The Long-Run Impacts of Regulated Price Cuts: Evidence from Medicare

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December 16, 2024

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Abstract

We investigate the effects of substantial Medicare price reductions in the medical device industry, which amounted to a 61% decrease over 10 years for certain device types. Analyzing over 20 years of administrative and proprietary data, we find these price cuts led to a 29% decline in new product introductions and an 80% decrease in patent filings, indicating significant reductions in innovation activity. Manufacturers reduced market entry and relied more heavily on outsourcing to other producers, which was associated with higher rates of product defects. Our calculations suggest the value of lost innovation may fully offset the direct cost savings from the price cuts. We propose that better-targeted pricing reforms could mitigate these negative effects. These findings underscore the need to balance cost containment with incentives for innovation and quality in policy design.

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The United States spends over $4.3 trillion annually on health care, with federal, state, and local governments collectively financing half of this expenditure (CMS, 2022). This substantial public investment not only provides essential health services but also shapes innovation and competitive dynamics within the industry. The vast scale of healthcare spending has drawn considerable criticism, with many arguing that a substantial portion is "wasteful," providing little to no direct improvement in patient outcomes (e.g., Shrank, Rogstad and Parekh, 2019). However, efforts to reduce spending may inadvertently suppress incentives for innovation—the driving force behind most advances in life expectancy and quality of care (Cutler, Rosen and Vijan 2006). This tension underscores the challenge faced by health care regulators: efforts to eliminate short-term "waste" must be balanced against promoting long-term technological progress.

In this paper, we explore this tension by providing empirical evidence on how changes in government payment regulations affect health care innovation, market structure, and product quality. We leverage a series of Medicare-mandated price cuts in the durable medical equipment (DME) market, combined with over 20 years of administrative and proprietary data on DME products, patents, and manufacturers. DME includes medical devices for home use, such as insulin pumps, CPAP machines, oxygen concentrators, and wheelchairs. The DME industry is an excellent empirical setting due to high government spending (Medicare spends over $9 billion per year) and significant research and development (R&D) activity. Policymakers have expressed concerns that Medicare's "generous payment rates" make the market "especially vulnerable to waste" (Committee on Small Business, 2012). Yet, the DME market has witnessed remarkable innovations that have significantly improved quality of life. For example, portable continuous oxygen therapy devices have replaced heavy, hazardous oxygen tanks and bulky, TV-sized consoles (American Association for Respiratory Care, 2013). Similarly, continuous glucose monitors now provide real-time blood sugar readings without needing physician visits or painful fingerstick tests.(Food and Drug Administration 2016, Hirsch 2018, Olczuk and Priefer 2018)

A key question is whether fiscal savings from price regulation come at the cost of slowing valuable medical innovation. We explore this question by studying a series of reforms enacted by the Centers for Medicare and Medicaid Services (CMS) after the Medicare Modernization Act of 2003, which aimed to lower Medicare DME spending due to concerns about overly generous payment rates. These reforms unfolded in three stages: a

9.5% nationwide price cut in 2009 targeting high-spending DME categories; supplier auctions between 2011 and 2016 in the largest 100 metropolitan statistical areas, leading to further price reductions; and a nationwide price cut in 2016 applying auction-generated prices more broadly. Together, these reforms lowered Medicare prices for affected categories by 61% on average over 7 to 10 years compared to unaffected categories.[1]

Although Medicare does not directly pay manufacturers, we hypothesize—and empirically confirm—that reducing reimbursement rates to suppliers, whether through direct price cuts or auctions, exerts downward pricing pressure on manufacturers, affecting their incentives to innovate and invest in quality improvements.

We begin by presenting a simple conceptual framework to understand the potential impact of Medicare price cuts. In our model, a firm decides whether to incur fixed R&D costs for innovation and chooses optimal product quality. Higher product quality increases demand but also requires higher production costs. We predict that Medicare price cuts reduce manufacturer revenue, product quality, and production costs. However, innovation is only weakly reduced, depending on whether firms can still cover fixed R&D costs despite lower margins.

We estimate the impact of these price cuts using a stacked difference-in-differences approach, comparing affected and unaffected DME categories over time. To corroborate our findings, we exploit additional variation in pre-reform Medicare market shares across DME categories, employing a dose-response model. Lastly, we examine firm-level outcomes by analyzing variation in firms' exposure to price cuts based on pre-reform product portfolios. We find consistent results across all three specifications and a range of outcomes.

Guided by our conceptual model, we examine four sets of outcomes: manufacturer revenue, innovation (measured by R&D spending, patents, and FDA device submissions), market structure (firm entry and outsourcing rates), and product quality (device repair rates and adverse events). We link multiple data sources, including FDA records, U.S. and global patents, and health care claims. Due to differing classification systems of device-related outcomes across databases, we use text analysis techniques to create a novel comprehensive database linking global patents, FDA device submissions, registrations, adverse events reports, Medicare fee schedules and claims, and private insurer claims across all medical device categories.

[1] Authors' analysis of Medicare claims data.

Manufacturers more exposed to price cuts experienced a significant revenue decline of 36% relative to those less exposed, demonstrating that lowering supplier reimbursement rates creates significant upstream revenue shocks. Correspondingly, manufacturers significantly reduced innovation in affected DME categories relative to unaffected ones: FDA device submissions decreased by 29%, U.S. patents fell by 80%, and firms with above median exposure to the price cuts reduced R&D spending by 41% relative to other firms. Despite the reduction in innovation quantity, we find no change in innovation quality or direction.

The cost-conscious environment also altered market structure. The number of new entrants decreased by 40%, driven by a 72% decline in U.S. manufacturers' entry, with no significant change among foreign manufacturers, perhaps reflecting their relative cost advantage. Furthermore, manufacturers increasingly outsourced production to contractors; among manufacturers still operating, outsourcing increased by 33%. Firms also reported lower cost of goods sold (COGS). These results suggest an increased reliance on global supply chains.

While cost-reduction measures may lead to more efficient production, our findings suggest trade-offs in product quality, consistent with predictions from our conceptual model. We observe a significant 0.8 percentage point increase in the repair and replacement rates for affected DME among Medicare beneficiaries, a 200% increase relative to the pre-period. FDA adverse event reports increased in affected DME categories despite decreasing utilization (Ji 2023), concentrated among manufacturers that outsourced production. Outsourcing manufacturers experienced a 129% increase in the likelihood of experiencing hospital-reported adverse events, compared with a marginally significant 22% increase among non-outsourcing firms.

Although a comprehensive welfare analysis is beyond this paper's scope, we provide suggestive evidence that the value of lost innovation may exceed public spending savings. We estimate annual R&D expenditure losses of $2.6 billion—a figure that may conservatively estimate the true value of innovation (Bloom, Schankerman and Van Reenen, 2013)—which is substantial relative to the $3.8 billion in Medicare savings.

However, our model suggests price cuts need not reduce innovation if firms can still cover fixed R&D costs. By more strategically targeting categories with higher profit margins, Medicare could reduce prices while minimizing negative effects on innovation—though product quality may still decline. Our calculations show that Medicare did not select cate-

gories with the highest profit margins, suggesting a more targeted approach could achieve savings while lessening the impact on innovation.

Our paper contributes to several strands of the literature. First, we provide empirical evidence on the effects of government price regulation on innovation, market structure, and product quality in the medical device industry—a sector that has received less attention than pharmaceuticals due to data limitations.[2] By integrating diverse data sources through text analysis, we offer a comprehensive examination of the long-term impacts of price regulation. Our study extends the broader literature on regulatory tools affecting innovation by examining the specific impact of price regulations.[3] Contrary to Clemens and Rogers (2023), we find that, in contemporary contexts, firms respond to cost-conscious procurement environments by reducing costs via outsourcing, which introduces challenges, notably the erosion of product quality.

Second, we contribute to research on the relationship between market profitability and medical innovation (Acemoglu and Linn 2004, Finkelstein 2004, Blume-Kohout and Sood 2013, Agha, Kim and Li 2022), providing, to our knowledge, the first quasi-experimental evidence on a large-scale health care price reform.[4]

Furthermore, by examining how Medicare price reforms affect global patenting, we provide the first direct evidence of the impacts of U.S. health policy on global innovation. Prior work on regulatory spillovers has primarily focused on the effects of Medicare prices and reforms on non-Medicare populations within the U.S. (Clemens and Gottlieb 2017, Einav et al. 2020, Barnett, Olenski and Sacarny 2023). Despite the widely held view that the U.S. plays a disproportionate role in driving global medical innovation, empirical evidence quantifying this influence has been limited.

Lastly, we examine how procurement prices affect the supply chain and the conse-

[2]Notable exceptions include Ding, Duggan and Starc (forthcoming), Grennan (2014), Grennan and Town (2020), Ji (2023), and Rogers (2023).

[3]Previous research has explored the impact on innovation from patent protection (Budish, Roin and Williams 2015), entry regulation (Grennan and Town 2020; Rogers 2023), billing rules (Dranove et al. 2022, Dranove, Garthwaite and Wu 2022), tort reforms (Galasso and Luo 2017), tax incentives (Dechezleprêtre et al. 2023), public R&D investments (Azoulay et al. 2019), and procurement policies (Cozzi and Impullitti 2010, Slavtchev and Wiederhold, 2016, Che, Iossa and Rey, 2021, Clemens and Rogers 2023).

[4]Existing evidence on the impact of medical technology price and innovation, exclusively in the pharmaceutical market, is limited to theoretical (Filson 2012), simulation-based (Abbott and Vernon 2007), and correlational (Civan and Maloney 2009, Giaccotto, Santerre and Vernon 2005) studies. See Philipson and Durie (2021) for a comprehensive review. Our estimated price elasticity of 1.09 for medical device patents is similar to the average elasticity in the pharmaceutical industry reported in these studies.

quences of outsourcing. While existing literature has explored the impact of price controls on market structure (Kyle 2007, Carranza, Clark and Houde 2015), our study is among the first to provide empirical evidence through a natural experiment. We establish a causal link between procurement pricing, outsourcing, and product quality, highlighting how cost-reduction strategies can inadvertently erode product quality.

This paper is organized as follows: Section 1 provides background, Section 2 describes a conceptual framework, Section 3 describes our data, Section 4 presents our empirical strategy, Section 5 presents results on innovation, Section 6 presents results on market structure and quality, Section 7 discusses the value of lost innovation and alternative payment reform options, and Section 8 concludes.

1 Setting

1.1 Medical Devices and Durable Medical Equipment

Medical devices are instruments or apparatuses intended for the diagnosis, treatment, or prevention of disease. Unlike pharmaceutical drugs, they do not achieve their function through chemical action.[5] These devices encompass a wide range of products, including diagnostic equipment (e.g., X-ray machines, electrocardiography (ECG) machines), therapeutic devices (e.g., infusion pumps), prosthetics (e.g., artificial limbs, dentures), implants (e.g., pacemakers, stents), and assistive devices (e.g. mobility scooters, communication aids).

The U.S. Food and Drug Administration (FDA) regulates medical devices through pre-market approval, clearance, and post-market surveillance. Devices are classified into three categories based on their risk level: Class I (low risk), Class II (moderate risk), and Class III (high risk). Class III devices typically require pre-market approval (PMA), necessitating manufacturers to provide data demonstrating safety and effectiveness. Class II devices typically are subject to either PMA or pre-market notification, known as 510(k), which requires proof that a new device is substantially equivalent to a previously approved device. Class I devices are generally exempt from either PMA and 510(k) but must be registered with the FDA.[6]

[5] https://www.fda.gov/media/131268/download

[6] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/

Durable medical equipment (DME) is a category of medical devices designed for home use, facilitating recovery after hospitalization or managing chronic illnesses. Examples of DME include wheelchairs, glucose monitors, oxygen concentrators, and nebulizers. DME devices can be classified as Class I, II, or III.

1.2 Innovation in Durable Medical Equipment

DME is an area with significant R&D activities, leading to technological advances that have profoundly improved quality of life.

Figure A1 illustrates how DME innovation has enhanced well-being over time. In the 1940s, oxygen therapy relied on cumbersome oxygen tanks, which were difficult to maneuver and posed fire hazards. These tanks also required frequent replacement. The invention of the first oxygen concentrator in the 1970s revolutionized therapy by extracting oxygen from ambient air, eliminating the need for tanks. Early concentrators, however, were bulky and limited user mobility. The introduction of portable oxygen concentrators in the 2000s allowed patients to move freely during therapy. Modern models are fully portable, weighing as little as three pounds, improving mobility during therapy (American Association for Respiratory Care, 2013). Another significant evolution occurred in noninvasive ventilators, which began with devices like the "iron lung." Today, these devices are fully portable during use (Taylor, 2024).

These advancements resulted from numerous incremental improvements, often formalized through patents. One notable example is the innovation in powered wheelchairs, exemplified by U.S. patent US-5944131-A. Filed before the Medicare price cuts and valued at $180 million (2016 USD), this patent describes a wheelchair with superior maneuverability, comfort, and user control via advanced drive wheel positioning, enhancing user independence. It has influenced over 230 subsequent patents across diverse technologies, including anti-tip mechanisms, suspension systems, patient support systems, obstacle navigation, and even automobile design.

Innovation in Continuous Positive Airway Pressure (CPAP) machines provides another example. Patent US-6112746-A, filed before Medicare price cuts and valued at $30 million (2000 USD), introduced a CPAP mask design offering a more comfortable seal and bet-

`overview-device-regulation`

ter fit for diverse facial structures, improving therapy effectiveness. This patent has been cited by 643 subsequent patents, including technologies ranging from respirator masks and infant oxygen masks to ventilator systems and vehicle catalytic converters.

Additional examples from DME categories affected by the price cuts—including infusion pumps and hospital beds—are presented in Appendix A.

1.3 Medicare Reform of Payments for DME

Medicare, the federal health insurance program for patients aged 65 and older in the U.S., covers DME under Part B. To receive DME benefits, patients must obtain a prescription from their physician and fill it with a Medicare-certified supplier—either a specialized DME store or pharmacy. Upon filling the prescription, Medicare reimburses suppliers based on predetermined rates. Patient cost-sharing is limited: while Part B requires a 20% coinsurance, nearly 90% of patients have supplemental insurance to cover this cost. (Ochieng, Cubanski and Neuman, 2024)

Historically, Medicare reimbursed DME based on fee schedules set by CMS, largely based on list prices from the late 1980s that were adjusted for inflation over time. Due to concerns about high prices in the DME sector, the Medicare Modernization Act of 2003 authorized future price cuts through supplier auctions. A year later, CMS hosted two Program Advisory and Oversight Committee (PAOC) meetings and specifically named the top three spending categories (oxygen equipment, wheelchairs, and nebulizers) most likely to be included in the price reform (Program Advisory and Oversight Committee, 2004). In 2007, Medicare announced the initial product categories for auctions and nine metropolitan statistical areas (MSA) where auctions would occur. Before implementing the auctions, Medicare introduced a nationwide 9.5% price reduction for these selected product categories in 2009. (Centers for Medicare and Medicaid Services, 2024)

In January 2011, the auctions began in the nine MSAs and expanded to an additional 91 MSAs by July 2013. The product categories subject to auctions also grew, eventually covering approximately half of total DME spending in these areas. With the exception of the first round, the product categories included in the auctions during our sample period were announced two years before their enactment date.[7] Prior research finds that the re-

[7]The original implementation date for the first round of auctions was January 2009, but CMS postponed the implementation by two years and instead imposed a one-time 9.5% price reduction for all treat-

form led to an average 45% price reduction in treated MSAs across all affected categories.[8]

In 2016, remaining MSAs and rural areas began setting prices based on a blend of auction-generated prices and existing fee schedules. By 2019, 13 product categories were subject to price cuts, while others continued under existing fee schedules. Over 7 to 10 years following the price cuts, treated categories experienced a statistically significant 61% reduction in average Medicare prices compared to unaffected categories across all MSAs and rural regions (raw trends shown in Figure A2, Panel (a)).[9] Between 2009 and 2019, annual Medicare spending in affected categories decreased from approximately $4.5 billion to $2 billion, while spending in unaffected categories increased from $4.5 billion to $6 billion (as shown in Figure A2, Panel (b)).

Assignment to the Medicare price cuts was based on product categories. The set of billing codes (Healthcare Common Procedure Coding System codes, or HCPCS codes) corresponding to each category is updated quarterly to reflect additions, deletions, and coding changes. These updates ensure that all products within a covered category remain subject to the reform, even if they receive new HCPCS codes. For instance, in the first quarter of 2011, codes K0734–K0737 were retired and replaced by E2622–E2625, all remaining under the same price reform.[10]

Although Medicare reimburses suppliers rather than manufacturers, we expect changes in Medicare prices to affect upstream manufacturer revenue and R&D activity. Since Medicare reimburses DME based on billing codes, which vary by product specifications (such as capacity, material, or size) but not by manufacturer brand or other indicators of product quality, suppliers can adjust their product offerings based on the reimbursement scheme. Under generous reimbursement rates, suppliers may demand higher quality products to attract more Medicare patients, who are insensitive to price due to insurance coverage but may be sensitive to product quality differences. Lower reimbursement rates, either from direct price cuts or through bidding at the billing code level, incentivize suppliers to source lower-cost products from manufacturers to maintain positive profit margins and to win

ment products in 2009.

[8]The auction rules required bids below existing fee schedule prices, resulting in weakly lower prices by definition (Ding, Duggan and Starc forthcoming, Ji 2023). Ji (2023) shows that flaws in the auction design led to prices below the competitive equilibrium, intensifying the downward pricing pressure from supplier competition.

[9]Authors' analysis of Medicare claims data.

[10]See https://dmecompetitivebid.com/Palmetto/Cbicrd1Rebid.Nsf/files/Quarterly_Updates_2011.pdf/$File/Quarterly_Updates_2011.pdf

Medicare contracts (which were awarded based on price bids for each billing code). This intuition of a cost-quality trade-off is formalized in Section 2. Empirical data also support the intuition that reductions in retail market prices impact negotiations between suppliers and manufacturers and manufacturer revenue. This effect is shown in Figure A3, which plots firm-level revenue for firms with varying exposure to the Medicare price cuts. The figure shows similar trends in log revenue across both groups prior to the price cuts and a clear divergence beginning with the first round of price cuts in 2009.

2 Conceptual Framework

We present a simple conceptual framework to illustrate the potential impact of Medicare price cuts on our outcomes of interest: innovation, production costs (which involve changes in supply chains), and product quality.

Consider a market with one firm that chooses among a set of potential innovations $I = \{1, 2, 3...\}$, one national insurer (Medicare) that determines a set of regulated prices $P = \{p_1, p_2, p_3...\}$ for these innovations, and fully insured individuals whose demand is $Q = \{q_1, q_2, q_3...\}$. Due to insurance coverage, demand is perfectly inelastic to price changes but increases concavely with product quality $S = \{s_1, s_2, s_3...\}$. Specifically, for any given innovation i, demand is $q_i = q(s_i)$, with $q'(s_i) > 0$ and $q''(s_i) \leq 0$, reflecting that consumer demand increases with quality but at a decreasing rate.

For each potential innovation $i \in I$, let Ω_i denote the fixed cost of the R&D process, and c_i the marginal cost of production once the innovation is realized.[11] R&D is successful with probability ϕ_i upon incurring the fixed cost. The marginal cost of production increases with product quality at an increasing rate: $c_i = c(s_i)$, with $c'(s_i) > 0$ and $c''(s_i) > 0$, reflecting the increasing complexity of quality improvements at higher quality levels.

The firm's profit-maximization problem occurs in two stages: First, the firm decides whether to incur the fixed R&D cost Ω_i to realize innovation i. In the second stage, the firm chooses the optimal product quality s_i to maximize expected profits.

[11] Unlike small-molecule drugs, the marginal production costs for most medical devices are not negligible. The manufacturing process significantly influences the final product's quality, similar to biologic drugs.

An innovation $i \in I$ is pursued if it generates non-negative expected profits:

$$E\Pi_i = \phi_i[(p_i - c(s^*))q(s^*) - \Omega_i] - (1 - \phi_i)\Omega_i \geq 0$$

where

$$s_i^* = argmax(p_i - c(s_i))q(s_i).$$

For a given set of prices P, let $\tilde{I}$ denote the set of innovations the firm decides to invest in: $\tilde{I} = \{i \in I | E\Pi_i \geq 0\}$.

Lemma 1. *The profit-maximizing quality s_i^* is increasing in the regulated price p_i, provided that $p_i > c_i(s_i)$.*

Proof. See Appendix Section C. □

The lemma indicates that as the regulated price p_i decreases, the firm reduces the optimal product quality s_i^*, leading to lower production costs (since $c'(s_i) > 0$).

Theorem 1. *The set of innovations the firm invests in $\tilde{I}$ is weakly increasing in the regulated price p_i. Let $\tilde{I}$ denote the set of innovations the firm invests in under the original set of regulated prices $P = \{p_1, p_2, p_3, \ldots\}$. There exists a set of prices $\dot{P} = \{\dot{p}_1, \dot{p}_2, \dot{p}_3, \ldots\}$ such that $\dot{P} \leq P$ and $\dot{P} \neq P$, while maintaining the same set of invested innovations $\tilde{I}$. That is, $\exists \dot{P} \leq P, \dot{P} \neq P$ such that $\dot{I} = \tilde{I}$. Moreover, there also exists a set of prices $\ddot{P} = \{\ddot{p}_1, \ddot{p}_2, \ddot{p}_3, \ldots\}$ such that $\ddot{P} \leq P$ and $\ddot{P} \neq P$, and the set of invested innovations is strictly smaller: $\ddot{I} \subset \tilde{I}$.*

Proof. See Appendix Section C. □

The theorem states that reducing prices does not necessarily decrease the number of innovations the firm invests in; instead, innovation may remain the same or decrease depending on how the price cuts affect the firm's expected profits. Figure 1 illustrates these concepts: Panel (a) shows the firm's expected profits for all potential innovations, ordered from highest to lowest, along the x-axis. The area under the curve represents the total profit. Panel (b) demonstrates how rotating the profit curve (by reducing prices strategically) can lower firm profits (shaded area) without reducing the set of invested innovations. In the extreme case, the social planner can set $p_i = \Omega_i/(\phi_i q_i) + c_i$ to maximize Medicare savings while still realizing the desired innovations. Panel (c) shows that a downward

shift in the profit curve (due to substantial uniform price cuts) can reduce both firm profits and the number of innovations pursued.

In summary, we generate three predictions from the theoretical framework. Following Medicare price cuts:

1. Manufacturer revenue declines (apparent from the profit function);
2. Product quality declines, as do production costs (Lemma);
3. Innovation weakly declines (Theorem).

We empirically test these predictions in Sections 5 and 6.

3 Data and Summary Statistics

In this section, we describe the datasets used, the construction of our baseline sample, and report summary statistics. Figure A4 provides a high-level overview of the data used to construct each of our key outcome variables.

3.1 Data and Sample Construction

We combine over 20 years of administrative and proprietary data sets, including FDA medical device submissions, U.S. and global patents, health care claims, and firm financial reports.

Patents are measured using Digital Science's Dimensions database, which covers all patent filings with the United States Patent and Trademark Office (USPTO) and over 100 other global offices between 1996 and 2016.[12] FDA device submissions from 1996 to 2016 are obtained from PMA and 510(k) databases, which cover all medical devices requiring FDA approval for the U.S. market. We use 100% Medicare claims data (1999–2019) and MarketScan data on private insurer claims (1996–2013) to measure DME prices and utilization among traditional Medicare beneficiaries and the privately insured, respectively, as well as device repairs and replacements as quality outcomes. Additional measures of product quality are constructed using the FDA's Manufacturer and User Facility Device

[12] We choose 2016 as the end date to ensure we capture the universe of global patents filed by the end of our study period, recognizing that patent applications are not observed until they are granted—a process that can take multiple years.

Experience (MAUDE) database on adverse events related to medical device use, available from 1992 to 2019. We measure contracting activities using the FDA Device Registration and Listing database. Manufacturer-level financial data and R&D expenditures for publicly traded firms are obtained from Compustat, supplemented with analogous information for private firms from Orbis. Patent valuations for patents filed by publicly traded firms are sourced from Kline et al. (2019). A detailed description of each dataset is provided in Appendix Section B.

To generate our baseline dataset, we link all data to DME product categories, as reforms were implemented at the category level. DME product categories are Medicare-assigned groupings of related Healthcare Common Procedure Coding System (HCPCS) codes—the billing codes for DME items. However, the FDA and patent data are organized differently. All FDA databases (PMA, 510(k), registration and listing, MAUDE) are organized by FDA product codes—a device classification system used by the FDA comprising approximately 6,500 codes.

We manually link FDA product codes to each DME product category by comparing HCPCS code descriptions within each product category, product category descriptions, and FDA product code descriptions. The full crosswalk is shown in Appendix Section B.3.

Patents are organized by the Cooperative Patent Classification (CPC) codes, which harmonize existing U.S. and European patent classification systems into a common system with approximately 250,000 distinct codes.[13] We link patent data to DME categories by first compiling a list of keywords and CPC codes corresponding to each DME product category description. Using the Dimensions platform (Hook, Porter and Herzog, 2018), we collect all global patents granted whose patent text contains all keywords and at least one CPC code.[14] The keywords and CPC codes are reported in Appendix Section B.4.

Our baseline dataset is a product category–year level panel dataset from 1996 to 2016, containing all 51 DME categories with at least one patent filed in the year prior to the announcement of the price reform. We assign the 13 product categories that experienced price cuts to the "treatment" group and the remaining 38 product categories to the "con-

[13] https://www.epo.org/en/searching-for-patents/helpful-resources/first-time-here/classification/cpc

[14] Unless the patent was filed in a non-CPC country (i.e. non-EU and non-U.S.), in which case we only match on keywords and not on CPC codes. The title and abstract of non-English patents were translated into English by Dimensions.

trol" group. Our baseline sample includes 236,656 DME-related global patents, of which over 100,000 are granted in the U.S. Our analysis of FDA submissions focuses on product categories for which a PMA or 510(k) would be required. Applying this restriction yields 8 treatment and 18 control product categories, covering a total of 3,690 unique device submissions.

We define our baseline sample of firms analogously, including all manufacturers that filed at least one patent in one of the treatment categories prior to the price cuts. Patents are linked to manufacturers by extracting patents by assignee name using the Dimensions platform. Our baseline sample includes 53 publicly traded medical device manufacturers that have patented in affected DME categories at least once prior to the price cuts. We focus on publicly traded firms because their financial data can be reliably observed in Compustat. In supplementary robustness analyses, we also include private firms (drawing data from Orbis), increasing our sample size to 486 manufacturers.

3.2 Variable Definitions

Product Category-Level Outcomes We analyze two innovation outcomes at the product category-year level: (1) the total number of FDA PMA and 510(k) submissions, and (2) the total number of patents filed in the U.S. These measures are related but distinct. FDA device submissions capture the introduction of unique products available to consumers, representing the final stage before market entry. Patents measure the generation of novel ("patentable") ideas, which may or may not materialize into products. A single patent can be associated with one or more products, and a given product may utilize technology from multiple patents. Since Class I devices are generally exempt from FDA approval, patents allow us to capture R&D activities in the exempt categories. Additionally, patents contain rich textual and citation information, enabling straightforward analysis of the direction and quality of new innovation.

We analyze two market structure outcomes: (1) the number of new manufacturers entering each product category-year, and (2) the number of newly FDA-registered manufacturing contractors in each product category-year. We define entry as new manufacturer names listed in the FDA device submission database within each product category-year that were not present in prior years. For both outcomes, we explore heterogeneity by

whether the firm is U.S.-based or foreign.

Product quality is analyzed using two data sources. First, we use Medicare claims to define repair and replacement rates per product category–year, calculated as the ratio of the number of all repair and replacement claims— including repairs, part replacements, and total replacements due to loss or damage[15]—to the total number of claims for each product category. Second, we use the FDA MAUDE to construct two measures: (1) the number of adverse events by all entities, and (2) the number of hospital-reported adverse events. MAUDE covers a wide range of adverse events, including device malfunction, injury, and death. Manufacturers, importers, and device user facilities (usually hospitals, but also outpatient facilities, nursing homes, and ambulatory surgical centers) are legally required to report adverse events associated with medical devices to the FDA. Other entities or individuals, including health care professionals and patients, can also report voluntarily. We prefer hospital-reported adverse events because hospitals are legally required to report and are not directly targeted by the price reforms, reducing the likelihood of endogenous changes in reporting propensity.

Manufacturer-Level Outcomes Our manufacturer-level analysis allows us to examine additional firm-level outcomes, such as R&D spending, revenue, and cost of goods sold (COGS).

For our baseline firms, we calculate the share of patents in treated product categories for each firm. Figure A5 shows the distribution of the share of patents subject to price reform across firms. We define a firm as treated if its share is above the median, and assign the treatment year as the year when the first treated DME product categories were announced.

We define the following outcomes at the manufacturer-year level: (1) log total revenue, (2) log R&D expenditure, (3) log cost of goods sold (COGS), and (4) indicators for whether a firm filed a patent in the treatment or control categories.

Details on the construction of these variable are provided in Appendix B.

[15] See https://med.noridianmedicare.com/web/jddme/topics/repairs/repairs

3.3 Summary Statistics

Table 1 provides an overview of the product categories and DME manufacturers in our study. Panel (a) presents summary statistics of product innovation and utilization for all DME product categories, treatment categories, and control categories in 2003, the last "pre-period" year before the MMA was passed in December, and discussions of likely affected product categories began to surface. The average product category had 179 patents and 4.0 FDA submissions in 2003. The average treatment category had 123 patents and 7.3 FDA submissions whereas the average control category had 198 patents and 2.6 FDA submissions. The average Medicare expenditure was $135 million among all product categories, $324 million among treatment categories, and $90 million among control categories, consistent with Medicare's intent of selecting the highest-spending categories for price cuts.

Panel (b) presents summary statistics for patent portfolios of DME manufacturers in our baseline sample for the year 2003. The average manufacturer in our baseline sample filed 5.4 DME patents in 2003. The average portfolio exposure to price reform was 23%. The distribution of manufacturer patent filings is highly skewed to the right. Due to this skewness, our firm-level analysis primarily focuses on the extensive margin of patenting outcomes—namely, whether a firm files any patents in a given year. Table A1 reports summary statistics for both publicly traded and privately owned manufacturers.

Figure A6 plots the raw trends for our three measures of innovation. Specifically, it illustrates the evolution of R&D spending (Panel (a)), patent filings (Panel (b)), and device introductions (Panel (c)). R&D spending, our earliest-stage measure of innovation, began to show signs of divergence between treatment and control as soon as the CMS named the top-three products most likely subject to the price reform in 2004. Patent trends, reflecting mid-to-late stage innovation, show a delayed yet gradual divergence, suggesting that ongoing projects continued while new investments tapered off. FDA submissions, representing the final stage before market entry, show the largest divergence in trends upon the implementation phase of the price cuts. Given firms' innovation investment decisions are forward-looking, we define the treatment year as the year a product category is announced for inclusion in the price reforms, rather than the year the reform is implemented. Specifically, we use 2004 as the treatment year for the three product categories identified during

the 2004 CMS PAOC meeting—oxygen equipment, wheelchairs, and nebulizers—as highly likely to experience price cuts. For later product categories, the treatment year is based on the first announcement of their inclusion in the reform: 2007 for CPAP, enteral nutrition, hospital beds, and walkers; 2011 for NPWT and support surfaces; and 2012 for commodes/bedpans/urinals, patient lifts, infusion pumps, and TENS. An exception applies to our analyses of Medicare prices and manufacturer revenues, which depend on the actual implementation of reforms. For these outcomes, we use the implementation year as the treatment year.

4 Empirical Strategy

4.1 Product Category Analysis

We estimate the effect of Medicare price cuts by comparing outcomes between product categories that were subject to the price cuts (treatment group) and those that were not (control group) during our study period.

To empirically quantify the impact of the price cuts on our outcomes of interest, we employ an event study specification with a stacked regression design similar to Cengiz et al. (2019). This approach assembles event-specific panel data for each wave of treatment product categories and all control product categories, avoiding potential biases from using staggered treatment designs in the presence of heterogeneous treatment effects (Goodman-Bacon 2018, Sun and Abraham 2021). All event-specific panels are then stacked while allowing unique time and product category fixed effects for each panel. We estimate the following event study specification:

$$Y_{i,t,k} = \gamma_{i,k} + \gamma_{t,k} + \sum_{r(i,t)\neq -1} \beta_r 1\{\text{Reform}\}_{i,k} \times I_{r(i,t)} + \varepsilon_{i,t,k}, \tag{1}$$

where i denotes product categories, t denotes calendar years, and k denotes price reform events. $\gamma_{i,k}$ and $\gamma_{t,k}$ denote event-by-product category fixed effects and event-by-calendar year fixed effects, respectively. $1\{\text{Reform}\}_i$ is an indicator for whether product category i in event panel k is subject to the price cuts. $I_{r(i,t)}$ are indicators for years relative to the announcement of the reform, which are normalized to zero for product cate-

gories not subject to the price cuts. We define $r(i,t) = 0$ as the year Medicare price cuts were first announced for the product category, since investors and manufacturers can respond to expected changes in revenue following the announcement, before the formal implementation of the price cuts. The coefficients of interest, β_r's, quantify the impact of the price cuts on the outcome of interest $Y_{i,t,k}$. Given the small number of treated product categories ($N^1 = 13$), to achieve reliable inference, we follow the approach of Conley and Taber (2011) and use control group residuals to compute standard errors. The larger size of our control groups ($N^0 = 38$) allows us to reliably estimate standard errors despite the small number of treated groups.

To obtain an overall estimate of the impact over the post-treatment period, we also estimate a difference-in-differences specification by replacing the relative year indicators with an indicator for the post-period ($1\{\text{Post}\}_t$). The estimating equation is given by

$$Y_{i,t,k} = \gamma_{i,k} + \gamma_{t,k} + \beta_1 1\{\text{Reform}\}_{i,k} \times 1\{\text{Post}\}_{t,k} + \varepsilon_{i,t,k}. \tag{2}$$

Our coefficient of interest is β_1. Since Medicare accounts for different shares of the total market spending in each product category, we expect the impact of Medicare price cuts to vary with the relative importance of Medicare in each market pre-reform. To leverage this variation, we estimate the following "dose-response" specification:

$$Y_{i,t,k} = \gamma_{i,k} + \gamma_{t,k} + \beta_1 1\{\text{Reform}\}_{i,k} \times 1\{\text{Post}\}_{t,k} \times \text{MedicareShare}_{i,k} + \varepsilon_{i,t,k}, \tag{3}$$

where $\text{MedicareShare}_{ik}$, ranging from 0 to 1, is calculated as the ratio of total Medicare fee-for-service expenditure on the given product category to the combined spending on the product category by Medicare, private insurance, and healthcare providers.[16] The coefficient β_1 captures the differential impact of the price cuts, scaled by the Medicare market share. Specifically, it represents the effect of the price cuts for a product category where Medicare constitutes 100% of the market, compared to one where Medicare has a 0% market share.

In addition to reporting pooled estimates across all years, we provide long-run (LR) estimates that capture the effect of price cuts seven to ten years after their implementation.

[16] Some DME can be purchased by health care providers for in-facility use. For instance, hospitals and nursing homes may purchase hospital beds and oxygen equipment. Our market share measure captures this business-to-business market in addition to the business-to-consumer market.

Since changes in medical innovation may take time to fully materialize, these LR estimates are our preferred estimates.

4.2 Manufacturer Portfolio Analysis

To examine the impact of the price reform on manufacturer financial outcomes and to assess heterogeneity across manufacturers, we estimate specifications analogous to equations (1) and (2) at the firm level. Specifically, we construct event-specific panel data for each DME manufacturer affected by the reform. We estimate the following specification:

$$Y_{j,t,k} = \gamma_{j,k} + \gamma_{t,k} + \sum_{r(j,t)\neq -1} \beta_r 1\{\text{Above Median Exposure}\}_{j,k} \times I_{r(j,t)} + \varepsilon_{j,t,k}. \tag{4}$$

where j denotes manufacturers, t denotes calendar years, and k denotes price reform events. $1\{\text{Above Median Exposure}\}_{j,k}$ indicates whether the manufacturer's exposure to the price reform is above the median among all device manufacturers. We define exposure as the share of a firm's patent portfolio during the pre-period that is affected by the reform. Other variables are defined analogously. We define $r(i,t) = 0$ as the year the first Medicare price reforms were announced for the treated product categories (2004), except manufacturer revenue, for which we define $r(i,t) = 0$ as the first year the price cuts were implemented (2009) since we expect revenue to be affected by actual prices rather than expected future prices. Our coefficients of interest, β_r, estimate the differential change in the outcome between firms with above- and below-median exposure.

We also report a pre-post version of the same specification, as shown in equation 5:

$$Y_{j,t,k} = \gamma_{j,k} + \gamma_{t,k} + \beta_1 1\{\text{Above Median Exposure}\}_{j,k} \times 1\{\text{Post}\}_{t,k} + \varepsilon_{j,t,k}. \tag{5}$$

As with every non-experimental research design, selection into treatment is a primary concern. Medicare selects product categories for price reform based on baseline pre-reform expenditures, potentially leading to inherent differences between treated and untreated categories. However, as shown in Figures A2, A3 and A6, despite the categories exhibiting different outcome levels, we do not find significant divergent pre-existing trends in the outcomes of interest, supporting the parallel trends assumption required for the validity of our Difference-in-Differences (DiD) approach.

5 Impact on Innovation

We begin by quantifying the magnitude of the Medicare price cuts, serving as the "first stage" effect in our analysis. Figure 2 (a) reports estimates of equation (1) for log Medicare price. Table A2 reports the corresponding DiD estimate, indicating a statistically significant 61% reduction (-0.94 in logs) in Medicare prices seven to ten years following the implementation of the price cuts. The table provides suggestive evidence that these price reforms spilled over into commercial insurance markets in the long run, marked by similarly large decreases in prices and quantities, although these estimates are only marginally significant.

We then empirically test the first prediction from our conceptual model: that Medicare price cuts reduce manufacturer revenue. Figure 2 (b) reports event study estimates of equation (4). Table 2 reports the corresponding DiD estimate, showing a statistically significant 36% reduction in log manufacturer revenue (-0.44 in logs) by years seven to ten following the implementation of the price cuts.

We now turn to the second prediction of our model: that price cuts may reduce innovation (if poorly targeted). Figure 3 displays our event-study estimates of changes in three innovation measures: R&D spending, patent filings, and FDA submissions. Table 2 reports the corresponding DiD estimates. Figure 3 Panel (a) shows a clear reduction in R&D spending among firms more exposed to the reform, relative to those that were less exposed. The effect increases in magnitude over time, amounting to a 41% reduction in the long run (-0.53 in logs, Table 2 Panel (c)). Figure 3 Panel (b) shows a slower and steadier decrease in the number of U.S. patents in affected DME categories relative to unaffected categories. As time progresses, the effects of price cuts become more pronounced and significant. The long-run estimates suggest that price cuts lead to 61 fewer patents per year per DME category, representing an 80% reduction relative to the pre-reform mean, although the point estimates are marginally significant (Table 2 Panel (a)). Importantly, we find no significant pre-existing trends in treated groups relative to control groups. Figure 3 Panel (c) shows a more delayed decline in FDA submissions, which in the long run amounts to a statistically significant 1.98 fewer new devices per category per year — a 29% decrease relative to pre-reform means (Table 2 Panel (a)). The event study estimates are noisier, likely due to the small number of new devices entering the market

each year. Reassuringly, we find consistent effects in the raw trends (Figure A6 Panel (c)), which show a clear drop in the number of submissions among the treated product categories.

The differing short-run impact of the price cuts on R&D spending, patenting rates, and FDA submissions, shown in Figure 3, is consistent with the different stages of the R&D process they represent. R&D spending encompasses expenditures across all stages, including the initial exploratory stage. Therefore we expect the most immediate response from this outcome as soon as firms anticipate reduced future profitability for their products. Patents represent a later-stage outcome, but earlier relative to FDA submissions; they serve to protect novel ideas and technologies and do not always lead to products. Furthermore, patent filing is a relatively low-cost process. As a result, firms may continue to patent technologies already in their pipeline due to the relatively low marginal cost and the potential for profits outside the U.S., but become less likely to start new projects in the treated categories due to the price cuts, consistent with the gradual decline in patenting shown in Panel (b). Finally, FDA clearance is the final stage before a new product enters the U.S. market after an R&D process that ranges from 3 to 7 years (Parikh, Roman and Kyle, 2018), consistent with the more delayed drop in FDA submissions in Panel (c).

Table 2 Panel (b) reports results from our dose-response specification, which indicate statistically significant decreases in both FDA submissions and patent filings, corroborating our product category-level analysis. Specifically, a 0.1 increase in Medicare market share is associated with 0.24 fewer FDA submissions and 9 fewer patents per year per product category in the long run following the price cuts.[17] These estimates imply a price elasticity of 1.09 for DME patents, which is roughly the average elasticity in the pharmaceutical industry found in prior studies (Philipson and Durie, 2021).[18]

Table 2 Panel (c) reports the results of our firm-level analysis. We find that firms that were more exposed to the price cuts experienced a significant 20 percentage point drop (37% relative to the pre-period mean) in the likelihood of filling a patent in a treated DME category relative to the less exposed firms. In contrast, these firms do not significantly

[17]The average treated DME category has a pre-reform Medicare market share of 0.58; thus, scaling our estimates in Panel (b) by this number implies average effects that resemble those in Panel (a).

[18]Our preferred price elasticity measure is computed using the dose-response estimate and the counterfactual LR patent counts absent policy changes. This elasticity has the interpretation of price elasticity most similar to those used in prior literature in the pharmaceutical industry as it estimates the Medicare price elasticity when Medicare has 100% of the market share.

change their patenting behavior in unaffected DME categories. The significant decrease in overall R&D expenses among the more exposed firms provides further evidence that firms are not merely shifting R&D from affected categories to unaffected ones. The fact that R&D did not shift to the unaffected product categories is consistent with firm profit-maximizing behavior: if there were opportunities to generate more profits in the unaffected categories, firms would have exploited those opportunities already, unless they faced financial frictions.[19]

Table A3 reports our estimates using the entire sample of 486 firms, without limiting to public firms for which we have financial information. The results are consistent with our main firm-level analysis.

5.1 Heterogeneity by Manufacturer Characteristics and International Spillovers

Although patenting and FDA submission rates are both decreasing on average, we find divergent trends between the number of FDA submissions from U.S. firms and foreign firms. Table 3 Panel (a) shows that while U.S. firms submit 3.84 fewer new devices per category per year in the long run (a 75% decrease), foreign firms submit 1.50 more devices (a 92% increase), with both changes being statistically significant. Interestingly, patent filings by both U.S. and foreign firms declined: US manufacturers filed 44.53 fewer patents per category per year in the U.S. (a 86% reduction), while foreign manufacturers filed 17.38 fewer (a 56% reduction).

The divergent patterns between FDA submissions and patenting may be explained by the differences in the R&D process these two measures capture. Patents capture innovations in new products or processes, while FDA submissions allow firms to market their products in the U.S. The U.S. market's increasing preference for lower-cost products may create a comparative advantage for foreign manufacturers who previously did not find it profitable to enter the U.S. market and to incur the high FDA approval cost. When price cuts increasingly put domestic firms at a disadvantage, anticipated market opportunities may induce more foreign firms to seek FDA approval for their existing products, even as

[19] An alternative explanation, as previously documented in Hortaçsu et al. (2024), is that divisions within a company often operate like independent entities, leading to significant friction when the firm attempts to optimize across these divisions.

the overall market profitability and level of innovation continue to decline.

Finally, Table 3 Panel (b) reports a marginally statistically significant 90 fewer patents filed abroad per category per year, a 73% reduction relative to the pre-period mean and comparable to the percent reduction in the number of patents filed in the U.S. Figure 3 Panel (d) shows the corresponding event study for patent filings in foreign jurisdictions. This pattern suggests that U.S. health policy may have substantial impacts on international R&D activity and product availability. Both U.S. and foreign firms reduced their patent filings overseas, by a statistically significant 24 patents per category per year and a marginally significant 73 patents per category per year, respectively.

5.2 Direction and Quality of Innovation

While the price cuts impacted the quantity of innovation, they did not measurably alter the direction and quality of innovation. As shown in Figure A7 Panel (a), we do not observe a statistically significant change in the extent to which patents filed in affected DME categories emphasized process or product innovations, suggesting that lower reimbursement rates do not spur cost-focused innovation. Instead, cheaper product alternatives may have already existed abroad, evidenced by the increase in foreign-made DME introduced in the U.S. In Panel (b), we also do not find statistically significant changes in the number of times patents filed in affected categories were cited, a commonly used measure of patent quality in the literature. Table A4 reports the corresponding DiD estimates.

6 Impact on Market Structure and Product Quality

The conceptual model in Section 2 predicts that Medicare price cuts would lower product quality and production costs. This follows from the notion that as prices fall, the return on investment in quality decreases, prompting firms to cut costs and lower quality. In this section, we empirically test these predictions. We first report results on changes in manufacturer costs and the supply chain adjustments consistent with cost-cutting strategies (Section 6.1). We then examine the impact on product quality (Section 6.2).

6.1 Changes in Production Cost and Market Structure

Table 4 Panel (a) presents our estimates of the changes in manufacturer entry and outsourcing, obtained from estimating equation (2). The results indicate a statistically significant 1.0 fewer entrant per category per year into affected DME categories relative to unaffected categories in the long run, a 40% decrease relative to the pre-period mean. This decrease is entirely driven by a statistically significant 72% drop in domestic entrants, while foreign firm entry rates show a statistically insignificant increase. These findings suggest that domestic firms are finding it increasingly difficult to compete in the U.S. market against foreign firms, which likely benefit from lower production costs, as the procurement environment becomes more cost-conscious.

Alongside the reduced entry, we observe increased outsourcing. Table 4 Panel (a) reports estimates from equation (2) on the number of newly contracted manufacturers. We find a statistically significant increase of 2.22 new contractors per product category per year in the long run (representing a 33% increase). Table 4 Panel (b) reports the corresponding dose-response estimates.

To assess whether cost-cutting efforts, including increased outsourcing, led to changes in production cost, we analyze the impact of price cuts on the cost of goods sold (COGS). COGS represents all costs directly allocated by the company to production, such as material, labor and overhead. Table 4 Panel (c) reports the DiD estimates statistically significant 33% reduction (-0.40 in logs) in the long run. This pattern is consistent with a reduction in manufacturing costs following the Medicare price cuts.[20]

Our findings suggest that manufacturers producing the treated products seek lower-cost production by outsourcing production to contractors. However, if outsourcing were efficient, why did firms not pursue it before the reforms? One possible explanation is that outsourcing can degrade product quality because manufacturers cannot directly manage in-house quality controls.[21] Additionally, outsourcing is costly and difficult to reverse. Under the previous, more generous pricing regime, firms producing lower-quality products

[20] An alternative explanation for this pattern could be that firms in our baseline sample sold fewer units following the price cut, leading to lower COGS. Although analysis of private and Medicare claims data suggests that the overall reduction in utilization appears too small to fully explain the reduction in COGS (Table A2).

[21] Indeed, one of the first questions asked in applications for medical device manufacturer liability insurance is whether the firm manufactures its product in its own facility or contracts out manufacturing.

might have been at a disadvantage when trying to attract quality-conscious consumers—especially considering that consumers in this market face little to no out-of-pocket expenses and are less sensitive to prices. In the next section, we explore this possibility by directly analyzing the impact of the price reforms on product quality.

6.2 Changes in Product Quality

We assess changes in product quality by analyzing DME repair and replacement rates and counts of FDA adverse event reports. Figure 4 shows a sharp increase in the Medicare DME repair and replacement rate after price cuts are enacted, which persists and continues to rise over the long run. Importantly, we do not observe significant pre-existing trends in treated groups relative to controls.

The first row of Table 5 provides the corresponding DiD estimate: a statistically significant 0.8 percentage point increase in the Medicare DME repair and replacement rate in the long run, a 200% increase relative to the pre-period. This dramatic increase in repair and replacement rates suggests a significant degradation in the quality of products used by Medicare beneficiaries. However, it is also possible that Medicare suppliers have become more proactive in offering repairs and replacements when revenue from the initial device sales falls. Therefore, we examine measures from a second, unrelated source: the FDA MAUDE database.

Figure A8 shows the total number of adverse event reports in each year, separately for affected and unaffected DME categories. These raw trends show a dramatic increase in the number of adverse event reports in affected categories. However, since MAUDE contains mandatory and voluntary reports from a variety of sources, these increases may be exaggerated since incentives to report may be influenced by the price cuts. For this reason, we focus on adverse event reports submitted by hospitals, since they are both legally required reports and not directly influenced by the price reforms. Furthermore, hospitals generally purchase their own medical devices directly from manufacturers, rather than buying from Medicare-contracted suppliers. Therefore, changes in hospital-reported quality metrics would indicate broader changes in product quality in the market and are not subject to supplier stocking decisions.[22] Our preferred measure is the likelihood that an adverse

[22]It is plausible that Medicare DME suppliers, which hospitals typically do not rely on for purchases, seek to preserve profit margins under low fixed-price contracts by shifting toward lower-cost DME sourced

event is reported in a given product category-year by hospitals. The second row of Table 5 provides the DiD estimate: a marginally significant 18 percentage point increase. We also show results using all reports in Table A5.

Moreover, the increase in adverse events is strongly associated with the use of contracting manufacturers. Table 5 shows that outsourcing manufacturers experience a statistically significant 129% increase in the likelihood of adverse events, compared with a marginally significant 22% increase among manufacturers that produce in-house.[23] Figure A9 provides the corresponding raw trends and event studies for hospital-reported adverse events related to products from firms that use foreign contract manufacturers. It is important to note that changes in total utilization cannot explain the increase in the number of overall adverse events. Table A2 shows that the total utilization of affected DME did not increase relative to unaffected DME.

7 Discussion

7.1 Value of Lost Innovation

A natural question arises regarding the value of the lost innovation and how it compares to the savings in public spending generated by the reform. In this section, we offer suggestive evidence that the value of lost innovation, as measured by patent filings and R&D spending, is substantial and may even exceed the direct savings generated by the payment reform.

Appraising the value of innovation is extremely difficult. Accordingly, we provide two potential estimations to establish a range of possible values. As a potential lower bound, we calculate the change in R&D spending following the price reform. This calculation serves as a lower bound since we expect profit-maximizing firms to engage in R&D activities that yield returns at least sufficient to recoup the R&D costs (on average). Additionally, Bloom, Schankerman and Van Reenen (2013) find that the social value of R&D is, on average, at least twice as high as the private value. According to Shackelford (2013),

from foreign or offshore manufacturers following the reform. This shift likely increases the prevalence of outsourced products in the U.S. market, potentially leading to a corresponding rise in adverse events associated with these products.

[23] We classify a firm as "outsourcing" across all years if it has outsourced production at any time.

firms in the Medical Equipment and Supplies industry allocated an average of $3.6 million towards R&D per patent granted, adjusted for inflation. Given our estimate of the long-run reduction of 61 patents per product category per year (Table 2, Panel (a)), across all 13 affected categories, we estimate a value of lost innovation, measured by reduced R&D expenditures, amounting to $2.9 billion annually following the price reform.

An additional, less conservative estimate comes from Kogan et al. (2017), who calculate the value of a patented innovation using changes in stock market values upon patent grant announcement. In Figure A10, we present the average decrease in the total annual value coming from new innovation, as measured by Kogan et al. (2017), in treated DME categories relative to unaffected categories. This measure suggests an estimated reduction in patent market value of $4 billion annually per DME category in the long run, or roughly $52 billion annually across all treated DME categories.[24]

Admittedly, estimates of patent market value may differ from their social value. One important factor is the phenomenon of "business stealing," whereby firms innovate to gain a competitive edge over rivals, resulting in private value for the firm but a lesser increase in social value. Estimates from Kogan et al. (2017) suggest that business stealing could account for as much as 80% of the patent market value. On the other hand, research by Bloom, Schankerman and Van Reenen (2013) indicates that the societal value of innovation typically exceeds its private value by at least a factor of two. Furthermore, the competitive dynamic of firms seeking to outperform each other through new product introductions has been empirically demonstrated to enhance consumer welfare (Petrin, 2002).

Despite these caveats, these estimates are large when compared to the savings to Medicare. We estimate that Medicare saved $3.8 billion annually in DME spending, adjusting for inflation.[25] Relative to this benchmark, our conservative and less conservative estimates of the value of forgone innovation account for 76% and 1368% of Medicare savings.[26]

[24]There are some important limitations with this approach. Most importantly, KPSS assigns patent values only to publicly traded firms, which leads us to impute patent values for privately traded firms using a similar approach to Kline et al. (2019). Our approach trains a machine learning model on patents from publicly traded firms using observable patent and Orbis firm characteristics to predict patent values for private firms. Our prediction strategy yields an r-squared of roughly 0.5. Patents from private firms represent approximately 66% of our sample. If we restrict only to publicly traded firms, we get similarly large estimates of lost innovation value relative to cost savings.

[25]It is worth noting that these savings do not account for potential savings in the privately insured market, which saw a similar-sized reduction in price (Table A2).

[26]If we consider both producer surplus and consumer surplus as relevant to welfare, the reduction in

7.2 Selection of Product Categories

Our conceptual framework (Section 2) suggests that regulated price cuts would reduce innovation, but only weakly. In this section, we explore whether Medicare could have implemented these price cuts in a way that generates savings without significantly hindering innovation.

While predicting R&D spending in advance can be challenging, regulators do have access to historical data on firms' past R&D expenditures, revenues, and product portfolios. This information allows them to make informed predictions about the average profitability of new innovations based on specific product attributes.

As a simple back-of-the-envelope exercise, we assess whether Medicare successfully targeted categories with the highest profitability (for which we would expect the least impact on innovation) by following their approach of selecting items for price cuts at the product category level. Figure 5 plots our estimated per-patent profit by product category, from the highest to the lowest, with the categories selected by Medicare for price reductions highlighted in red. This figure is generated using data up to 2005, prior to the price cuts. We estimate the average patent profitability using the following approach.

We first estimate the average revenue associated with the average patent of product category i by estimating the following regression:

$$y_{j,t} = \gamma_j + \tau_t + \sum_i \alpha_i \sum_{t-4}^{t} \frac{1}{5} \text{PatentCount}_{i,j,t} + \epsilon_{j,t}, \tag{6}$$

where we regress manufacturer j's R&D spending in year t on manufacturer fixed effects (γ_j), year fixed effects (τ_t), and the average number of patents the firm filed in each product category over the five years prior to t. We assume that the R&D expenses associated with a patent are incurred evenly in the five years prior to its submission, reflecting the typical length of medical device R&D, which ranges from 3 to 7 years (Parikh, Roman and Kyle, 2018).

We then estimate an analogous specification for manufacturer revenue:

Medicare spending primarily entails a transfer from producers to consumers. Thus, the welfare gain stems from the reduced deadweight loss from raising Medicare funds through taxation. Assuming a marginal cost of public funds ranging from 9% to 16% (Browning 1976), these welfare gains amount to $342 to $608 million annually. Importantly, this figure is nearly an order of magnitude smaller than even our most conservative estimate of the value of lost innovation.

$$y_{j,t} = \gamma_j + \tau_t + \sum_i \beta_i \sum_t^{t+4} \frac{1}{5} \text{PatentCount}_{i,j,t} + \epsilon_{j,t}, \tag{7}$$

where we regress manufacturer revenue on the average patent counts in the five years following the patent submission (years t through $t+4$), assuming that the revenue generated from each patent is evenly distributed over this period.

The differences between the two sets of coefficients, $\beta_i - \alpha_i$, produce our estimates of the profits associated with the average patent in product group i. For manufacturers whose portfolios include more than DME patents, we scale their R&D and revenue by the share of their stock market value attributed to their DME patents before we estimate these equations.

In a well-targeted price reform, we would expect Medicare to prioritize product categories with the highest profit margins (i.e., those on the left side of the graph). However, in practice, the selected categories are spread across the entire distribution. This outcome is not entirely surprising, as Medicare based its selections on total Medicare spending, which does not perfectly correlate with profit margins relative to R&D spending. Nevertheless, this analysis highlights that a more targeted approach could potentially reduce Medicare spending while minimizing negative impacts on medical innovation.[27]

8 Conclusion

This paper examines the impact of regulated price cuts on innovation, market structure, and product quality, in the setting of the medical device market. We construct a comprehensive linkage across a wide array of administrative and proprietary data on multiple domains of the medical device industry, encompassing global patents, FDA databases, health care claims, and firm financial data. We find that the series of Medicare price cuts, which collectively reduced prices by 61% over a 7- to 10-year period, led to a 29% decline in new product submissions and a 80% reduction in patent filings, indicating a substantial slowdown in innovation. Additionally, manufacturers responded to these price cuts by reducing

[27] Some product categories may have negative average profitability due to market-level shocks. One example is the breast prosthesis product category, which during the data period included multiple breast implants that were later linked to cancer and subject to major class action lawsuits and FDA recalls (di Pompeo et al., 2022).

market entry and increasing outsourcing to contracted manufacturers, a shift that was associated with higher rates of product defects. While the price cuts generated immediate fiscal savings, our analysis suggests that the long-term cost of lost innovation may outweigh these savings.

These findings highlight the balance governments must maintain when implementing price regulations in innovative sectors. While reducing procurement costs is often a key policy goal, particularly in health care where cost containment is a perennial challenge, our study demonstrates that such measures can disrupt the market dynamics, alter investment in research and development, and ultimately reduce product quality. These unintended consequences could hinder technological advancements that drive long-term social welfare. An industry that thrives on continued technological progress, such as health care, may be especially vulnerable to such trade-offs.

The design of government regulations, therefore, plays a pivotal role in mitigating these risks. Our study suggests that with better targeting, Medicare could have selected different product categories for price reductions, potentially avoiding the adverse effects on innovation. Our analysis provides valuable guidance for ongoing policy discussions, especially in light of proposed reforms such as those in the Inflation Reduction Act, which aim to reduce health care costs through price controls on pharmaceutical drugs. Policymakers must weigh the short-term benefits of cost savings against the long-term risks of stifling innovation, disrupting market structures, and compromising product quality.

Our research also raises critical questions about the broader economic and social impacts of these regulatory shifts. For instance, the outsourcing of production not only affects the quality of medical devices but also has implications for employment in the domestic manufacturing sector. As jobs move overseas, what happens to the displaced workforce, and how does this impact local economies? Moreover, as lower-quality products enter the market, could this lead to worsening health outcomes over time, driving up health care costs and offsetting the initial savings from price cuts? We leave these important questions to future research.

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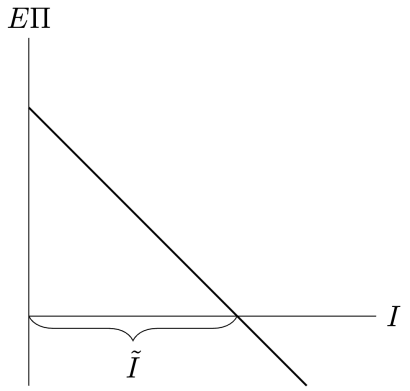
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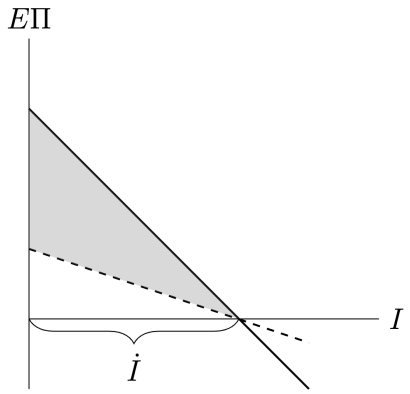
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Figure 1. Potential Impact of Medicare Price Cuts on Innovation

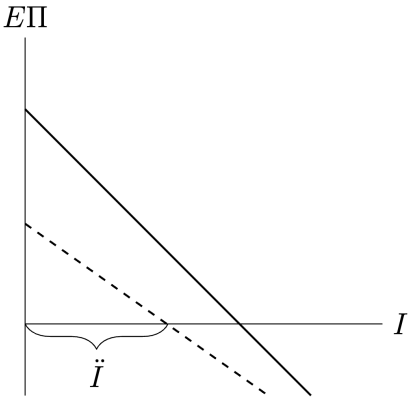
(a) Potential and Invested Innovation by Expected Profits



(b) Price Cut Leads to No Change in Investments in Innovation



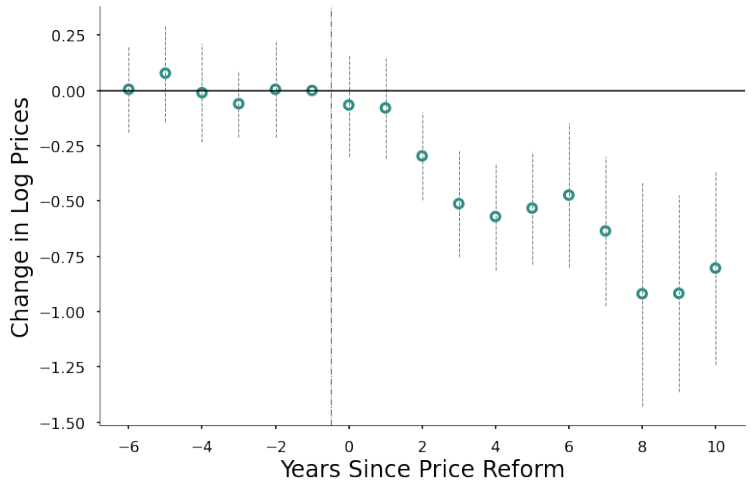
(c) Price Cut Leads to Less Investments in Innovation



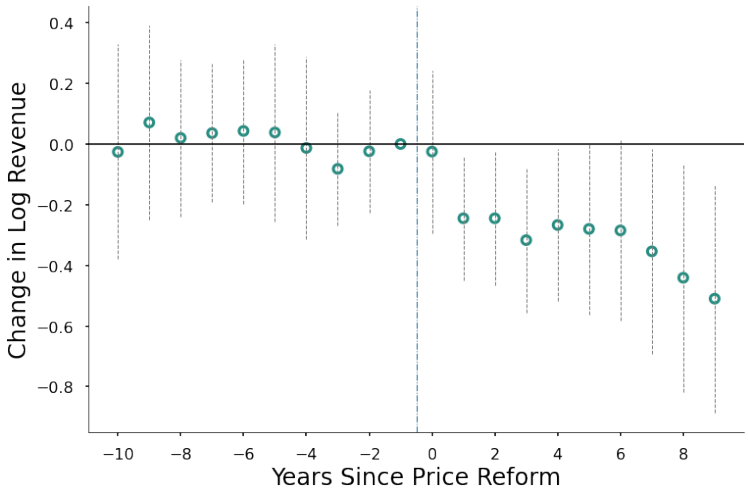
Note: Figure illustrates the potential impact of Medicare price cuts on the set of innovation the firm invests in. The y-axis illustrates firm profits. The x-axis illustrates the set of potential innovation (I).

Figure 2. Event Study: Medicare Prices and Manufacturer Revenues.

(a) Medicare Prices

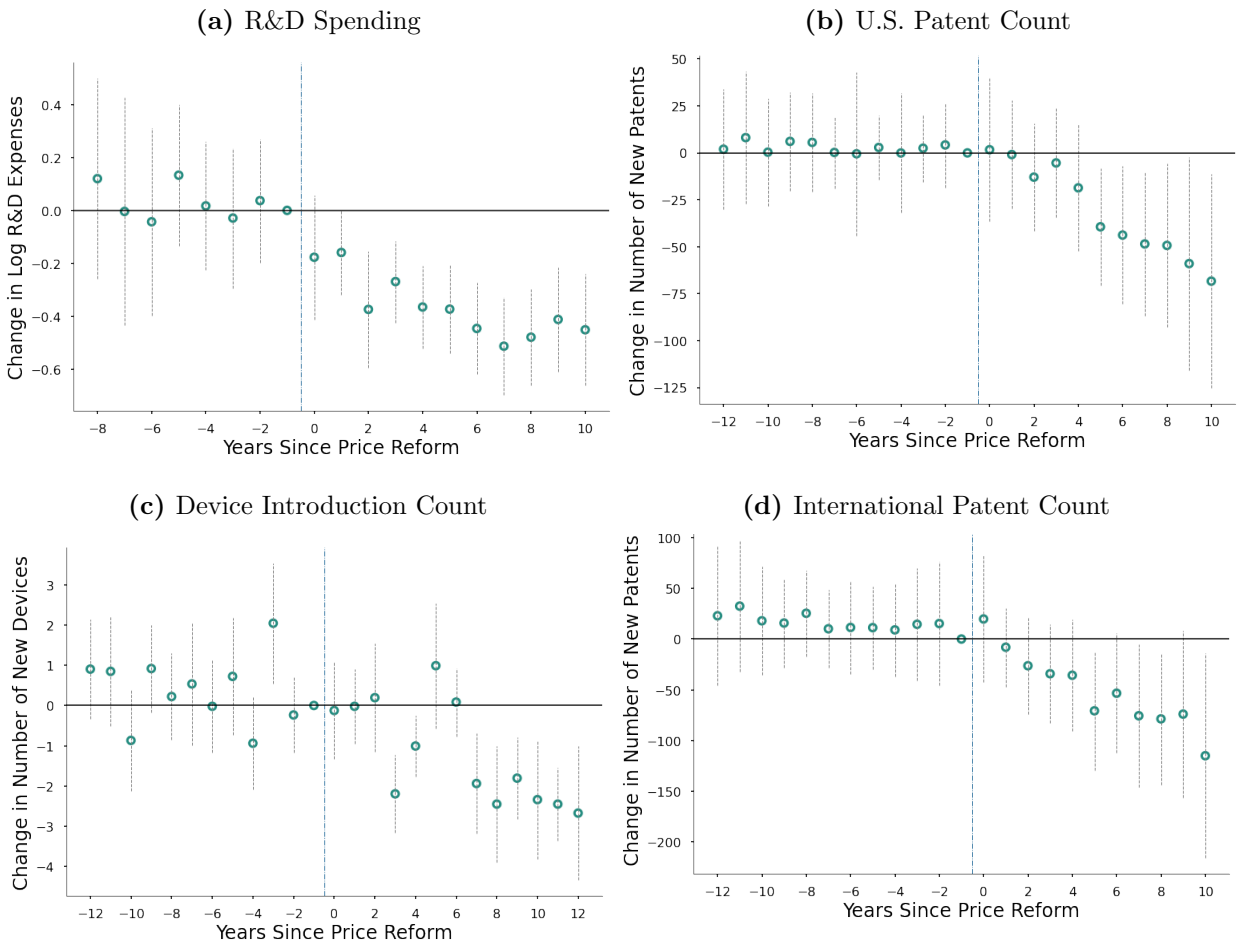


(b) Manufacturer Revenues



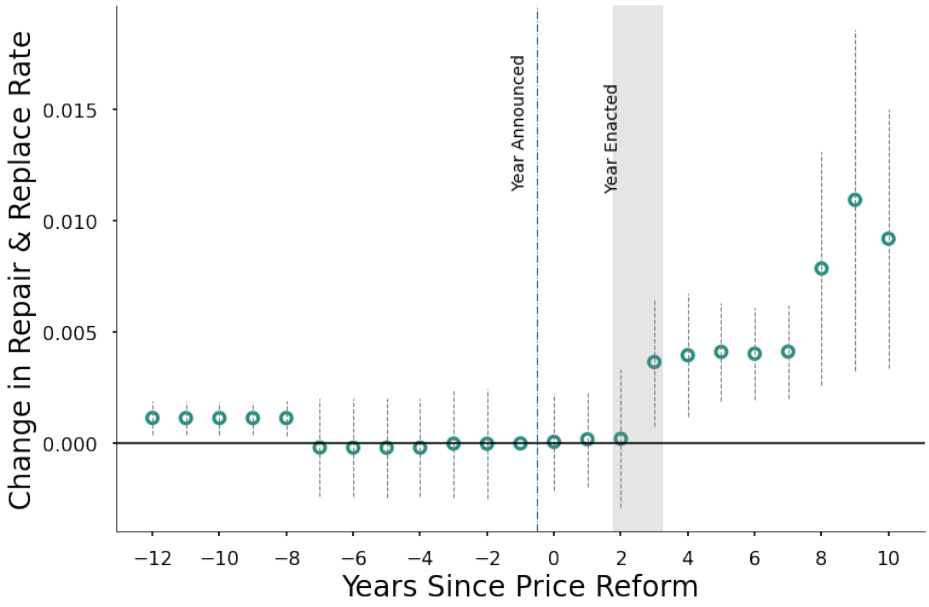
Note: Panel (a) reports the coefficients obtained from estimating equation (1) for log Medicare price. Panel (b) reports event study coefficients obtained from estimating equation (4) for log firm revenues. In both panels, the coefficient for period $t = -1$ is normalized to zero. Unlike for outcomes on innovation and the supply chain, relative years in this figure are defined based on the reform implementation rather than the announcement year, since mechanically Medicare prices would only change following the reform implementation, and manufacturer revenues are largely determined by Medicare prices. The dashed vertical lines report the 95% confidence intervals.

Figure 3. Event Study: Innovation.



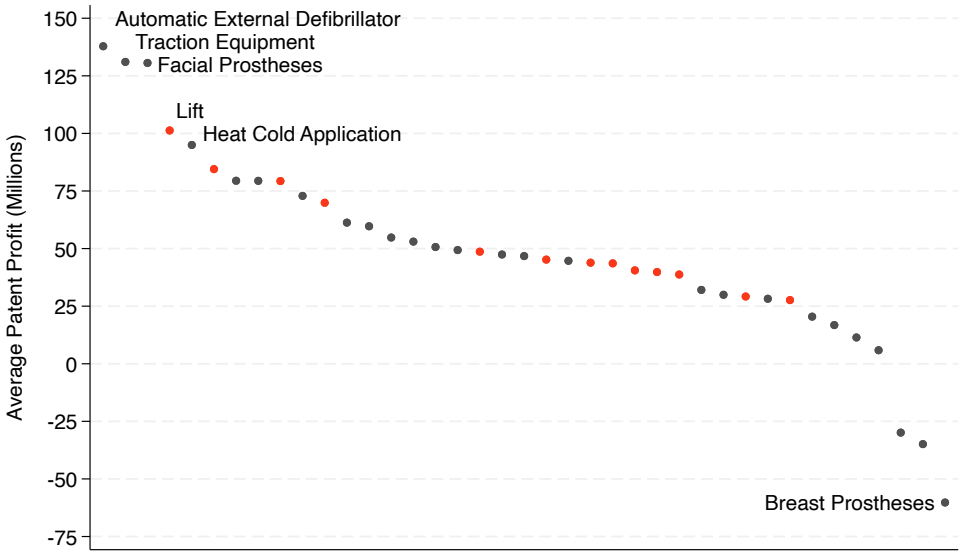
Note: Panel (a) presents the coefficients obtained from estimating equation (4) for R&D spending. It illustrates the temporal evolution of outcomes in firms with above median exposure to the price reforms, relative to firms with below median exposure. Panels (b), (c), and (d) present the coefficients obtained from estimating equation (1) for U.S. patent count, FDA submissions, and international (non-U.S.) patent count, respectively. They illustrate the temporal evolution of outcomes in DME categories affected by the event, relative to those unaffected, with a reference period at $t = -1$. Dashed lines around the point estimates report the 95% confidence intervals. All panels report all available years of data for the outcome.

Figure 4. Event Study: Product Quality.



Note: Figure presents the coefficients obtained from estimating equation (1) for repair and replacement rate. It shows the temporal evolution of the outcome in DME categories affected by the event, relative to those unaffected, with a reference period at $t = -1$. The dashed lines around the point estimates show the 95% confidence intervals.

Figure 5. Average Patent Profitability by Product Category



Note: The figure shows estimated profits per patent by product category, which are ordered along the x-axis by average profits per patent. The estimated profits are computed following the procedure described in Section 7.2. Product categories affected by price cuts are shown in red.

Table 1. Summary Statistics

	All DME Categories	Affected Categories	Unaffected Categories
Panel (a): Product Categories			
Number of Patents	178.53	122.69	197.63
(S.D.)	(424.59)	(194.63)	(479.44)
Number of PMA/510(k)'s	4.00	7.25	2.56
(S.D.)	(5.19)	(7.48)	(3.07)
Medicare Expenditures ($M)	135.40	323.80	89.50
(S.D.)	(316.40)	(555.20)	(207.50)
Medicare Market Share	-	0.58	-
(S.D.)	-	(0.27)	-
Panel (b): Manufacturers (N = 53)			
Patents	5.42	1.92	3.49
(S.D.)	(12.98)	(3.80)	(12.0)
R&D ($M)	398.92	-	-
(S.D.)	(1151.36)	-	-
Revenue ($M)	6912.00	-	-
(S.D.)	(22239.01)	-	-
Cost of Goods Sold ($M)	4014.27	-	-
(S.D.)	(15342.42)	-	-
Portfolio Affected	0.23	-	-
(S.D.)	(0.26)	-	-

Note: Table reports summary statistics from 2003, separately for all product categories, product categories that were subject to price reform, and product categories that were not subject to the reform during the sample period. Panel (a) reports the mean and standard deviation at the product category level. The total number of categories represented in our patent data is 51, with 13 affected categories and 38 unaffected categories, respectively. The total number of categories represented in our FDA submission data is 26, with 8 affected categories and 18 unaffected categories, respectively. Panel (b) reports the mean and standard deviation of variables at the manufacturer level for our baseline sample of firms.

Table 2. Impact of Medicare Price Cuts on Innovation

		Change with Price Reform		
	Pre-Mean	Estimate	LR Estimate	Elasticity
	(1)	(2)	(3)	(4)
Panel (a): DME Category-Level				
Number of PMA/510(k)'s per Year	6.75	-0.70*	-1.98***	0.62
		(0.35)	(0.41)	
Patent Filings in U.S. per Year	76.69	-25.11	-61.07+	0.85
		(28.75)	(31.65)	
Panel (b): Dose Response				
Number of PMA/510(k)'s per Year	6.75	0.05	-2.35***	0.64
		(1.11)	(0.57)	
Patent Filings in U.S. per Year	76.69	-62.15*	-90.42*	1.09
		(30.04)	(37.12)	
Panel (c): Manufacturer-Level				
Log Revenue	4.81	-0.26	-0.44*	-
		(0.20)	(0.20)	
Log R&D Expenses	2.28	-0.44**	-0.53***	-
		(0.15)	(0.16)	
Pr of Filing Affected DME Patent	0.54	-0.13	-0.20**	-
		(0.09)	(0.06)	
Pr of Filing Unaffected DME Patent	0.29	0.04	0.08	-
		(0.11)	(0.10)	

Note: This table reports estimates for innovation outcomes from equations (2), (3), and (5). Column (1) reports pre-event averages for treated groups. Column (2) reports estimates with standard errors in parentheses. Column (3) reports long-run (LR) estimates and Column (4) reports the elasticity of innovation with respect to LR Medicare price changes in the respective specification (DME level or dose-response). Due to increasing patent counts in all categories across time, elasticities for patents are calculated using imputed counterfactual LR patent counts (absent policy changes), rather than the pre-mean. Panel (a) covers DME category-level analysis from equation (2). Panel (b) covers continuous dose-response estimates based on pre-reform market shares from equation (3). Panel (c) covers firm-level impacts from equation (5). Statistical significance is marked as +, *, **, and *** for levels 0.10, 0.05, 0.01, and 0.001, respectively.

Table 3. Heterogeneity in Impact of Medicare Price Cuts on Innovation

	Change with Price Reform		
	Pre-Mean	Estimate	LR Estimate
	(1)	(2)	(3)
Panel (a): U.S. Innovation			
Number of PMA/510(k)'s per Year	6.75	-0.70*	-1.98***
		(0.35)	(0.41)
U.S. Manufacturers	5.13	-1.97***	-3.84***
		(0.27)	(0.34)
Foreign Manufacturers	1.63	1.00**	1.50**
		(0.31)	(0.47)
Patent Filings in U.S. per Year	76.69	-25.11	-61.07+
		(28.75)	(31.65)
U.S. Manufacturers	51.75	-17.88	-44.53+
		(21.62)	(22.95)
Foreign Manufacturers	31.25	-6.23	-17.38+
		(8.74)	(10.53)
Panel (b): Global Innovation			
Patent Filings Abroad per Year	124.38	-51.21	-90.05+
		(45.14)	(46.70)
U.S. Manufacturers	53.58	-14.26	-23.56**
		(15.19)	(9.07)
Foreign Manufacturers	74.92	-41.67	-72.99+
		(33.64)	(41.60)

Note: Panel (a) replicates Table 2 Panel (a) separately for U.S. and foreign manufacturers. Panel (b) reports estimates from equation (2) for the number of patents in the affected categories filed outside the U.S., in total, by U.S. manufacturers, and by foreign manufacturers, respectively. Statistical significance is marked as +, *, **, and *** for levels 0.10, 0.05, 0.01, and 0.001, respectively.

Table 4. Impact of Medicare Price Cuts on DME Supply Chain

		Change with Price Reform	
	Pre-Mean	Estimate	LR Estimate
	(1)	(2)	(3)
Panel (a): DME Category Level			
Number of Entrants	2.50	-0.34+	-1.00***
		(0.20)	(0.25)
U.S. Entrants	2.13	-0.75***	-1.54***
		(0.16)	(0.18)
Foreign Entrants	0.38	0.18+	0.22
		(0.10)	(0.20)
Number of New Contractors	6.69	2.19	2.22***
		(1.60)	(0.54)
Panel (b): Dose Response			
Number of Entrants	2.50	-0.16	-1.27***
		(0.39)	(0.36)
U.S. Entrants	2.13	-1.11***	-2.17***
		(0.32)	(0.25)
Foreign Entrants	0.38	0.64**	0.51+
		(0.20)	(0.29)
Number of New Contractors	6.69	3.59	3.63***
		(2.29)	(0.62)
Panel (c): Firm Level			
Log Cost of Goods Sold	3.76	-0.30+	-0.40*
		(0.17)	(0.16)

Note: The table presents estimates from equations (2), (3), and (5) for supply chain outcomes. Column (1) reports the pre-reform averages for treated groups. Column (2) reports the estimates, with standard errors in parentheses. Column (3) reports the long-run estimates (years 7–10). Panel (a) reports DME category-level analysis. Panel (b) reports dose-response estimates based on pre-reform Medicare market shares. Panel (c) reports firm-level estimates of the log cost of goods sold. Statistical significance is denoted by +, *, **, and *** at the 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Table 5. Impact of Medicare Price Cuts on Product Quality

		Change with Price Reform	
	Pre-Mean	Estimate	LR Estimate
	(1)	(2)	(3)
Repair & Replace Rate	0.004	0.004***	0.008***
		(0.0001)	(0.0002)
Likelihood of Facility-Reported Adverse Events	0.85	0.12^{+}	0.18^{+}
		(0.07)	(0.09)
Contracting Manufacturers	0.31	0.19**	0.40***
		(0.08)	(0.12)
Non-Contractors	0.69	0.11	0.15^{+}
		(0.07)	(0.09)

Note: Table reports results from estimating equation (2) for our product quality outcomes. Column (1) reports pre-event averages for treated groups. Column (2) reports estimates with standard errors in parentheses. Column (3) reports long-run impacts. Statistical significance is marked as +, *, **, and *** for levels 0.10, 0.05, 0.01, and 0.001, respectively.

Online Appendix

The Long-Run Impacts of Regulated Price Cuts: Evidence from Medicare

- Section A: The Value of DME Innovation – More Examples
- Section B: Details on Data and Variable Construction
- Section C: Proof of Theorem and Lemma
- Section D: Additional Tables and Figures

A The Value of DME Innovation—More Examples

Overview

This appendix delves into highly influential patents within treated Durable Medical Equipment (DME) categories. These patents, each with over 200 forward citations, underscore their technological significance and their spillovers into other technology categories. They represent key innovations in their fields and have made substantial impacts both within and outside the medical technology sector.

Counts of Highly Cited Patents by Treated DME Category

Below, we present a list of affected DME categories in our analysis, highlighting the number of patents cited over 200 times:

Counts of Highly Cited Patents in DME Categories

DME Category	Patent Counts
Infusion Pumps & Related Drugs	373
TENS	168
NPWT	34
Oxygen Supplies/Equipment	18
CPAP	15
Hospital Beds/Accessories	8
Wheelchairs	3
Nebulizers & Related Drugs	2
Enteral Nutrition	2

This list details the level of technological sophistication across our treated DME categories.

Selected Patents and Their Impact

Infusion Pump

US-5931814-A Dermally affixed injection device (Hoffman La Roche Inc, 1997) has 808 citations and a patent value of 315M USD. This new injection device, incorporating components typical of infusion pump systems, is smaller, simpler, more reliable, safer, more energy-efficient, and easier to manufacture than previous models. These improvements potentially enhance comfort and safety for patients requiring regular injections or infusions.
The device has influenced a wide array of technologies, including Advanced Drug Delivery Systems, Analyte Monitoring and Management, Safety and Protective Features for Needles, Wearable Medication Devices, Needle and Cannula Design Innovations, Medical Sensor Technologies, Diagnostic and Therapeutic Applications, and Medical Device Manufacturing Techniques.

Hospital Bed

US-6208250-B1 Patient position detection apparatus for a bed (Hill Rom Co Inc, 1999) with 366 citations and valued at 29.8M USD, represents an advanced tool for monitoring hospital patients. It offers precise tracking of patient movement, customizable alerts for various patient needs, and convenient features for caregivers, contributing to enhanced patient care and safety.
Its impact extends to Enhanced Patient Monitoring Systems, Bed Design and Functional Enhancements, Healthcare Facility Communication Systems, Remote Patient Monitoring and Alert Systems, Safety and Preventive Care Devices, Medical Sensors and Analysis Tools, and Patient Comfort and Rehabilitation Technologies. Its impact is also found in non-healthcare settings, such as influencing innovations in smart home systems and security monitoring.

B Details on Data and Variable Construction

B.1 Data Description

In this section, we provide additional details on each dataset we use to construct our baseline sample for analysis.

FDA Device Submissions (PMA and 510(k) Databases) We use two FDA databases on device approvals: the pre-market approval (PMA) database and the 510(k) database. The PMA database contains information about medical devices that have undergone a rigorous review process, which typically involves clinical trials and other extensive testing, to demonstrate their safety and effectiveness. Most Class III devices must go through the PMA process before they can be sold in the US market. The 510(k) database contains information about devices that have been deemed substantially equivalent to devices already on the market, and therefore require a less lengthy review process. Most Class II devices are required to complete the 510(k) process. Together, the PMA and 510(k) databases capture the majority of late-stage innovative activity in these device categories. In both data sets, we observe the universe of FDA device submissions including the submitting company name, device brand name, product codes and descriptions, and submission and approval dates. For both databases, we include all submissions between 1996 and 2018.

Dimensions Patent Grants Extract Dimensions is a comprehensive database that provides detailed information on patents issued by the United States Patent and Trademark Office (USPTO) and global patent offices across 100 countries. This database includes essential patent information such as the patent title, abstract, description, claims, filing date, and approval date, where applicable. To ensure that we observe close to the universe of patents in our sample years, we restrict our analysis to data between 1996 and 2016, as the patent applications can take three or more years before they are granted and publicly posted.

Patent Market Valuations To assess the value of innovation, we utilize patent market values (in millions USD) obtained from Kogan et al. (2017) (referred to as KPSS). KPSS determines a patent's market value based on the subsequent increase in the patent assignee's stock price following a USPTO announcement of patent issuance. However, the data have two limitations. First, since stock prices are only available for publicly traded companies, this data is limited to patent values assigned to such firms. Second, KPSS exclusively reports patent values for patents filed in the US and does not include those filed in other countries. We discuss how we apply the data to our setting in Section 7.

FDA Registration Database The FDA requires all products sold in the US to be registered in this database. The variables include the name of the registering establishment, proprietary name of the product, product code, device classification (I, II or III), establishment type (e.g. manufacturer, contract manufacturer, exporter) and the location of the establishment (US state or foreign country). In principle, these data cover the universe of medical devices (including DME) available for sale in the US. In practice, the database has two important limitations. First, the data are reported at the registration event level; for establishments that registered multiple brand names across different product codes, there was no straightforward way to establish a one-to-one correspondence between the registered brand name and the associated product code. Second, the data do not include inactive registrations; for example, a firm that registered a given product in 2005 that stopped selling the product (thus stopped registering in subsequent years) would not be captured in later years' data. We address these data issues in two ways. First, we use yearly snapshots from WayBackMachine for 2009, 2010, 2011, 2013, and 2020 to enhance our sample by capturing currently inactive registrations. Second, we focus on firm-level events, which we can identify in the data, rather than device-related events, which we cannot. We record whether the contractors are US-based or foreign. Nonetheless, due to these data limitations, we restrict the use of the registration data only to our analysis of firm contracting behavior.

Medicare Data We use the 100% Traditional Medicare enrollment and claims data from 2009 to 2019, which encompassed health care claims for all beneficiaries under Traditional Medicare. For each

DME claim, we observe the date of the claim, the HCPCS code, the Medicare price, and the quantity purchased. We supplement these data with publicly available Medicare DME fee schedules.

MarketScan We use the MarketScan data, a national sample of health insurance claims of commercially insured individuals. The data layout is analogous to the Medicare data described above. We use the MarketScan data to measure DME price and utilization of the privately insured. Our MarketScan data cover 1996 to 2013.

FDA Adverse Event Reports (MAUDE). The FDA's Manufacturer and User Facility Device Experience (MAUDE) database enables us to measure the safety of medical devices based on adverse event reports from 1992 to 2019. These reports include events such as deaths, hospitalizations, and life-threatening incidents, as well as minor events like product breaks, across FDA device types. Following Ensign and Cohen (2017), we address data and coding issues in the MAUDE database.

Orbis The Orbis database by Bureau van Dijk is a comprehensive global database on public and private firms. We use the Orbis database to obtain firm attributes used for imputing patent valuation for private firms.

Compustat The Compustat database includes firm financial and stock market data for publicly traded firms. From this data, we gather revenue and R&D expenses for publicly traded firms in our sample, all in millions USD. Continually updated patent data from Kogan et al. (2017), which provides firm identifiers for patents filed by publicly traded firms, enables a direct linkage of these data to patents. If there are no public firm identifiers for a given patent, the patent is assumed to be filed by a private firm.

B.2 Variable Definitions

Constructing the Medicare Market Share We define the "Medicare market share" as the ratio between total fee-for-service Medicare spending on DME and the sum of DME spending by fee-for-service Medicare, private insurance, and health care providers. We compute total Medicare spending for each DME category using the 100% Medicare claims data. We estimate the total private insurance spending for each DME category using the MarketScan data: we compute the total DME spending in each DME category and scale them up by the percent of the privately insured population covered by the MarketScan, using enrollment estimates from the Kaiser Family Foundation.[28] We compute the total DME spending by health care providers using the Supply Guide data from ECRI Institute. The Supply Guide contains transaction-level information on the purchase of medical devices and supplies by health systems, hospitals, nursing homes, and other providers. Over 2,000 providers are covered. We compute the total DME spending in each category in the Supply Guide and scale them up by the percent of providers of each type covered by the Supply Guide, to obtain a national estimate. One limitation of our definition of Medicare share is that we do not observe the spending in each DME category for Medicaid and Medicare Advantage. Given that our first set of reforms was announced in 2006, we expect Medicare Advantage to be relatively minor. We also expect Medicaid to play a relatively minor role since it generally accounts for a small amount of spending due to low payment rates and prior literature has shown that for this reason, Medicaid does not appear to influence innovative activities. (Garthwaite, Sachs and Stern, 2021)

[28] https://www.kff.org/other/state-indicator/total-population/

B.3 DME Product Category to FDA Product Code Crosswalk

DME Product Categories	FDA Product Codes
Automatic External Defibrillator	MKJ, NSA
Breast Prostheses	NOJ
Canes/Crutches	IPR, IPS, KHY
Commodes/Bed Pans/Urinals	ILS, FOB, FNP
CPAP	BZD, NFB, NHK, NMC, QLN, QBY
CPM Device	BXB
Dynamic Splint	HSP
Enteral Nutrition	BSS, LZH, EZK, FPD, FRQ, KNT, PIF, PIO, PLI, PNR, PRM, PRP, PRR, PRY, PRW, PSB
Eye Prostheses	HQT, HQH, NCK
Facial Prostheses	FZE
Glucose Monitor	NBW
Heat/Cold Application	ILY, IOB, LBG, NHN, NZY, IME, IMD, OMW, ILO, IMA, IRT, OZC
HFCWO Device	BYI
Hospital Beds/Accessories	FNL, LLI, OSI, FNK, FNJ
Impotence Aid	LKY
Infusion Pumps & Related Drugs	FIH, FRN, LZG
Intravenous Immune Globulin	PKP
IPPB	BZD, NFB, NHK, NMC
Lenses	NAI, NJH, HQG, LPL, LPM, MVN, NCZ, NIC, HQD, MUW, MWL, NUU, HQZ, HJX
Lift	FNG, FSA
Lower Limb Orthoses	ILG, ITM, ITQ, ITS, ITW, OHI, PMV
Lower Limb Prostheses	ISW, KFX
LSO	IPY, IQE
Mech In-Exsufflation Devices	NHJ
Nebulizers & Related Drugs	CAF, NVO, NVP, CCQ
NPWT	OMP, OKO, BTA, OEI, OJR, OTK
Orthopedic Footwear	KNP
Osteogenesis Stimulator	LOF, LPQ
Ostomy Supplies	NDS, EXD, EXA, EXB, EXE, EXG, EXH, EZQ, EZR, EZS, FON, GDS, PQE
Other Neuromuscular Stimulators	KPI, GZC
Oxygen Supplies/Equipment	ECX, CAN, CAT, BZB, CAW, BYJ, OGL, BYL, BYK, DQA, BTT, OBN, OGG, BYP
Parenteral Nutrition	POR
Pneumatic Compression Device	JOW
SIO	IPW
SO	IQK
Speech Generating Devices	ILP, ILQ
Support Surfaces	INX, IOQ, MOC, FNM
Surgical Dressings	KGX, KGN, MGQ, FRO, NAB, NAD, HMP, FQM
TENS	GZJ
TLSO	IQF, MRI
Tracheostomy Supplies	JOH, BTO, NXA, OGP, OGV, OGW
Traction Equipment	ITH, ILZ, IRS
Ultraviolet Devices	FTC
Upper Limb Orthoses	ILE, ILH, IOY, IQI
Upper Limb Prostheses	PAE, IQQ, IQW, IQX, IQZ, IRA, IRD, IRE, ISZ, KFT, KFW, KGH
Urological Supplies	EYA, EYB, EYC, EYI, EYJ, EYK, EZB, EZC, EZD, EZL, FCM, FGF, FGH, FGI, GBL, GBM, KNY, KOD, LJH, MJC, NOW, NWQ, NWR, OHR, PPA, PPB, PPC, PPD, PPF, PPG, PIH, FHA, MNG, EXI, EXJ, EYT, EYZ, FAQ, FCN, FFH, FOC, KNX, NNW, NNX, NNY, NNZ, NOA, NZU
Ventilators	NOU, NQY
Voice Prostheses	ESE, EWL, MCK
Walkers	ITJ, NXE, INP
Wheelchairs	IMS, IMX, IMY, IMZ, INC, INE, KID, KNO, IML, IMM, IMN, IMO, IMP, IMQ, IMR, IMW, INA, INB, IQB, KNN, LFF, IOR, LBE, ITI, IQC, IMK, IPL

B.4 Keywords and CPC Codes for Patent Search

DME Product Categories	Keywords	CPC Codes
Automatic External Defibrillator	Automatic External Defibrillator	
Breast Prostheses	(external Breast Prostheses) OR (Breast Prosthetic)	
Canes/Crutches	(Cane OR Crutches OR Crutch)	A61H3/02
Commodes/Bed Pans/Urinals	Commodes OR (Bed Pans) OR Urinals	A61G9
CPAP	(Continuous Positive Airway Pressure) OR (CPAP Machine)	A61M16
CPM Device	Continuous Passive Motion Knee	
Diabetic Shoes	Diabetic Shoes	
Dynamic Splint	Dynamic Splint	
Enteral Nutrition	Enteral Feeding Kit	
Eye Prostheses	(Eye Prostheses) OR (Eye Prosthetic)	
Facial Prostheses	(Facial Prostheses) OR (Facial Prosthetic)	
Glucose Monitor	Glucose Monitor	A61B5
Heat/Cold Application	medical AND (heat OR hot OR cold) AND (heatlamp OR phototherapy OR Hydrocollator)	
HFCWO Device	(high-frequency chest wall oscillation vest) OR (HFCWO Device)	
Hospital Beds/Accessories	HOSPITAL BED	A61G7
Impotence Aid	Male Vacuum Erection, penis pump	
Infusion Pumps & Related Drugs	INFUSION AND (PUMPS OR pump)	A61M
Intravenous Immune Globulin	INTRAVENOUS IMMUNE GLOBULIN	A61
IPPB	(Intermittent positive pressure breathing (machine OR device)) OR (IPPB AND (machine OR device))	
Lenses	(contact lens) OR eyeglasses OR bifocals	A61F9 OR G02C
Lift	lift	A61G7/10
Lower Limb Orthoses	orthosis AND (knee OR leg OR foot OR hip OR ankle)	
Lower Limb Prostheses	(prosthetic OR prosthesis) AND (leg OR knee OR foot)	
LSO	(Lumbar OR Lumbo) AND Sacral AND (Orthosis OR Brace OR Support)	A61F5/028
Mech In-Exsufflation Devices	Mechanical insufflation-exsufflation OR (Cough Assist In-Exsufflator)	A61M16
Nebulizers & Related Drugs	Nebulizers	A61M16
NPWT	(Negative pressure wound therapy) OR (NPWT)	A61M1/90
Orthopedic Footwear	orthopedic FOOTWEAR NOT diabetic	
Osteogenesis Stimulator	(mechanical bone growth stimulation) OR (OSTEOGENESIS AND (stimulator OR stimulation))	A61H23
Ostomy Supplies	ostomoy OR colostomy OR ileostomy OR urethrostomy supplies	A61F5/44
Other Neuromuscular Stimulators	Pelvic Floor Electrical Stimulator OR (Neuromuscular (Stimulator OR stimulation))	
Oxygen Supplies/Equipment	Oxygen (Supplies OR Equipment)	A61M16
Parenteral Nutrition	total parenteral nutrition	A61M5
Pneumatic Compression Device	Deep vein thrombosis therapy device	A61H
SIO	Sacroiliac Orthosis	
SO	Cranial Cervical Orthosis	
Speech Generating Devices	(voice OR speech) AND aid	H04R23
Support Surfaces	(Pressure support surfaces) OR (Air-Fluidized Beds) OR (Alternating Pressure and Low Air Loss Mattress)	A61G7/057
Surgical Dressings	Surgical Dressing	A61F13
TENS	(Transcutaneous Electrical Nerve Stimulation) OR (TENS)	A61N1
TLSO	(Thoracic Lumbar Sacral Orthosis) OR (TLSO AND lumbar)	
Tracheostomy Supplies	Tracheostomy AND (supplies OR equipment OR supply OR accessories)	
Traction Equipment	(cervical traction device) OR (lumbar traction device) OR (pelvic traction)	
Ultraviolet Devices	Ultraviolet AND (therapeutic OR therapy)	A61N5/06
Upper Limb Orthoses	(arm OR hand OR elbow) AND Orthoses	
Upper Limb Prostheses	(arm OR hand OR elbow) AND (prosthesis OR prosthetic)	A61F2/54
Urological Supplies	(Urological OR urinary OR Urostomy OR urethral) AND (collection OR catheter OR irrigation OR insert)	A61
Ventilators	Ventilator	A61M16
Voice Prostheses	(Artificial Larynx) OR (Tracheostomy Speaking Valve) OR (Voice Prosthesis)	A61F
Walkers	walker	A61H3
Wheelchairs	Wheelchair	A61G5

Note: All keywords and patent texts are converted to lowercase before executing the search.

C Proof of Theorem and Lemma

Lemma 1. *The profit-maximizing quality s_i^* is increasing in the regulated price p_i, provided that $p_i > c_i(s_i)$.*

Proof. The first-order condition for profit maximization problem implicitly defines s^*:

$$(p_i - c(s_i^*))q'(s_i^*) = q(s_i^*)c'(s_i^*)$$

Differentiating both sides with respect to p_i and rearrange:

$$\frac{ds_i^*}{dp_i} = \frac{q'(s_i^*)}{c''(s_i^*)q(s_i^*) + 2c'(s_i^*)q'(s_i^*) - (p_i - c(s_i^*))q''(s_i^*)}$$

However, since $q'(s_i^*) > 0$, $c'(s_i^*) > 0$, $q''(s_i^*) \leq 0$, and $c''(s_i^*) \geq 0$, it follows that:

$$\frac{ds_i^*}{dp_i} > 0$$

□

Theorem 1. *The set of invested innovation is weakly increasing in regulated price. Let $\tilde{I}$ denote the set of invested innovations under the original set of regulated prices $P = \{p_1, p_2, p_3, \ldots\}$. There exists a set of prices $\dot{P} = \{\dot{p}_1, \dot{p}_2, \dot{p}_3, \ldots\}$ such that $\dot{P} \leq P$ and $\dot{P} \neq P$, while maintaining the same set of invested innovations $\tilde{I}$. That is, $\exists \dot{P} \leq P, \dot{P} \neq P$ such that $\dot{I} = \tilde{I}$. Moreover, there also exists a set of prices $\ddot{P} = \{\ddot{p}_1, \ddot{p}_2, \ddot{p}_3, \ldots\}$ such that $\ddot{P} \leq P$ and $\ddot{P} \neq P$, and the set of invested innovations is strictly smaller: $\ddot{I} \subset \tilde{I}$.*

Proof. Consider the set of innovations $I = \{1, 2, 3, \ldots\}$ and let $\tilde{I} \subseteq I$ be the set of invested innovations under the original prices $P = \{p_1, p_2, p_3, \ldots\}$. An innovation $i \in I$ is invested if it generates non-negative expected profits:

$$\phi_i[(p_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i \geq 0$$

Consider a new set of prices $\dot{P} = \{\dot{p}_1, \dot{p}_2, \dot{p}_3, \ldots\}$ such that $\dot{P} \leq P$ and $\dot{P} \neq P$. Define $\epsilon_i = p_i - \dot{p}_i \geq 0$. We seek ϵ_i small enough such that:

$$\phi_i[(\dot{p}_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i \geq 0$$

Consider the function:

$$\Pi_i(\epsilon_i) = \phi_i[(p_i - \epsilon_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i$$

This function $\Pi_i(\epsilon_i)$ is continuous in ϵ. At $\epsilon = 0$:

$$\Pi_i(0) = \phi_i[(p_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i \geq 0$$

Since $\Pi_i(\epsilon_i)$ is continuous, by the intermediate value theorem, for any ϵ_i sufficiently close to 0, we have:

$$\Pi_i(\epsilon_i) = \phi_i[(p_i - \epsilon_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i \geq 0$$

Therefore, for sufficiently small ϵ_i, the inequality:

$$\phi_i[(\dot{p}_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i \geq 0$$

holds for all $i \in \tilde{I}$. Hence, $\dot{I} = \tilde{I}$.
Now, consider a larger price cut. Specifically, choose $\ddot{P} = \{\ddot{p}_1, \ddot{p}_2, \ddot{p}_3, \ldots\}$ where $\ddot{p}_i = p_i - \delta_i$ and $\delta_i > 0$ is large enough such that:

$$\phi_i[(\ddot{p}_i - c(s_i^*))q(s_i^*) - \Omega_i] - (1 - \phi_i)\Omega_i < 0$$

We need to find a δ_i such that:

$$\phi_i\left[(p_i - c(s_i^*))q(s_i^*) - \Omega_i\right] - (1 - \phi_i)\Omega_i < \phi_i\delta_i q(s_i^*)$$

This implies:

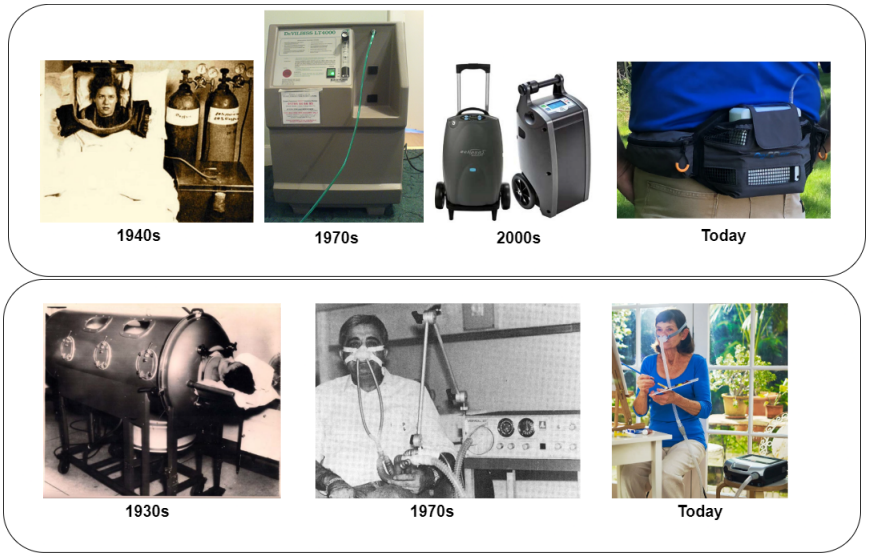
$$\delta_i q(s_i^*) > [(p_i - c(s_i^*))q(s_i^*) - \Omega_i] - \frac{(1-\phi_i)}{\phi_i}\Omega_i$$

Since the right-hand side is finite, there exists a sufficiently large δ_i such that the inequality holds.
For such a price cut, some innovations $i \in \tilde{I}$ will no longer satisfy the non-negative profit condition.
Therefore, the set of invested innovations $\ddot{I}$ will be strictly smaller than $\tilde{I}$, i.e., $\ddot{I} \subset \tilde{I}$.
Hence, there exists a set of prices $\dot{P} \leq P$ and $\dot{P} \neq P$ such that $\dot{I} = \tilde{I}$, and there also exists a set of prices $\ddot{P} \leq P$ and $\ddot{P} \neq P$ such that $\ddot{I} \subset \tilde{I}$.

□

D Additional Tables and Figures

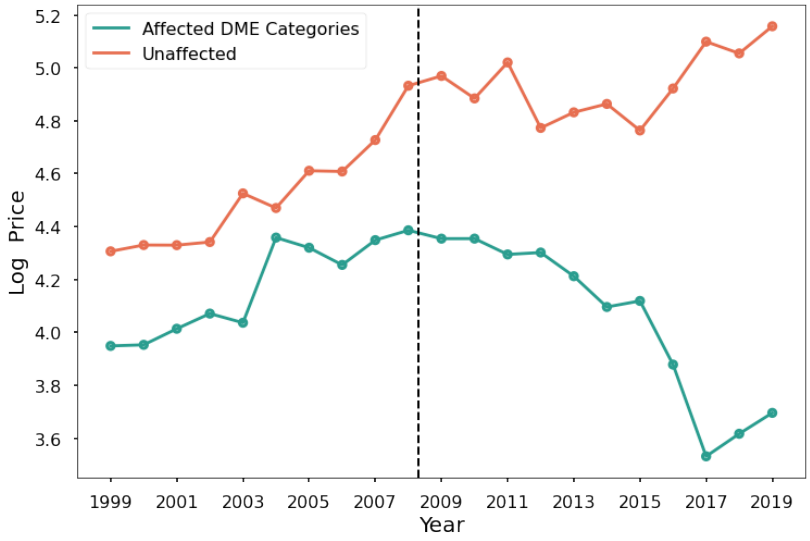
Figure A1. Examples of DME Innovation



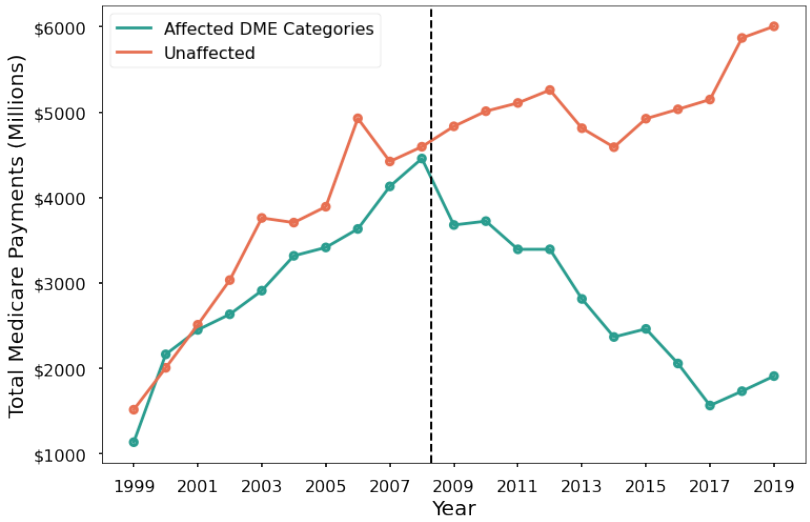
Note: The figure shows the evolution of oxygen therapy (top) and non-invasive ventilators (bottom) over time.

Figure A2. Raw Trends in Medicare Price and Payments

(a) Log Medicare Price

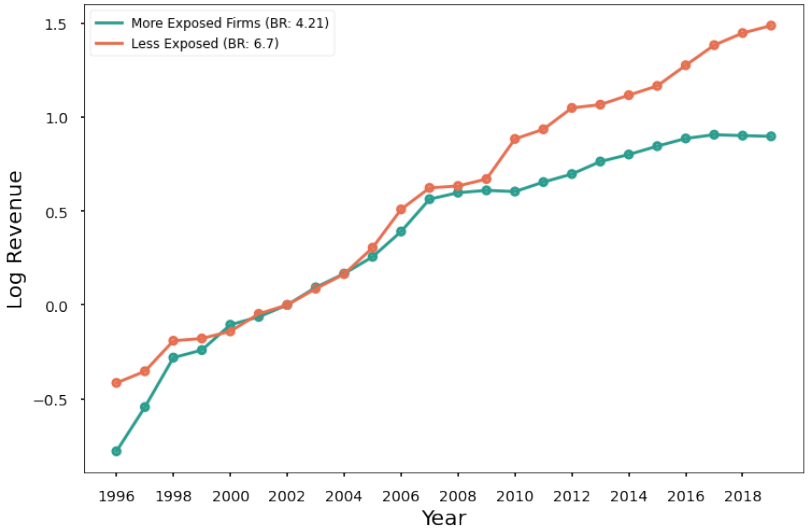


(b) Medicare Payments



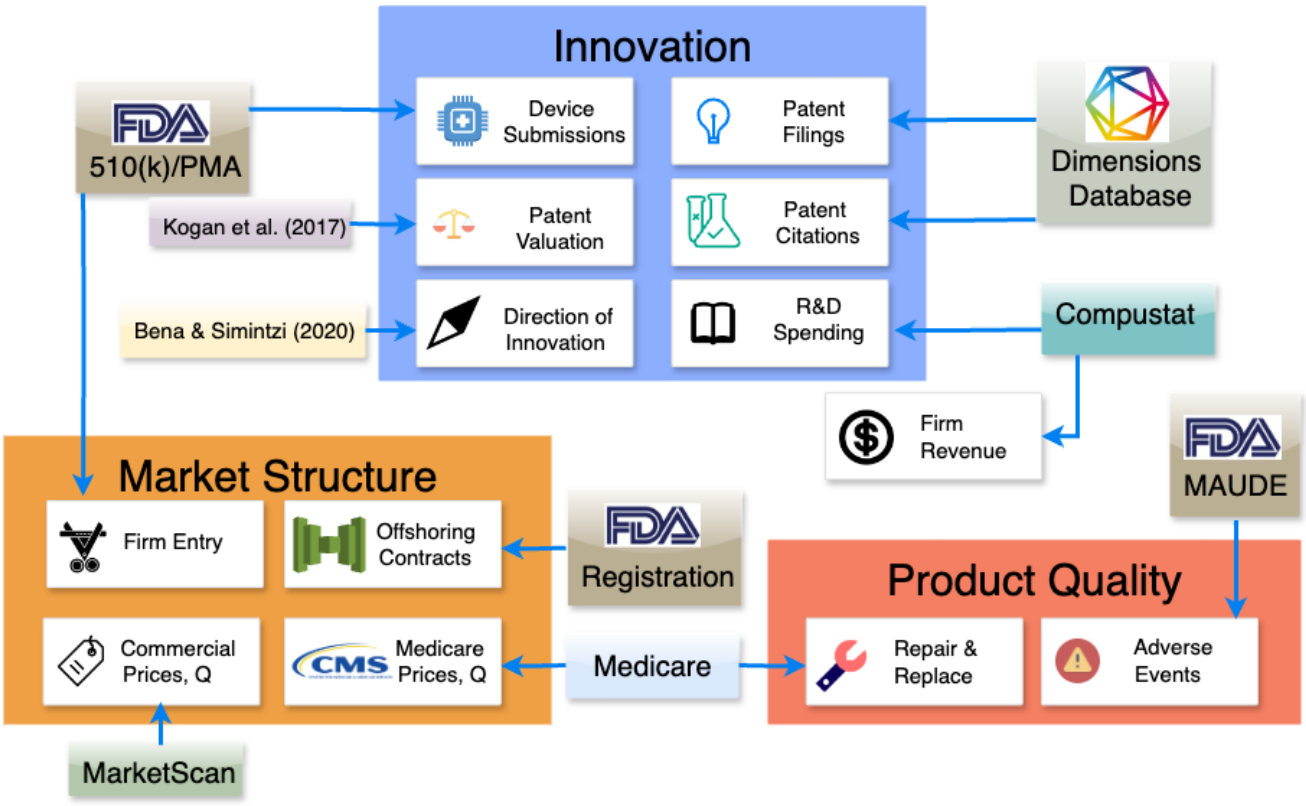
Note: The figure plots the trends in average log Medicare price in panel (a) and total Medicare reimbursements in panel (b), separately for DME categories subject to the price cuts and those that are not.

Figure A3. Raw Trends in Firm Revenue



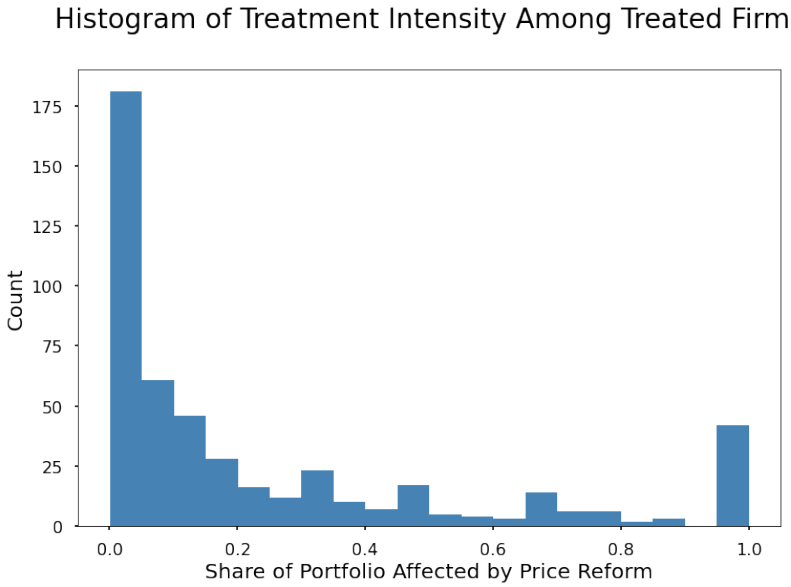
Note: The figure plots log revenue per year, separately for firms with above and below median exposure to the reforms. Both groups are plotted relative to their 2002 mean, the year before the Medicare Modernization Act of 2003 which authorized Medicare to cut DME prices at a future date.

Figure A4. Data and Variables



Note: The figure illustrates the data used for the construction of our three sets of key variables: innovation, market structure, and product quality.

Figure A5. Share of Manufacturers' Patent Portfolios Affected by Price Reform



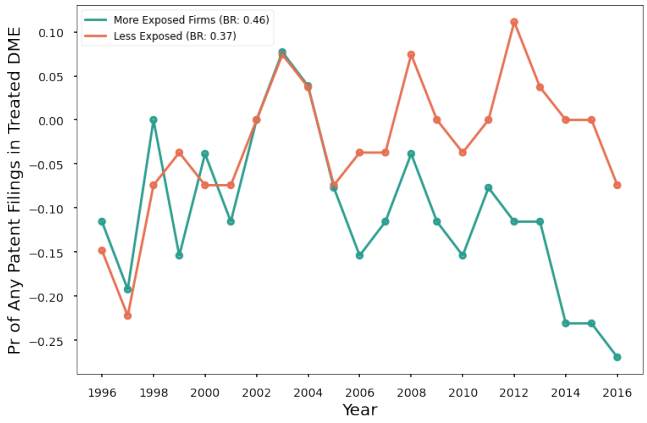
Note: The figure presents a histogram depicting the distribution of firms based on different values of patent portfolio exposure to price reform. The figure includes the 486 firms in our firm-level analysis. No firms have zero exposure since all firms must have had at least one affected DME patent pre-reform to be included in our sample. A share value of one corresponds to a 100% exposure to price reform, indicating that all of the patents held by the firm prior to the reform were in affected DME categories.

Figure A6. Raw Trends in Innovation

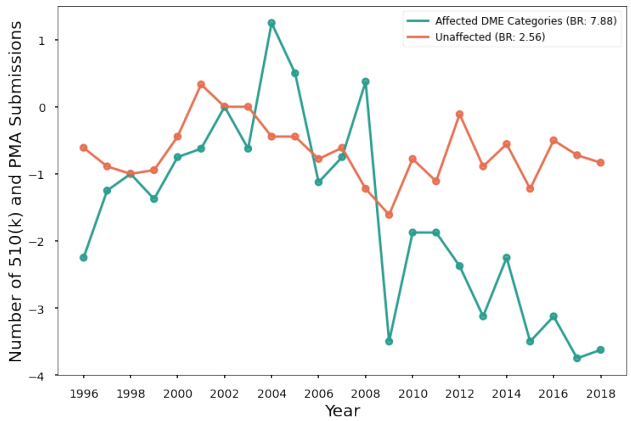
(a) Log R&D Spending



(b) Patent Filings



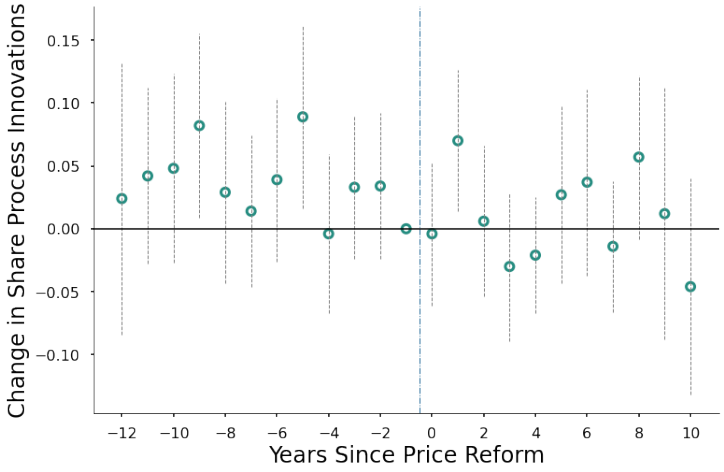
(c) Pre-Market Approval and 510(k) Submissions



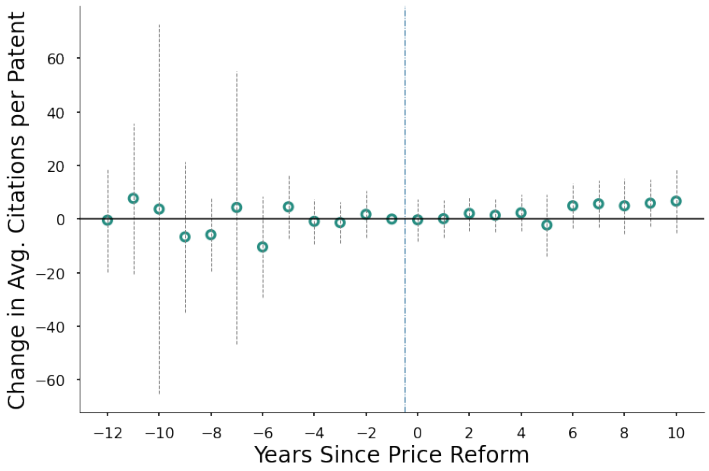
Note: Panel (a) plots R&D spending per year, separately for manufacturers with above and below median exposure to the reforms. Panel (b) plots the probability a manufacturer files any patent in the affected categories in each year, separately for manufacturers with above and below median exposure to the reforms. Panel (c) plots the number of PMAs and 510(k)s submitted per year, separately for DME categories affected by price reform and those unaffected. Data in each group are plotted relative to its 2002 mean, the year prior to the Medicare Modernization Act of 2003 which authorized Medicare to cut DME prices at a future date.

Figure A7. Direction and Quality of Innovation

(a) Change in Share of Process Innovations

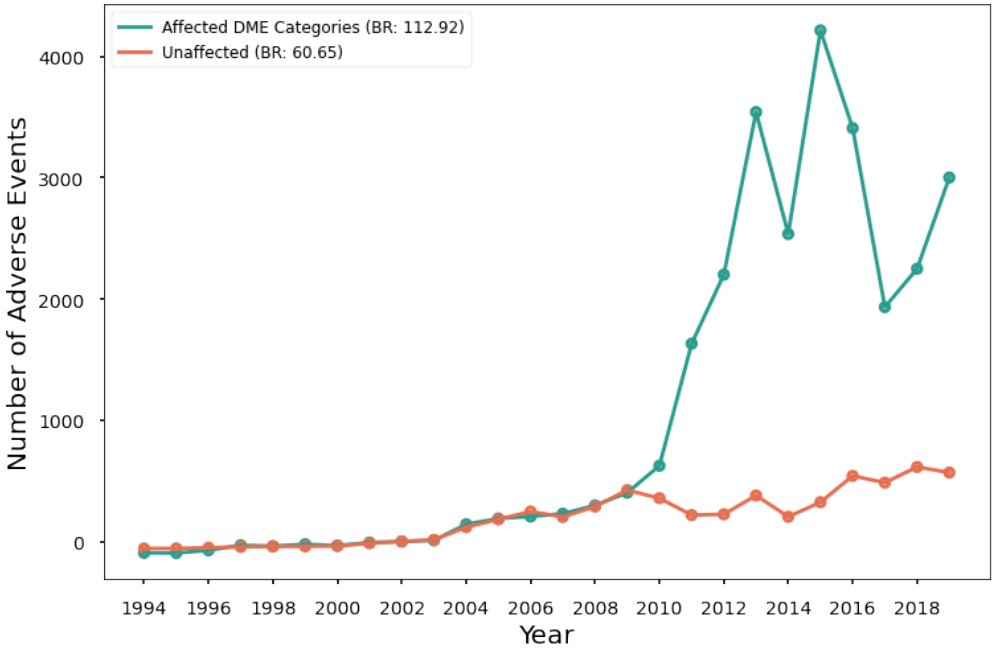


(b) Change in Avg. Patent Citation Count



Note: The figure presents the coefficients obtained from estimating equation (1) for the share of patents that include process innovations and the average number of citations per patent. It illustrates the temporal evolution of outcomes in DME categories affected by the event, relative to those unaffected, with a reference period at $t = -1$. The dashed lines around the point estimates show the 95% confidence intervals.

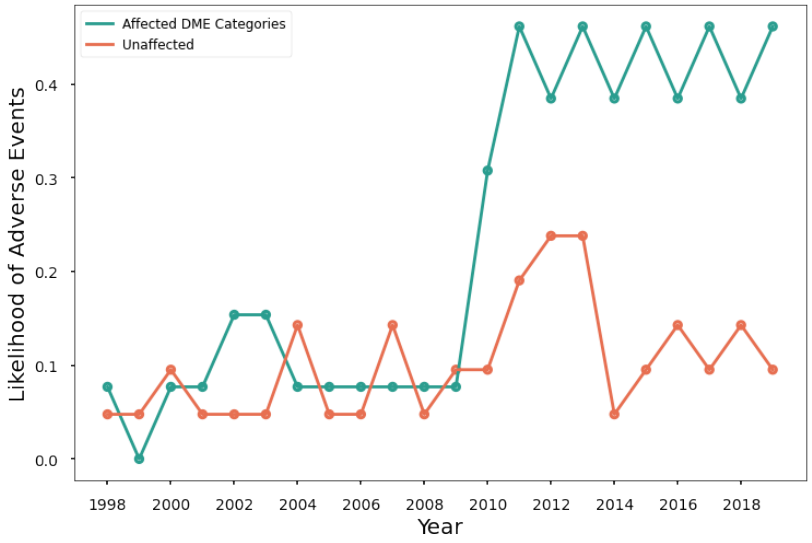
Figure A8. Raw Trends in All Reported Adverse Events



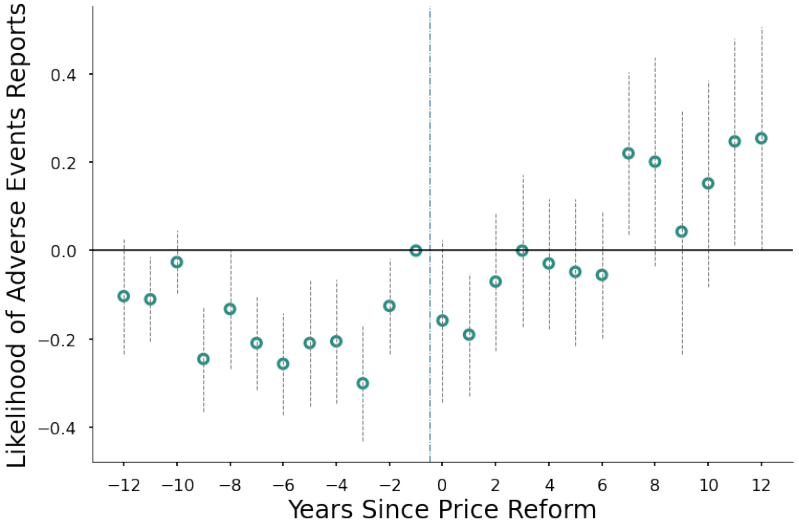
Note: Figure reports the total number of adverse events reported to the MAUDE database, separately by affected and unaffected DME categories. Reports by mandatory and voluntary reporters are included.

Figure A9. Likelihood of Hospital-Reported Adverse Event, Contractors

(a) Raw Trends by Treatment Status

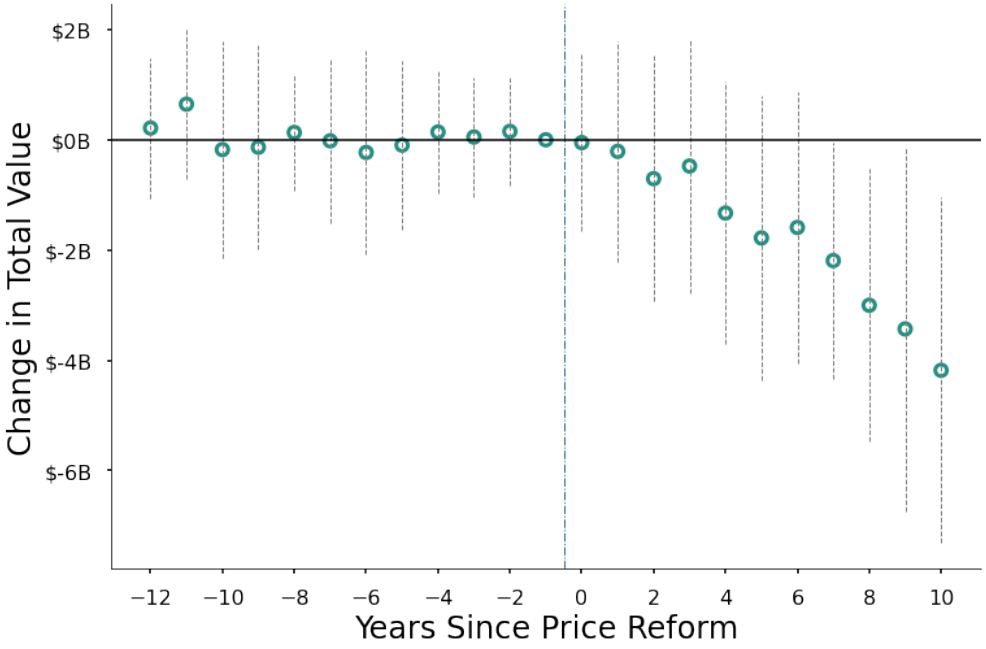


(b) Event Study



Panel (a) provides the raw trends of the likelihood of any adverse event reports occurring within affected and unaffected DME categories reported by user facilities, focusing on manufacturers that use a contractor. Panel (b) shows the estimates of equation (1) when applied to this same outcome, comparing affected and unaffected DME categories. The dashed lines around the point estimates show the 95% confidence intervals.

Figure A10. Event Study: Change in Total Value of Innovation.



Notes: The figure presents the coefficients obtained from estimating equation (1) for our total innovation value outcome derived from Kogan et al. (2017). It illustrates the temporal evolution of the sum of the market value of all patents filed within a given year and treated DME category relative to that of those filed in untreated categories, with a reference period at $t = -1$. The dashed lines around the point estimates show the 95% confidence intervals.

Table A1. Summary Statistics of Entire DME Manufacturer Sample

	2003					*1996-2016*				
	Mean	S.D.	P25	P50	P75	Mean	S.D.	P25	P50	P75
Number of Health-Related Patents	14.29	33.52	0	2	10	13.91	40.49	0	1	9
Number of DME Patents	2.34	6.14	0	0	2	2.39	7.25	0	0	1
Number of Affected DME Patents	0.90	3.11	0	0	1	0.96	3.74	0	0	0
Number of Unaffected DME Patents	1.44	5.01	0	0	1	1.43	5.36	0	0	1
Share of Portfolio Affected by Price Reform	0.25	0.31	0.03	0.10	0.34	-	-	-	-	-
Number of Manufacturers	486									

Note: The table reports summary statistics from 2003, separately for all product categories and the entire sample period (1996-2016). P25, P50, and P75 signify firms in the 25th, 50th, and 75th percentile, respectively. Panel A reports the mean, standard deviation, and percentiles at the product category level. Panel B reports the total number of manufacturers in the sample.

Table A2. Impact of Price Reform on Price and Quantity

	Change with Price Reform	
	Estimate	LR Estimate
	(1)	(2)
Panel (a): DME Category Level		
Medicare		
Log Price	-0.54**	-0.94***
	(0.18)	(0.27)
Log Quantity	-0.13	-0.13
	(0.25)	(0.25)
Commercial Insurers		
Log Price	-0.16	-0.24+
	(0.13)	(0.13)
Log Quantity	-0.12	-0.17
	(0.20)	(0.24)
Panel (b): Dose Response		
Medicare		
Log Price	-0.77***	-1.19***
	(0.18)	(0.27)
Log Quantity	-0.25	-0.19
	(0.38)	(0.31)
Commercial Insurers		
Log Price	-0.25	-0.29
	(0.17)	(0.18)
Log Quantity	-0.38	-0.50+
	(0.26)	(0.30)

Note: This table reports outcomes from equations (2) and (5), detailing changes in price and quantity outcomes. Column (1) reports estimates with standard errors in parentheses. Column (2) reports long-run impacts. Panel (a) reports DME category-level analysis. Panel (b) reports continuous dose-response outcomes based on pre-reform market shares. LR estimate for commercial insurers is based on year 7 only, instead of years 7 to 10, due to data availability. Estimates for Medicare price and quantity use the implementation date rather than the announcement date to define relative years, since mechanically Medicare price would not change before the implementation date. Statistical significance is marked as +, *, **, and *** for levels 0.10, 0.05, 0.01, and 0.001, respectively.

Table A3. Impact of Price Reform on Innovation, Entire Firm Sample

		Change with Price Reform	
	Pre-Mean	Estimate	LR Estimate
	(1)	(2)	(3)
Pr of Filing Affected DME Patent	0.35	-0.05	-0.06+
		(0.03)	(0.03)
Pr of Filing Unaffected DME Patent	0.11	-0.03	-0.01
		(0.03)	(0.03)

Note: This table displays outcomes from equations (2) and (5), detailing changes in the patenting outcomes at the firm level. Column (1) reports pre-event averages for treated groups. Column (2) reports estimates with standard errors in parentheses. Column (3) reports long-run estimates and Column (4) reports the elasticity of innovation with respect to long-run Medicare price changes in the respective specification (DME level). The sample includes all 486 manufacturers that have filed at least one patent in the treated DME categories prior to the price cuts. Statistical significance is marked as +, *, **, and *** for levels 0.10, 0.05, 0.01, and 0.001, respectively.

Table A4. Impact of Price Reform on Direction and Quality of Innovation.

		Change with Price Reform	
	Pre-Event Mean	Estimate	LR Estimate
	(1)	(2)	(3)
Share of Patents on Process Innovation	0.18	-0.03	-0.02
		(0.02)	(0.03)
Share of Patents on Product Innovation	0.82	0.03	0.02
		(0.02)	(0.03)
Citations per Patent	6.68	-0.56	4.76
		(10.86)	(5.52)

Note: The table presents results from estimating equation 2 for our direction and quality of innovation outcomes. Column (1) reports the pre-event (before price reform) mean across treated groups. Column (2) reports the estimates, with standard errors reported in parentheses below the estimates. Column (3) reports the percent change in the outcome relative to the pre-event mean. Table reports estimates of the change in the direction of innovation or citations at the DME category level. Statistical significance is denoted by +, *, **, and *** correspond to significance levels of 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Table A5. Impact of Medicare Price Cuts on Overall Adverse Event Reports

		Change with Price Reform	
	Pre-Mean	Estimate	LR Estimate
	(1)	(2)	(3)
Number of Adverse Event Reports	898.5	2136.9	677.7
		(1326.0)	(2621.3)
Contracting Manufacturers	2.7	177.8	65.2
		(127.6)	(166.2)
Non-Contractors	895.8	1959.1	612.5
		(1312.2)	(2606.4)

Note: Table reports results from estimating equation (2) for our overall adverse event report outcomes. Column (1) reports pre-event averages for treated groups. Column (2) reports estimates with standard errors in parentheses. Column (3) reports long-run impacts. Table reports estimates for the following outcomes: the number of adverse event reports from all sources and specifically by type of manufacturer. Statistical significance is marked as +, *, **, and *** for levels 0.10, 0.05, 0.01, and 0.001, respectively.