel A) and 3.15 using *SE2* (Panel B) with a 10% significant level. Columns (2), (3), and (4) report results when we evaluate the effect on innovation of each individual factor: VC, NIH, and CC. We find that each of the three factors positively impacts innovation on its own (Columns 2–4, Panels A and B). VC financing turns out to be the most important single factor (Column 2) and the number of research universities is the least important (Column 4). Some interesting results emerge with possible policy implications. For example, while the availability of research universities is important for innovation on its own, it is even more important when coupled with NIH grants or VC (the coefficient on the triple-difference term in Column (4) is smaller compared to the coefficients reported in Columns (7) and (8)). In comparison, in Column (9), where all factors are present in a state, the coefficients are 6.27 and 8.07 with a 1% significant level, using *SE1* and *SE2* respectively. This finding implies that when all factors are present in a state, the impact of the supply-side environment on innovation is the highest, in terms of both magnitude and significance. Many policy makers have tried to replicate the success of California in terms of innovation. California is one of the states that has all three factors. The results reported in Column (9) in Panels A and B suggest that providing the most favorable supply-side environment is an essential ingredient to foster innovation. This finding shows that innovation occurs at the trilateral intersection of industry, government, and academia, and provides evidence that supports the triple helix model (Etzkowitz and Leydesdorff, 2000; Viale and Etzkowitz, 2010; Etzkowitz, 2008).

The coefficients on the control variables are as expected. The results show that innovation is positively related to GDP per capita,

Table 7
Triple-difference regression model: Excluding California.

	(1)	(2)	(3)	(4)
Shock Time Dummy × *NCD Category Dummy* × *SE Dummy*	8.18	5.40	4.62	3.98
	(5.26)	(4.09)	(3.40)	(2.68)
Shock Time Dummy × *NCD Category Dummy*	0.33	0.60	0.69	0.87
	(1.48)	(2.98)	(1.56)	(1.71)
Shock Time Dummy × *SE Dummy*	−6.83	−0.73	−3.83	−0.54
	(−4.84)	(−1.32)	(−3.26)	(−0.5)
NCD Category Dummy × *SE Dummy*	−9.38	−6.49	−5.62	−4.55
	(−4.89)	(−2.88)	(−3.68)	(−3.51)
Shock Time Dummy	−3.08	−3.6	−2.00	−2.44
	(−12.84)	(−10.99)	(−3.89)	(−4.26)
NCD Category Dummy	−0.03	−0.38	−0.53	−0.80
	(−0.15)	(−1.95)	(−0.85)	(−1.14)
SE Dummy	9.69	5.22	6.61	4.52
	(6.12)	(2.66)	(4.90)	(3.83)
Log(GDP per Capita)	4.85	5.31	1.64	2.17
	(8.66)	(8.31)	(2.91)	(3.75)
Unemployment Rate/10	−1.19	−1.27	−0.52	−0.55
	(−4.34)	(−4.34)	(−1.67)	(−1.65)
Log(Population/10,000)	2.19	2.39	1.93	2.13
	(7.94)	(7.95)	(10.62)	(10.42)
Log(1 + # of Firms in a Category)	3.00	3.02	0.19	0.19
	(8.07)	(8.02)	(2.10)	(2.06)
Adj R^2	0.3009	0.2858	0.2188	0.2046
Number of observations	10,584	10,584	18,522	18,522

This table reports regression results of the triple-difference model (Eq. (1)). We replicate Table 6 but we exclude California from the sample. Columns (1) and (2) use a one-to-one matched sample. 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. The number of observations in Columns (1) and (2) is 10,584, calculated as eight categories (four in the treatment group and four in the control group) multiplied by 27 years and 49 states, i.e., 8 × 27 × 49 = 10, 584. Columns (3) and (4) report regression results when we use all seven NCDs received by the categories to construct the treatment group. We again construct a one-to-one matched sample. The number of observations in Columns (3) and (4) is 18,522, calculated as 14 categories (seven in the treatment group and seven in the control group) multiplied by 27 years and 49 states, i.e., 14 × 27 × 49 = 18, 522. The supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 in Columns (1) and (3) and by *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3 in Columns (2) and (4). 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. 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 all models we include state-level *Log(GDP per Capita)*, *Unemployment Rate/10*, and *Log(Population/10,000)*, as well as a category-level and *Log(1 + # of Firms in a Category)* 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.

population, and the number of firms in a category; and negatively related to the unemployment rate.

The results in Table 5 imply that firms in device categories that experience an increase in product demand are able to respond with more innovation in the presence of an enabling supply-side environment. We now assess the economic significance of these results based on the regression model estimates in Column (9), Panel (A) of Table 5. 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 −8.98 for the dependent variable, $(Number\ of\ FDA\ Filings)_{k,i,t}$. If we set $(SE\ Dummy)_{i,t}$ 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 6.70. The dummy variable, $(SE\ Dummy)_{i,t}$, being zero indicates that the quality of the environment to foster innovation in state *i* in year *t* is not favorable, and $(SE\ Dummy)_{i,t}$ being one indicates a favorable environment. Thus, if state *i* improves its environment to nurture innovation in year *t*, i.e., $(SE\ Dummy)_{i,t}$ increases from zero to one, then the number of FDA filings in the treatment category *k* will increase by more than 15 in state *i* in year *t*.[43] That is, on average, if a state improves the supply-side environment there is an economically meaningful, almost sixteen-fold increase in product innovation.[44]

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

We now focus on Table 6 which reports regression results using different samples. Specifically, Columns (1) and (2) report results using a one-to-one matched sample, where a matching category for each treatment category is identified. We use a proxy for market share to match the treatment group with an appropriate control group as explained in Section 3. For example, the 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 Columns (1) and (2) of Table 6 includes four treatment categories and four corresponding matched control categories. The supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 in Column (1) and by *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3 in Column (2). We find that the coefficient estimate for the triple-difference variable, $(Shock\ Time\ Dummy)_{k,t} \times (NCD\ Category\ Dummy)_k \times (SE\ Dummy)_{i,t}$, is positive and significant for both regression specifications. The coefficient on the triple interaction term is 11.55 using *SE1* and 9.32 using *SE2*, with *t*-statistics of 3.24 and 3.60, respectively. These findings provide further evidence that the quality of the supply-side

[43] It is estimated as 6.70 − (−8.98) = 15.68. 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.

[44] Our results are robust to different regression specifications (unreported and available upon request): (i) drop the *Shock Time Dummy* and replace it with year fixed effects, and (ii) drop *SE Dummy* and replace it with state-fixed effects. Results are also robust to the inclusion of both year and state fixed effects.

Table 8
Triple-difference regression model: Alternative measures for supply-side environment.

	(1)	(2)	(3)
Shock Time Dummy × NCD Category Dummy × SE Proxy	1.08	0.36	0.51
	(1.98)	(2.00)	(2.17)
Shock Time Dummy × NCD Category Dummy	0.47	−0.54	−0.26
	(0.50)	(−1.27)	(−0.61)
Shock Time Dummy × SE Proxy	−1.74	−0.58	−0.59
	(−5.57)	(−4.45)	(−3.16)
NCD Category Dummy × SE Proxy	−0.28	0.12	0.08
	(−0.37)	(0.45)	(0.20)
Shock Time Dummy	−4.01	−1.51	−2.37
	(−5.43)	(−3.61)	(−5.44)
NCD Category Dummy	−0.54	−0.27	−0.28
	(−0.54)	(−0.65)	(−1.09)
SE Proxy	2.26	0.80	0.97
	(4.62)	(4.04)	(3.35)
Log(GDP per Capita)	2.23	3.12	3.21
	(4.81)	(4.81)	(5.23)
Unemployment Rate/10	−0.41	−0.00	0.39
	(−2.12)	(−0.00)	(1.88)
Log(Population/10,000)	1.25	1.98	2.12
	(6.26)	(5.93)	(6.17)
Log(1 + # of Firms in a Category)	1.09	0.99	1.01
	(4.43)	(4.29)	(4.35)
Adj R^2	0.2452	0.2432	0.2437
Number of observations	22,800	16,853	18,050

This table reports regression results of the triple-difference model (Eq. (1)) using alternative measures for the supply-side environment. We use the sample used in Column (9) of Table 5. In Column (1), *SE Proxy* is a continuous measure that proxies for the supply-side environment based on the VC and NIH dollar amounts in a state in a year. Because VC and NIH in dollar terms are skewed, we first transform VC to log(VC + 1) and NIH to log(NIH + 1). We then normalize log(VC + 1) and log(NIH + 1) to mean 0 and standard deviation of 1. Last, we sum these two normalized variables to get a continuous measure of the supply-side environment. In Columns (2) and (3) the proxies for the supply-side environment are *R&D per GDP* and *SBIR/100*, respectively. 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. 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 all models we include state-level *Log (GDP per Capita)*, *Unemployment Rate/10*, and *Log(Population/10,000)*, as well as a category-level and *Log(1 + # of Firms in a Category)* 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.

environment is an essential condition for innovation to occur when innovative opportunities arise.

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 of Columns (1) and (2) of Table 6 using all seven NCDs and report the results in Columns (3) and (4), respectively. The results in Columns (3) and (4) show that the coefficient estimate for the triple-difference term is positive and significant for both model specifications. The parameter of interest, β_1 in Eq. (1), has a point estimate of 7.77 and 8.41 with a *t*-statistic of 4.22 and 3.75, using *SE1* and *SE2* respectively. These findings provide strong evidence that firms operating in better supply-side environments are more able to take advantage of the new innovative opportunities.

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

5. Robustness tests

In this section we report results from a series of additional sensitivity tests that we perform to insure the validity and robustness of our results.

5.1. Regression results excluding California

One possible concern is that our results might be driven by the outlier California, which hosts 22.31% of all private medical device firms. To alleviate this concern, we rerun all models in Table 6 while excluding California. We report the results in Table 7. We find that the coefficient of the triple-difference term is still positive, significant and economically meaningful after excluding California from the sample. This finding provides evidence that our results are not outlier-driven and thus further buttresses the robustness of our results.

5.2. Alternative measures of supply-side environment

We construct and use alternative measures of the supply-side environment to further test the robustness of our main results. First, we construct a continuous measure of the supply-side environment index using the dollar amount of VC and NIH grants, rerun the main test of Column (9) of Table 5, and report the results in Columns (1) of Table 8. Because the dollar amount of VC and NIH is skewed, we take the log, and because we have some zeroes we add one before taking the log. Then we standardize the variables to mean zero and a standard deviation of one (since VC and NIH are not on the same scale) and then sum them to construct a continuous index for the supply-side environment. The results are qualitatively the same as our main findings in Column (9) of Table 5.

Second, we use alternative continuous variables to proxy for the quality of the supply-side environment. Columns (2) and (3) of Table 8 use *R&D per GDP* and *SBIR/100* as a proxy for the supply-side environment, respectively. We find that the results still hold.

Third, we construct the dummy variable, $(SE\ Dummy)_{i,t}$, based on either *SE1* or *SE2*, in different ways and find that our results are

Table 9
Triple-difference regression model: Alternative measures for innovation.

	(1)	(2)	(3)	(4)
Shock Time Dummy × NCD Category Dummy × SE Dummy	6.00	6.27	7.54	8.14
	(2.35)	(2.46)	(4.01)	(3.90)
Shock Time Dummy × NCD Category Dummy	−0.16	−0.02	0.05	0.19
	(−0.51)	(−0.05)	(0.13)	(0.41)
Shock Time Dummy × SE Dummy	−9.83	−9.75	−5.27	−5.30
	(−6.22)	(−6.65)	(−4.52)	(−4.71)
NCD Category Dummy × SE Dummy	−3.01	−3.26	−2.84	−3.29
	(−0.81)	(−0.89)	(−0.77)	(−0.89)
Shock Time Dummy	−2.25	−2.22	−3.12	−3.08
	(−5.04)	(−5.17)	(−5.61)	(−5.79)
NCD Category Dummy	−0.10	−0.25	−0.20	−0.35
	(−0.38)	(−1.00)	(−0.59)	(−1.07)
SE Dummy	12.36	12.35	11.32	11.43
	(5.54)	(5.84)	(4.72)	(4.91)
Log(GDP per Capita)	3.19	3.16	3.86	3.83
	(5.40)	(5.47)	(5.75)	(5.84)
Unemployment Rate/10	−0.67	−0.68	−1.20	−1.22
	(−2.98)	(−2.96)	(−4.43)	(−4.42)
Log(Population/10,000)	1.64	1.63	1.79	1.78
	(6.45)	(6.59)	(6.68)	(6.85)
Log(1 + # of Firms in a Category)	1.08	1.07	1.09	1.08
	(4.44)	(4.52)	(4.48)	(4.56)
Adj R^2	0.2847	0.286	0.285	0.2879
Number of observations	22,800	22,800	22,800	22,800

This table reports regression results of the triple-difference model (Eq. (1)) using alternative measures for innovation. We use the sample used in Column (9) of Table 5. The supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 in Columns (1) and (2) and by *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3 in Columns (3) and (4). 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.

robust to all the transformations being tested. We try the following variations: (i) the dummy variable, $(SE\ Dummy)_{i,t}$, takes a value of one in state *i* in year *t* if it is more than the median or mean across states in year *t*, and takes a value of zero otherwise; and (ii) $(SE\ Dummy)_{i,t}$ 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. For brevity, the results of these two tests are not reported but are available upon request.

Overall, the findings in this subsection show that our results are not driven by a particular way of constructing the measure of the supply-side environment.

5.3. Alternative measures of innovation

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. We rerun our main model of Column (9) Table 5 using these alternative measures of innovation and report results in Table 9. The supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 in Columns (1) and (2) and by *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3 in Columns (3) and (4). 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. The coefficients associated with the triple-difference term are positive and significant in all regression specifications, confirming our main result that innovation is greater for the treatment group after the demand shock in states that have a better supply-side environment.

5.4. Number of firms in a state

While there are medical device firms in all states, some states have a higher concentration of firms (Table 2). One concern could be that our findings are driven by the number of firms initially present in a state. To address this concern, we rerun the model reported in Column (9) of Table 5 and all four models of Table 6, while including *Log(1 + # of Firms in a State)* as an additional control variable. We report the results in Table 10. The results show that our results hold.

5.5. Pre- and post-event window length

We now restrict the pre-event period to the same length as the post-event period and also vary the pre- and post-event window from three years before and after to seven years before and after. We rerun our main model of Column (9) of Table 5 and report results in Table 11. In Panel A the supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy* + *NIH Number Dummy* + *CC Dummy* = 3 and in Panel B by *SE2* = 1 if *VC Amount Dummy* + *NIH Amount Dummy* + *CC Dummy* = 3. Columns (1) through (5) report results when the pre- and post-event window varies from three years before and after the event to seven years before and after the event. In Column (6) the pre-event window is seven years and the post-event window is ten years (data availability limits our pre-event window to seven years). We find that the coefficient on the triple-difference term is insignificant in Columns (1) and (2) in Panels A and B, when the pre- and post-event window is three and four years before and after the NCD event. Yet, the coefficient on the triple-difference term is positive and becomes significant in Columns (3)–(6) in both panels. Moreover, the significance increases as the length of the pre- and post-event windows increase. These findings imply 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 three to seven 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.

Table 10
Triple-difference regression model: Number of firms in a state.

	(1)	(2)	(3)	(4)	(5)	(6)
Shock Time Dummy × NCD Category Dummy × SE Dummy	6.27	8.06	11.55	9.32	7.77	8.41
	(2.52)	(4.25)	(3.23)	(3.57)	(4.13)	(3.85)
Shock Time Dummy × NCD Category Dummy	−0.10	0.12	0.26	0.65	0.67	0.93
	(−0.30)	(0.30)	(0.92)	(1.85)	(1.66)	(1.91)
Shock Time Dummy × SE Dummy	−10.13	−5.89	−14.20	−7.00	−9.10	−7.19
	(−6.38)	(−4.83)	(−4.41)	(−3.36)	(−5.22)	(−4.95)
NCD Category Dummy × SE Dummy	−3.10	−2.94	−14.59	−14.96	−10.72	−13.89
	(−0.82)	(−0.78)	(−2.80)	(−2.81)	(−3.46)	(−4.50)
Shock Time Dummy	−0.12	−1.08	0.11	−1.06	0.35	−0.46
	(−0.60)	(−3.54)	(0.43)	(−4.79)	(0.80)	(−0.97)
NCD Category Dummy	−0.11	−0.21	0.08	−0.40	−0.43	−0.78
	(−0.40)	(−0.61)	(0.47)	(−2.26)	(−0.87)	(−1.26)
SE Dummy	12.34	11.43	20.38	20.60	14.72	19.33
	(5.62)	(4.80)	(4.78)	(4.59)	(5.61)	(7.38)
Log(GDP per Capita)	0.93	1.69	1.19	2.05	−1.45	−0.63
	(2.87)	(4.14)	(4.68)	(6.69)	(−2.14)	(−0.98)
Unemployment Rate/10	0.15	−0.41	0.93	0.15	0.73	0.07
	(0.64)	(−1.67)	(2.95)	(0.44)	(2.20)	(0.22)
Log(Population/10,000)	0.28	0.49	0.30	0.54	0.09	0.25
	(2.71)	(4.08)	(1.97)	(3.44)	(0.66)	(1.76)
Log(1 + # of Firms in a Category)	1.06	1.06	3.21	3.20	0.25	0.25
	(4.61)	(4.65)	(9.01)	(9.15)	(2.77)	(2.75)
Log(1 + # of Firms in a State)	1.17	1.11	2.11	2.03	2.01	1.97
	(6.84)	(6.92)	(6.98)	(6.97)	(9.09)	(9.12)
Adj R^2	0.3142	0.3130	0.4174	0.4273	0.3626	0.3834
Number of observations	22,800	22,800	10,800	10,800	18,900	18,900

This table reports regression results of the triple-difference model (Eq. (1)) including *Log(1 + # of Firms in a State)* as an additional control variable for different regression specifications. In Columns (1) and (2) we use the sample used in Column (9) of Table 5. In Columns (3) through (6) we use the sample used in Columns (1) through (4) of Table 6, respectively. Thus, Columns (1) and (2) use the sample when all non-NCD medical device categories are in the control group; Columns (3) and (4) use a one-to-one matched sample; and Columns (5) and (6) use all seven NCDs received by the categories to construct the treatment group. The supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy + NIH Number Dummy + CC Dummy* = 3 in Columns (1), (3), and (5) and by *SE2* = 1 if *VC Amount Dummy + NIH Amount Dummy + CC Dummy* = 3 in Columns (2), (4), and (6). For detailed variable definitions see Appendix B. Errors are robust and clustered at the device category level. *T*-statistics are in parentheses.

Table 11
Pre- and post-event window length.

	(1)	(2)	(3)	(4)	(5)	(6)
Panel A: The supply-side environment is proxied by *SE1 = 1* if *VC Number Dummy + NIH Number Dummy + CC Dummy = 3*						
Shock Time Dummy × NCD Category Dummy × SE Dummy	3.32	5.06	5.71	4.91	5.34	5.52
	(0.95)	(1.49)	(1.70)	(1.86)	(2.16)	(2.34)
Shock Time Dummy × NCD Category Dummy	−0.33	−0.23	−0.26	−0.27	−0.25	−0.19
	(−1.57)	(−0.97)	(−1.15)	(−1.20)	(−1.06)	(−0.76)
Shock Time Dummy × SE Dummy	−3.57	−6.36	−7.44	−7.42	−7.74	−8.49
	(−2.11)	(−3.23)	(−4.26)	(−5.22)	(−5.67)	(−6.19)
NCD Category Dummy × SE Dummy	−2.50	−4.13	−4.31	−3.11	−3.11	−3.11
	(−0.71)	(−1.02)	(−1.03)	(−0.83)	(−0.83)	(−0.83)
Shock Time Dummy	−2.10	−2.50	−2.72	−2.77	−2.77	−2.51
	(−5.77)	(−5.64)	(−5.77)	(−5.79)	(−5.77)	(−5.53)
NCD Category Dummy	−0.09	−0.23	−0.18	−0.16	−0.15	−0.14
	(−0.30)	(−0.74)	(−0.64)	(−0.62)	(−0.58)	(−0.54)
SE Dummy	7.98	10.20	11.39	11.58	11.71	12.12
	(3.83)	(4.09)	(4.90)	(5.55)	(5.56)	(5.63)
Log(GDP per Capita)	7.41	6.80	6.14	5.45	5.11	3.85
	(6.35)	(6.77)	(6.78)	(6.50)	(6.54)	(6.11)
Unemployment Rate/10	3.80	2.33	0.95	0.17	−0.23	−0.80
	(4.72)	(3.82)	(2.27)	(0.48)	(−0.72)	(−2.70)
Log(Population/10,000)	2.02	2.05	2.01	1.99	1.96	1.85
	(7.14)	(6.90)	(7.32)	(7.54)	(7.47)	(7.14)
Log(1 + # of Firms in a Category)	1.10	1.21	1.23	1.23	1.20	1.17
	(4.46)	(4.16)	(4.18)	(4.19)	(4.19)	(4.19)
Adj R^2	0.3068	0.2899	0.2907	0.2998	0.2988	0.2928
Number of observations	5700	7600	9500	11,400	12,350	15,200
Panel B: The supply-side environment is proxied by *SE2 = 1* if *VC Amount Dummy + NIH Amount Dummy + CC Dummy = 3*						
Shock Time Dummy × NCD Category Dummy × SE Dummy	−1.11	2.15	3.59	4.59	5.51	6.02
	(−0.39)	(0.88)	(1.76)	(2.66)	(3.46)	(3.96)
Shock Time Dummy × NCD Category Dummy	−0.05	0.04	0.02	−0.06	−0.04	0.00
	(−0.19)	(0.15)	(0.07)	(−0.23)	(−0.13)	(0.00)
Shock Time Dummy × SE Dummy	2.58	−0.84	−1.41	−1.41	−2.45	−4.52
	(1.15)	(−0.46)	(−0.87)	(−1.02)	(−1.97)	(−3.90)
NCD Category Dummy × SE Dummy	−1.42	−2.89	−2.87	−2.96	−2.96	−2.96
	(−0.35)	(−0.61)	(−0.68)	(−0.78)	(−0.78)	(−0.78)
Shock Time Dummy	−2.62	−3.00	−3.40	−3.60	−3.63	−3.32
	(−5.97)	(−5.71)	(−6.13)	(−6.22)	(−6.20)	(−6.01)
NCD Category Dummy	−0.20	−0.38	−0.34	−0.26	−0.25	−0.24
	(−0.60)	(−1.09)	(−1.06)	(−0.80)	(−0.77)	(−0.74)
SE Dummy	9.86	12.44	11.07	10.53	10.65	11.06
	(4.15)	(4.58)	(4.47)	(4.64)	(4.67)	(4.76)
Log(GDP per Capita)	8.78	7.85	7.06	6.30	5.98	4.46
	(6.55)	(6.80)	(6.93)	(6.76)	(6.75)	(6.39)
Unemployment Rate/10	3.39	2.09	0.73	−0.36	−0.87	−1.63
	(4.55)	(3.68)	(1.85)	(−1.14)	(−2.70)	(−4.72)
Log(Population/10,000)	1.93	1.99	2.16	2.26	2.23	2.12
	(7.02)	(6.66)	(7.51)	(7.87)	(7.76)	(7.42)
Log(1 + # of Firms in a Category)	1.10	1.21	1.23	1.24	1.21	1.18
	(4.48)	(4.16)	(4.20)	(4.22)	(4.22)	(4.18)

(*continued on next page*)

Table 11 (*continued*)

	(1)	(2)	(3)	(4)	(5)	(6)
Adj R^2	0.3396	0.3211	0.2925	0.2895	0.2881	0.2798
Number of observations	5700	7600	9500	11,400	12,350	15,200

This table reports regression results of the triple-difference model (Eq. (1)) using event windows of varying lengths. We use the sample used in Column (9) of Table 5. In Panel A the supply-side environment is proxied by *SE1* = 1 if *VC Number Dummy + NIH Number Dummy + CC Dummy* = 3 and in Panel B by *SE2* = 1 if *VC Amount Dummy + NIH Amount Dummy + CC Dummy* = 3. Columns (1) through (5) report results when the pre-event and post-event window varies from three years before and after the event to seven years before and after the event. In Column (6) the pre-event window is seven years and the post-event window is ten years. Errors are robust and clustered at the device category level. For detailed variable definitions see Appendix B. *T*-statistics are in parentheses.

6. Conclusion

Traditionally, research and policies for innovation have been concerned primarily with either supply- or demand-side factors. 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) have been considered for their role in fostering innovation. Demand-driven policies have been shown to 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). Yet, a crucial lacuna in the literature is our understanding of whether and how the interaction of the demand- and supply-side factors affects innovation. We show that innovation is dependent upon favorable supply-side factors pertaining to firms that strive to achieve and keep their competitive advantage, and demand-side factors pertaining to regulators and market end users that create innovative opportunities for firms (Coombs et al., 1987; Martin, 1994). We provide empirical evidence that the interaction of the demand- and supply-side factors is a key ingredient for the innovation process.

We take advantage of a quasi-natural experiment setting in the medical device industry. The Medicare NCDs at the national level are a positive exogenous shock to the demand for medical devices. Our measure of innovation is the number of FDA filings in a medical device category. This measure captures product innovation. We define and measure the quality of the supply-side environment at the state level. Employing a triple-difference testing approach, we find that private medical device firms in states with a better supply-side environment 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-side factors play essential roles in stimulating and nurturing innovative activities.

We also provide evidence that each of the supply-side factors: industry financing (VCs), government funding (NIH grants), and the presence of research universities are important for nurturing innovation. We show that the intersection of these factors enhances innovation. The highest level of innovation is achieved in the presence of all three supply-side factors, which provides evidence in support of the importance of the trilateral intersection of university, industry, and government (Etzkowitz and Leydesdorff, 2000; Viale and Etzkowitz, 2010; Etzkowitz, 2008).

An advantage of our study is that we are able to precisely observe a shift in product demand. We identify a set of shocks that increase the demand for product innovation. Conditional on these positive shifts, we explore the role of a firm's supply-side environment in fostering innovation. We find that firms that have a favorable supply-side environment, are more able to respond to and take advantage of the positive shift in demand for innovation. Our study shows that the interaction of the demand- and supply-side factors is important for innovation.

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: Parts 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 in advance the prospective

payment amounts that health providers will receive for services provided to Medicare enrollees. 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 (Neumann et al., 2005, p. 244). 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 (Neumann et al., 2005, 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 (Neumann et al., 2005). 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 (Neumann et al., 2005, p. 244). The CMS relies on its own medical experts and occasionally requests a formal health technology assessment from the Agency for Healthcare Research and Quality (Neumann et al., 2005).

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.
- *R&D per GDP* – R&D as a percentage of gross domestic product in state i year t.
- *SBIR/100* – the average annual Federal Small Business Innovation Research Funding divided by 100 per $1 Million of Gross Domestic Product in state i year t.
- *Log(GDP per Capita)* – the logarithmic transformation of the state-level GDP per capita in year t.
- *Unemployment Rate/10* – state-level unemployment rate in year t divided by ten.
- *Log(Population/10,000)* – the logarithmic transformation of state-level population in millions.
- *Log(1 + # of Firms in a Category)* – the logarithmic transformation of one plus the number of private medical device firms in category k year t.
- *Log(1 + # of Firms in a State)* – the logarithmic transformation of one plus the number of private medical device firms in state i year t.

References

Acemoglu, D., Linn, J., 2004. Market size in innovation: Theory and evidence from the pharmaceutical industry. Q. J. Econ. 119, 1049–1090.

Ackerly, D.C., Valverde, A.M., Diener, L.W., Dossary, K.L., Schulman, K.A., 2009. Fueling innovation in medical devices (and beyond): Venture capital in health care. Health Aff. 28, 68–75.

Acs, Z.J., Audretsch, D.B., 1987. An empirical examination of small firm growth. Econ. Lett. 25, 363–366.

Acs, Z.J., Audretsch, D.B., 1988. Testing the Schumpeterian hypothesis. East. Econ. J. 14, 129–140.

Acs, Z.J., Audretsch, D.B., 1993. In: Acs, Z.J., Audretsch, D.B. (Eds.), Small Firms and Entrepreneurship: An East-West Perspective. Cambridge University Press, Cambridge, MA.

Adner, R., Levinthal, D., 2001. Demand heterogeneity and technology evolution: Implications for product and process innovation. Manag. Sci. 47, 611–628.

Albert, M., Avery, D., Narin, F., McAllister, P., 1991. Direct validation of citation counts as indicators of industrially important patents. Res. Policy 20, 251–259.

Alcácer, J., Gittelman, M., 2006. Patent citations as a measure of knowledge flows: The influence of examiner citations. Rev. Econ. Stat. 88, 774–779.

Alcácer, J., Gittelman, M., Sampat, B., 2009. Applicant and examiner citations in U.S. patents: An overview and analysis. Res. Policy 38, 415–427.

Astebro, T.B., Dahlin, K.B., 2005. Opportunity knocks. Res. Policy 34, 1404–1418.

Belderbos, R., Carree, M., Diederen, B., Lokshin, B., Veugelers, R., 2004. Heterogeneity in R&D cooperation strategies. Int. J. Ind. Organ. 22, 1237–1263.

Bertrand, M., Duflo, E., Mullainathan, S., 2004. How much should we trust differences-in-differences estimates? Q. J. Econ. 119, 249–275.

Blume-Kohout, M.E., 2012. Does targeted, disease-specific public research funding influence pharmaceutical innovation? J. Policy Anal. Manag. 31, 641–660.

Blume-Kohout, M.E., Sood, N., 2013. Market size and innovation: Effects of Medicare Part D on pharmaceutical research and development. J. Public Econ. 97, 327–336.

Bound, J., Cummins, C., Griliches, Z., Hall, B.H., Jaffe, A., 1984. Who does R&D and who patents? In: Griliches, Z. (Ed.), R&D, Patents and Productivity. University of Chicago Press, Chicago, IL.

Budish, E., Roin, B.N., Williams, H., 2015. Do firms underinvest in long-term research? Evidence from cancer clinical trials. Am. Econ. Rev. 105, 2044–2085.

Butler, A., Cornaggia, J., 2011. Does access to external finance improve productivity? Evidence from a natural experiment. J. Financ. Econ. 99, 184–203.

Chava, Sudheer, Oettl, Alexander, Subramanian, Ajay, Subramanian, Krishnamurthy, 2013. Banking deregulation and innovation. J. Financ. Econ. 109, 759–774.

Chemmanur, T.J., Fulghieri, P., 2014. Entrepreneurial finance and innovation: An introduction and agenda for future research. Rev. Financ. Stud. 27, 1–19.

Cockburn, I.M., Henderson, R.M., 2001. Publicly funded science and the productivity of the pharmaceutical industry. In: In: Jaffe, A.B., Lerner, J., Stern, S. (Eds.), Innovation Policy and the Economy, vol. 1 MIT Press, Cambridge, MA.

Cohen, W.M., Nelson, R.R., Walsh, J.P., 2002. Links and impacts: The influence of public research on industrial R&D. Manag. Sci. 48, 1–23.

Colyvas, J., Crow, M., Gelijns, A., Mazzoleni, R., Nelson, R.R., Rosenberg, N., Sampat, B.N., 2002. How do university inventions get into practice? Manag. Sci. 48, 61–72.

Coombs, R., Saviotti, P., Walsh, V., 1987. Economics and technological change. Rowman & Littlefield Publishers.

Darby, M.R., Zucker, L.G., 2003. Growing by leaps and inches: creative destruction, real cost reduction, and inching up. Econ. Inq. 41, 1–19.
Dosi, G., 1982. Technological paradigms and technological trajectories: A suggested interpretation of the determinants and directions of technical change. Res. Policy 11, 147–162.
Dubois, P., de Mouzon, O., Scott-Morton, F., Seabright, P., 2015. Market size and pharmaceutical innovation. RAND J. Econ. 46, 844–871.
Edler, J., Georghiou, L., 2007. Public procurement and innovation – resurrecting the demand side. Res. Policy 36, 949–963.
Edler, J., Yeow, J., 2016. Connecting demand and supply: The role of intermediation in public procurement of innovation. Res. Policy 45, 414–426.
Etzkowitz, H., 1993. Technology transfer: The second academic revolution. Technol. Access Rep. 6, 7–9.
Etzkowitz, H., 2008. The Triple Helix: University-Industry-Government Innovation in Action. Routledge, Abingdon, United Kingdom.
Etzkowitz, H., Leydesdorff, L., 2000. The dynamics of innovation: From national systems and "mode 2" to a triple helix of university-industry-government relations. Res. Policy 29, 109–123.
Fagerberg, J., Srholec, M., 2008. National innovation systems, capabilities and economic development. Res. Policy 37, 1417–1435.
Fagerberg, J., Srholec, M., Verspagen, B., 2010. Innovation and economic development. In: Hall, B.H., Rosenberg, N. (Eds.), Handbook of the Economics of Innovation. Elsevier.
Fargen, K., Frei, D., Fiorella, D., McDougall, C., Myers, P., Hirsch, J., Mocco, J., 2013. The FDA approval process for medical devices: An inherently flawed system or a valuable pathway for innovation. J. Neurointerv. Surg. 5, 269–275.
Finkelstein, A., 2004. Static and dynamic effects of health policy: Evidence from the vaccine industry. Q. J. Econ. 119, 527–564.
Foote, S., 2002. Why Medicare cannot promulgate a national coverage rule: A case of regula mortis. J. Health Polit. Policy Law 27, 707–730.
Gjerde, K.A.P., Slotnick, S.A., Sobel, M.J., 2002. New product innovation with multiple features and technology constraints. Manag. Sci. 48, 1268–1284.
Greenhalgh, C., Rogers, M., 2010. In: Greenhalgh, C., Rogers, M. (Eds.), Innovation, Intellectual Property, and Economic Growth. Princeton University Press, Princeton, NJ.
Hall, B.H., Jaffe, A., Trajtenberg, M., 2005. Market value and patent citations. RAND J. Econ. 36, 16–38.
Hall, B.H., Link, A.N., Scott, J.T., 2001. Barriers inhibiting industry from partnering with universities: Evidence from the advanced technology program. J. Technol. Transfer 26, 87–98.
Hall, B.H., Link, A.N., Scott, J.T., 2003. Universities as research partners. Rev. Econ. Stat. 85, 485–491.
Harhoff, D., Narin, F., Scherer, F.M., Vopel, K., 1999. Citation frequency and the value of patented inventions. Rev. Econ. Stat. 81, 511–515.
Harhoff, D., Scherer, F.M., Vopel, K., 2003. Citations, family size, opposition and the value of patent rights. Res. Policy 32, 1343–1363.
Von Hippel, E., 1986. Lead users: A source of novel product concepts. Manag. Sci. 32, 791–806.
Hirschey, M., Skiba, H., Wintoki, M.B., 2012. The size, concentration and evolution of corporate R&D spending in U.S. firms from 1976 to 2010: evidence and implications. J. Corp. Finance 18, 496–518.
Holtzman, Y., 2012. The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad. WTP Advisors Report.
Iansiti, M., 2000. How the incumbent can win: Managing technological transitions in the semiconductor industry. Manag. Sci. 46, 169–185.
Klevorick, A.K., Levin, R.C., Nelson, R.R., Winter, S.G., 1995. On the sources and significance of interindustry differences in technological opportunities. Res. Policy 24, 185–205.
Kortum, S., Lerner, J., 2000. Assessing the contribution of venture capital to innovation. RAND J. Econ. 31, 674–692.
Kruger, K., Kruger, M., 2012. The medical device sector. In: Burns, L. (Ed.), The Business of Healthcare Innovation. Cambridge University Press, Cambridge, UK.
Kyle, M., McGahan, A., 2012. Investments in pharmaceuticals before and after TRIPS. Rev. Econ. Stat. 94, 1157–1172.
Lichtenberg, F.R., 2015. The impact of pharmaceutical innovation on premature cancer mortality in Canada, 2000–2011. Int. J. Health Econ. Manag. 15, 339–359.
Mansfield, E., 1995. Academic research underlying industrial innovations: Sources, characteristics, and financing. Rev. Econ. Stat. 77, 55–65.
Mansfield, E., 1997. Links between academic research and industrial innovations. In: David, P., Steinmueller, E. (Eds.), A Production Tension: University-Industry Collaboration in the Era of Knowledge-Based Economic Development. Stanford University Press, Palo Alto, CA.
Martin, M.J.C., 1994. Managing Innovation and Entrepreneurship in Technology-Based Firms. New Jersey, USA, John Wiley & Sons.
Meyer, B.D., 1995. Natural and quasi-experiments in economics. J. Bus. Econ. Stat. 13, 151–161.
Mohnen, P., Hoareau, C., 2003. What type of enterprise forges close links with universities and government labs? Evidence from CIS 2. Manag. Decis. Econ. 24, 133–145.
Moser, P., Ohmstedt, J., Rhode, P.W., 2017. Patent citations – an analysis of quality differences and citing practices in hybrid corn. Manag. Sci (forthcoming).
Mowery, D., Rosenberg, N., 1979. The influence of market demand upon innovation: A critical review of some recent empirical studies. Res. Policy 8, 102–153.
Mowery, D.C., Shane, S., 2002. Introduction to the special issue on university entrepreneurship and technology transfer. Manag. Sci. 48, 5–9.
Neumann, P.J., Divi, N., Beinfeld, M.T., Levine, B., Keenan, P.S., Halpern, E.F., Gazelle, G.S., 2005. Medicare's national coverage decisions, 1999–2003: Quality of evidence and review times. Health Aff. 24, 243–254.
Newell, R.G., Jaffe, A.B., Stavins, R.N., 1999. The induced innovation hypothesis and energy-saving technological change. Q. J. Econ. 114, 941–975.
Owen-Smith, J., Riccaboni, M., Pammolli, F., Powell, W.W., 2002. A comparison of U.S. and European university-industry relations in the life sciences. Manag. Sci. 48, 24–43.
Phillips, G., Sertsios, G., 2016. Financing decisions and new product introductions of private and publicly traded firms. Working Paper. Tuck School of Business at Dartmouth and NBER.
Popp, D., 2002. Induced innovation and energy prices. Am. Econ. Rev. 92, 160–180.
Rogers, E., 2003. Diffusion of innovations, 5th ed. Free Press.
Samila, S., Sorenson, O., 2010. Venture capital as a catalyst to commercialization. Resour. Policy 39, 1348–1360.
Sampat, B., Williams, H., 2015. How do patents affect follow-on innovation? Evidence from the human genome. Working Paper.
Schmookler, J., 1962. Economic sources of inventive activity. J. Econ. Hist. 22, 1–20.
Schmookler, J., 1966. Invention and economic growth. Harvard University Press, Massachusetts. USA.
Schumpeter, J., 1939. In: Fels, R. (Ed.), Business Cycles. A Theoretical, Historical and Statistical Analysis of the Capitalist Process. Abridged, With an Introduction. McGraw-Hill Book Company, New York Toronto London.
Shane, S.A., Ulrich, K.T., 2004. 50th anniversary article: Technological innovation, product development, and entrepreneurship in management science. Manag. Sci. 50, 133–144.
di Stefano, G., Gambardella, A., Verona, G., 2012. Technology push and demand pull perspectives in innovation studies: Current findings and future research directions. Res. Policy 41, 1283–1295.
Toole, A.A., 2012. The impact of public basic research on industrial innovation: Evidence from the pharmaceutical industry. Res. Policy 41, 1–12.
Trajtenberg, M., 1990. A penny for your quotes: Patent citations and the value of innovations. RAND J. Econ. 21, 172–187.
US-Congress, C., 1984. Federal policies and the medical devices industry. U.S. Congress, Office of Technology Assessment.
Veugelers, R., Cassiman, B., 2005. R&D cooperation between firms and universities. Some empirical evidence from Belgian manufacturing. Int. J. Ind. Organ. 23, 355–379.
Viale, R., Etzkowitz, H., 2010. The capitalization of knowledge: A triple helix of university-industry-government. Edward Elgar, Cheltenham, United Kingdom.
Weiss, A.R., Birnbaum, P.H., 1989. Technological infrastructure and the implementation of technological strategies. Manag. Sci. 35, 1014–1026.
Williams, H.L., 2015. Intellectual property rights and innovation: Evidence from health care markets. Working Paper.
Yin, W., 2008. Market incentives and pharmaceutical innovation. J. Health Econ. 27, 1060–1077.
Yin, W., 2009. R&D policy, agency costs and innovation in personalized medicine. J. Health Econ. 28, 950–962.
Zirger, B.J., Maidique, M.A., 1990. A model of new product development: An empirical test. Manag. Sci. 36, 867–883.
Zmud, R.W., 1984. An examination of "push-pull" theory applied to process innovation in knowledge work. Manag. Sci. 30, 727–738.
Zucker, L.G., Darby, M.R., Brewer, M.B., 1998. Intellectual human capital and the birth of U. S. biotechnology enterprises. Am. Econ. Rev. 88, 290–306.
Zucker, L.G., Darby, M.R., Armstrong, J.S., 2002. Commercializing knowledge: University science, knowledge capture, and firm performance in biotechnology. Manag. Sci. 48, 138–153.