Product Safety Standards and Technological Innovation: Evidence from the 1968 Radiation Control

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Abstract

This paper studies how stricter safety standards shape technological development by drawing evidence from the 1968 Radiation Control for Health and Safety Act. The Act mandated performance standards to mitigate radiation risks in electronic products. I find firms developed new technologies reducing the risk of diagnostic X-ray medical equipment to adapt to the regulation. I also document an increase in innovations representing new radiation-generating medical devices, with evidence of technological complementarity. Alternative explanations, including the introduction of the CT scan, are ruled out. Back-of-the-envelope calculations indicate welfare gains through health improvements and private market value driven by these induced innovations.

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"While modern technology has enriched our daily lives, it has sometimes yields unexpected and unfortunate side effects...Now modern science must be put to work on these hazards — particularly the hazards which confront the consumer."

— Lyndon B. Johnson

1 Introduction

Both historically and today, consumer product safety regulation is a ubiquitous policy tool addressing market failures due to asymmetric information. In the United States, for example, approximately 15,000 types of products are under the regulation of the Consumer Product Safety Commission (CPSC)[1], and the Food and Drug Administration (FDA) is in responsible for the oversight of more than $2.7 trillion in consumption of food, medical products, and tobacco.[2] Although aiming to safeguard consumers from potential hazards, such regulations have become a source of controversy, especially in the context of innovation (Maresova, 2023).[3] On the one hand, by scaling up compliance costs and entry costs, stricter safety standards have the potential to both impede the development of new technologies and the commercialization of new products (Peltzman, 1973). On the other hand, by reducing quality uncertainties, tighter regulatory scrutiny can increase consumers' willingness to pay for regulated products and thus spur innovation (Carpenter, Grimmer and Lomazoff, 2010). Therefore, it is crucial to understand the nexus and strike a delicate balance between timely access to new technologies and the imposition of rigorous safety standards.

To shed new light on this ongoing debate, I assess the causal effect of product safety standards on firms' patenting activities in medical devices.[4][5] Credibly capturing this *full* causal

[1]See https://www.cpsc.gov/Newsroom/FOIA/Guide-to-Public-Information, last accessed February 14, 2025.

[2]See https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance, last accessed February 14, 2025.

[3]See for example, in the (de)regulation for artificial intelligence in medical technologies, https://www.nytimes.com/2023/03/03/technolog/artificial-intelligence-regulation-congress.html, and https://www.meddeviceonline.com/doc/the-fda-regulatory-landscape-for-ai-in-medical-devices-0001 last accessed February 14, 2025.

[4]For example, some experts argue that regulations could hinder technological progress given the early state of AI development, while others believe they must be implemented immediately to ensure AI systems are developed and deployed responsibly. See https://www.brookings.edu/articles/balancing-market-innovation-incentives-and-regulation-in-ai-challenges-and-opportunities/, last accessed February 14, 2025.

[5]Interestingly, for medical device per se, there is an ongoing debate regarding how the FDA should set up regulatory tools towards AI and machine learning technologies (see for example, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device, last accessed February 14, 2025). By the end of July 2023, 692 AI-enabled medical devices had received marketing authorization from the FDA, of which more than 75% are for radiology applications (Hill, 2024).

effect is challenging today, especially in the healthcare sector. This is because multiple regulatory pathways are simultaneously governing the safety and effectiveness of medical products in the current regime, which would make extrapolations to zero inherently speculative. To address this issue, I drew on a large-scale consumer product safety regulation in U.S. history as an ideal natural experiment: the Radiation Control for Health and Safety Act (RCHSA) in 1968. For the first time and at the federal level, this regulation safeguarded consumers from excessive and unnecessary radiation emitted by electronic products. The RCHSA mandated minimum safety performance standards and a series of compliance and enforcement measures, conceptually increasing compliance costs and potentially influencing firms' strategic decisions to mitigate the negative effects of regulatory pressure. Focusing on diagnostic X-ray devices, I show that certain *innovations*, which reduce products' radiation risks, could be a key channel through which firms adapt to regulation. Providing empirical evidence for this channel, to my knowledge, is novel in the literature discussing healthcare market.

Economic theories suggest the effect of safety standards on innovation is ambiguous. To illustrate the key mechanisms at play, I developed a model following Viscusi and Moore (1993) who conceptualize how firms strike a balance between product safety and product novelty. In this model, the extent to which safety standards affect firms' incentives to innovate hinges on two key factors: the innovation types and the nature of the regulatory costs (e.g., direct compliance costs, administrative hassles, product liability costs, etc.). Two testable predictions are generated: First, firms can develop new technologies to improve products' safety features ("*safety innovation*") in order to comply with stricter regulations. Second, firms are also incentivized to develop new products as long as such new products and safety innovation are complementary in production.[6]

In the empirical section of my paper, I use a difference-in-differences (DID) framework to estimate the induced innovation effects, exploiting variation across patent subclasses over time. To distinguish the treatment and control groups, I leverage the detailed patent classification system known as the *Cooperative Patent Classification* (CPC). The treatment group consists of all patents filed under the broad patent class `A61B6`, representing apparatus for radiation diagnosis. In my primary control group, I include all patents relating to diagnostic medical equipment based on *non-radiation* technology under the patent class `A61B`. Accounting for potential spillovers across technology types and medical products (Grennan, Gupta and Lederman, 2020), I further constructed two alternative control groups using drug patents and medical implant patents.

[6]The detailed framework is outlined in the appendix, Section A.2.

My analysis begins with assessing the effect of safety standards on the quantity of innovation, measured by the raw (and also citation-weighted) patent counts under each patent subclass per year. Using the universe of granted patents applied for at the United States Patent and Trademark Office (USPTO) between 1960 and 1980, I find introducing stricter safety standards led to a significant increase in patent counts relating to diagnostic X-ray devices. When comparing point estimates derived from different control groups, my findings further suggest some spillovers resulting from the RCHSA may extend to medical implant patents.

Meanwhile, I document the surge in innovation is composed of both a new wave of technologies protecting patients from unnecessary radiation exposure (*radiation reducing technologies*) and an increase in new devices emitting radiation (*radiation generating technologies/devices*). I relied on the detailed CPC code and selecting patent subclasses closely relevant to either radiation protection or radiation emission. Within a tightening regulatory environment, the patent count for both radiation-reducing and radiation-generating technologies significantly increased. I then provide additional empirical evidence that these two technologies are complementary to each other. Further, I show firms are the primary contributors to this historical spike in patenting activities, whereas independent inventors responded little following the RCHSA. Putting together, these findings are aligned with the premise of my theoretical framework: the induced innovation reflects shifts in firms' incentives to adapt to the regulation; increased radiation-reducing technologies further push the innovation of radiation-generating devices by substantially decreasing the marginal cost of doing so.

This paper also quantifies how stricter safety standards affected the *quality* of innovation using two metrics: the number of age-adjusted forward citations received per patent and the resultant increase in firms' market value. Across the distribution of patent quality, I find higher safety standards increased the share of high-quality patents per subclass. Specifically, there was an increase of 102.6% in the number of age-adjusted forward citations among high-quality patents (as measured by the cumulative citations within the same cohort), relative to their low-quality counterparts. Regarding private market value, the RCHSA also led to a rise of 2.3% in the stock price of U.S. publicly traded firms. To sum up, my results highlight that stricter safety standards have the potential to enhance innovation quality and improve welfare.

In my paper, I also implemented a variety of empirical tests to investigate relevant mechanisms. I first explore whether these findings resulted from increased compliance costs. To do so, I look to both qualitative and quantitative evidence. First, immediate enforce-

ment and compliance actions following the passage of the RCHSA indicate an upsurge in regulatory compliance burdens. Second, institutional features suggest firms could leverage innovation and invention as a channel to combat the regulation.[7] Quantitatively, I focus on one specific radiation reducing technology: apparatus or devices for preventing over-radiation errors and enhancing dosage management. This technology is commonly integrated into X-ray medical devices rather than being standalone products (e.g., protective shields), suggesting it's less likely to be categorized as product innovation. Restricting my treatment group to this technology does not substantially change my main results.

In addition to regulatory compliance costs, I also discuss alternative mechanisms at play. To begin, I argue the rise in patenting rates cannot be exclusively driven by increased product liability risks. By examining changes in the number of lawsuits against X-ray medical devices, I didn't document a significant, drastic increase in product liability risk. Moreover, I found limited responses in innovation from GE, who should face higher litigation risk relative to its competitors. Finally, I show foreign firms, who typically face lower product liability risk but similar regulatory compliance costs relative to the U.S. firms, also engaged in patenting X-ray medical technologies.

My paper also delves into the question of whether a demand-driven force is responsible for the increased patenting activities. On the one hand, if safety regulation effectively resolves the asymmetric information between buyers and sellers, the resultant expansion of market size could directly stimulate firms' incentives for innovation (Acemoglu and Linn, 2004). On the other hand, if the RCHSA provided informational shock and raised consumers' aversion to radiation-emitting electronic products, it could discourage firms from innovating. Using digitized data from an early version of the National Hospital Discharge Survey (1968 - 1970), I found the RCHSA did not immediately increase the utilization of radiology services, suggesting that the demand-side channel may not be the primary driver of increased patenting activities, at least in the short run. Further, I provide qualitative evidence demonstrating the RCHSA did not substantively shape the public perceptions towards medical radiation.

Along with the RCHSA, there was a notable breakthrough in radiation-based medical technologies: the clinical application of computed tomography (CT) in late 1972. To rule out its confounding effects on follow-on innovation, I conducted several tests. First, I directly excluded patents within the same subclass as CT in my sample and limited the reference

[7]Note the RCHSA explicitly required manufacturers to "take new means" to correct existing defects and lower radiation emissions; the FDA also specified medical recommendations for "the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures" as an approach to radiation protection.

period to 1960-1971. I found my primary estimates are still robust. Second, I re-estimated the innovation effects among domestic firms: Using foreign patents of each subclass as a benchmark, I controlled for common technology or demand trends taking place in the same technological areas. This additional exercise also yielded similar results, suggesting the surge in patenting could not be solely explained by the entry of CT in 1972.[8]

To shed light on the welfare implications of higher safety standards, I provide some simple back-of-the-envelope calculations. My calculations capture two types of welfare gains under the RCHSA: (1) Stricter regulation induces firms to develop new technologies that reduce radiation emissions, thereby lowering the incidence rate of cancers due to radiation exposure. The resulting value of a statistical life (VSL) saved amounts to $6.84 billion (in 1969 dollars) at best. (2) Safety regulation increases the private market value per patent. Meanwhile, the RCHSA led to an increase of $1.82 million (in 1969 dollars) per year at the subclass level.

In light of these findings, my paper contributes to several strands of literature. First, my work speaks to recent empirical research emphasizing the link between product quality regulation and firms' innovation activities, especially in the healthcare sector. For example, Stern (2017) found regulatory uncertainty due to prolonged approval times can bring disadvantages in the regulatory approval process for high-risk medical devices and hinder product entry. Grennan and Town (2020) analyzed the impact of regulating product entry and quality information requirements on an oligopoly equilibrium and consumer welfare.[9] Both studies utilized cross-group variation and focused on "*mid-stage innovations*" (Grennan and Town, 2020). My paper instead exploits a quasi-experiment policy shock to shed light on how quality regulations affect research and development at even *earlier* stages.[10] In this regard, the only paper close to mine is Rogers (2023), finding that by reducing approval costs, deregulating medical devices from Class III (*high regulation*) to II (*moderate regulation*) led to an increase in both patenting rates and FDA submission rates among affected med-

[8] In the appendix (Section A.6), I explore an indirect channel at play: All structural factors mentioned above (compliance costs, liability risk, shifts in demand, and technological breakthrough) have the potential to alter product market structure in the X-ray medical device industry. In turn, any resulting changes in competition pressure could distort firms' innovation incentives (Aghion et al., 2005).

[9] Exploiting variation in pre-marketing testing requirements within EU and US medical device regulations, Grennan and Town (2020) found evidence of valuable learning from more stringent requirements and discussed the welfare implications with a structural model.

[10] It is interesting to note that Grennan and Town (2020) mentioned "While our exercise here, estimating the welfare effects of the access/uncertainty trade-off for an exogenously given set of "mid-stage" innovations, is an important step toward better understanding this phenomenon, a more complete understanding would allow for the regulatory regime to effect research and development at even earlier stages. Analysis of this type would require a significant extension to the theory and additional data on innovative activities of the firms."

ical device types. Meanwhile, when shifting from Class II (*moderate regulation*) to Class I (*minimum regulation*), manufacturers are incentivized to emphasize safety features in both product development and patenting because of the exposure to higher-level litigation risk.

My paper provides a complementary analysis to Rogers (2023) but is essentially distinct in two aspects: First, in contrast to Rogers (2023) who emphasizes the role of FDA's general (de)regulation in the current context, I exploit a historical setting to assess a key channel through which product safety regulations distort firms' innovation incentives: regulatory compliance costs. Back in the 1960s and early 1970s, the historical FDA regulatory scheme did not involve a pre-marketing approval process and other administrative requirements for medical devices. This unique setting enables me to directly rule out many other confounding factors within the regulatory pathway.[11] Second, when quantifying the innovation effect of product safety regulations, my paper accounts for the interplay between different technologies. That said, I identify two key attributes of medical X-ray machine patents: radiation reducing technologies and radiation generating technologies. Leveraging this intriguing feature, I demonstrate in a context wherein innovations are complementaries in production, quality regulations targeting safety performance can result in unexpected positive spillovers on the development of new products. In terms of policy implications, my work highlights the delicacy of product safety regulation in general: because of the interaction between different technologies, regulations would not necessarily hinder innovation and can impose unexpected effects. This historical study thus provides a novel angle to a wide-ranging economic trade-off between safety regulation and innovation.

More broadly, this paper contributes to the extensive and still emerging studies discussing the determinants of innovation. In particular, my work adds to a line of literature exploring how changes in the regulatory environment shape innovation. Prior studies have heavily emphasized the role of labor inputs regulation (Acharya, Baghai and Subramanian, 2013; Griffith and Macartney, 2014; Bena, Ortiz-Molina and Simintzi, 2022), environment regulation, and product entry/commercializing regulation (Stern, 2017; Byrski, 2021). In the case of medical innovation, previous papers focus on patent protection (Budish, Roin and Williams, 2015), billing rules (Dranove, Garthwaite and Wu, 2022; Dranove et al., 2022), tort reforms (Galasso and Luo, 2017), product liability (Galasso and Luo, 2022, 2024), public investment (Azoulay et al., 2019), procurement policies (Clemens and Rogers, 2023), and

[11] Not until 1976, the FDA began to provide systematic assurance of the safety and effectiveness of general medical devices by creating a three-class, risk-based classification system and establishing both the regulatory pathways for the entry of new medical devices and the postmarket requirements. The premarket regulations include Premarket Approval (PMA) and premarket notification (501(k)). The postmarket requirements include registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices.

price reform (Ji and Rogers, 2024). To my knowledge, empirical work directly addressing the interaction between product safety standards and innovation is quite limited.

Lastly, the literature studying the impact of the RCHSA *per se* is surprisingly scarce to my knowledge, given the large scale of this legislation. A notable exception is Birnbaum (1984), who argues the regulation increases consumer and competitor uncertainty, leading firms to decrease their incentives to innovate. In both methodology and rationale, my work makes key contributions to the study of this nationwide regulation and differentiates that from Birnbaum (1984).[12]

The rest of this paper proceeds as follows: Section 2 provides the institutional background of the Radiation Control for Health and Safety Act of 1968. Section 3 describes a number of datasets enabling me to implement the empirical analyses. Section 4 specified the baseline empirical strategy and some threats to identification. Section 5 presents the main results. Section 6 discusses and tests some alternative mechanisms, Section 7 provides a back-of-the-envelop calculation and discusses the welfare implications. Section 8 finally concludes.

2 Historical Background

This section summarizes the institutional background of the RCHSA in 1968. Section 2.1 summarizes prior regulatory regimes for radiation and medical devices. Section 2.2 describes the legislative history of the RCHSA. Section 2.3 outlines the formulation of minimum safety standards. Section 2.4 presents the detailed features of compliance and enforcement actions within the RCHSA, and in section 2.5, I briefly show the efforts to educate consumers and operators of X-ray machines under the RCHSA (and why they failed).

2.1 Prior Regulatory Regimes

2.1.1 History of Medical Device Regulation

The regulatory regime for pharmaceutical products and medical device in US was established under two milestone legislative actions, the *Pure Food and Drug Act of 1906* and the *Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938*. In Figure 1, I show a series of key

[12]There are several key differences between Birnbaum (1984) and mine in terms of methodology. First, the measure of innovation he took only includes patents of radiant energy, whereas my focus is medical technology relying on X-ray.[13] Second, rather than checking the correlation as Birnbaum (1984), I exploit the RCHSA as a quasi-experiment and characterize a number of control groups to capture the causal effect on innovation. Eventually, I advance my discussion on mechanisms at play by providing several empirical tests instead of purely relying on qualitative arguments.

regulations and laws governing the safety and efficiency of medical device. In the original 1906 Act, the FDA was granted the power to regulate "*all medicines and preparations ... for internal or external use ... intended for cure, mitigation or prevention of diseases ...*" In the 1938 Act, the requirement of pre-market notification for the safety of new drugs was imposed.

However, the regulation for medical device lagged substantially compared to drugs in the history. It was not until the 1938 Amendments that the word "device" appeared in the statutes. The FDA "*embarked upon the prosecution of defective medical devices moving in interstate commerce.*" Medical devices were defined as (*21 U.S.C. § 321 (h)*):

> ... instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, care, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

Prior to 1976, the FDA does not have the same authority over device manufacturers as it does over drug manufacturers. Device manufacturers were not mandated to register with the Secretary of the Department of Health, Education and Welfare at all. They also don't need to demonstrate the new device is safe, reliable, or effective. No administrative agencies have official authority or power to approve the entry and marketing of medical device. In the meantime, a device manufacturer can even refuse the Secretary to inspect records, files, papers, processes, production control procedures, and facilities in case of suspected adulteration or misbranding. As noted in Finck (1974), the FDA typically has to rely on complaints to its own discoveries before regulatory authority can be revoked. Therefore, the regulatory scheme did not ensure the discovery of deficient medical devices prior to the marketing process at all.

In terms of ex-post regulation, the FDA could take actions against a defective medical device. First, the FDA can seize one single defective device. An *in rem* proceeding would follow and the FDA can seek to have the device declared adulterated or misbranded. Second, the FDA may secure an injunction against shipments of the defective device in interstate commerce if the device has been declared adulterated or misbranded and experienced a further hearing. Third, if the device is believed to create imminent danger to health, the FDA is empowered to make unlimited seizures.

Overall, the FDA had no power to require that manufacturers of most medical devices notify FDA that they were in the device business and imposed no premarket regulations. The Medical Device Amendments of 1976 established an elaborate and detailed scheme, more than doubling the length of the FFDCA (1938). The primary goal of this 1976 Amendment

is to "provide reasonable assurance of the safety and effectiveness of medical devices" (FDA).[14]

The FDA was granted the authority to (1) create a three-class, risk-based classification system for all medical devices, (2) establish the regulatory pathways for new medical devices (devices that were not on the market prior to May 28, 1976, or had been significantly modified) to get to market, (3) create the regulatory pathway for new investigational medical devices to be studied in patients, (4) establish several key postmarket requirements: registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices, and (5) ban devices. Most importantly, the 1976 Amendments provided regulation based on the degree of potential risk posed by a device.

2.1.2 Landscape of Radiation Control

Before the RCHSA of 1968 was in effect, several states had taken action to address radiation control. According to the technical reports from the Food and Drug Administration (1972),

> "Since 1951, a total of 46 States and the Commonwealth of Puerto Rico have enacted specific laws for the regulation of ionizing radiation. Some of these laws are restricted to certain occupations or are amendments to existing statutes...The technical details of regulatory control are generally not included in these enabling acts; rather this authority is delegated to State agencies."

These state-level regulations can be categorized into three groups: the management of radioactive waste and environment protection (e.g., Alabama, Alaska, Arizona, Arkansas, California, Louisiana, North Dakota, New Mexico, and Pennsylvania), credentialing operators of X-ray machines (e.g., Illinois, Kentucky, New Hampshire, New York, Texas, Wyoming), and the registration of electronic products (e.g., Indiana, Kansas).

However, such prior regulations proved both "inconsistent and ineffective" (Tran, 2006). For example, although the general radiation regulatory regime in New York City was one of the most comprehensive in the 1970s, Hanson Blatz, the director of the Office of Radiation for the NYC Department of Health, claimed that

> "While the New York City Department of Health had adopted and enforced standards to protect citizens from excessive or unnecessary radiation, citizen inquires and complaints revealed that unnecessary radiation was being emitted

[14] See https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states, last accessed February 14, 2025.

> from various products...Shielding of X-ray equipment to protect passerby was dependent on an honor system that many operators overlooked."

Most importantly, according to 21 C.F.R. 1020, the RCHSA would preempt all relevant state regulations.

> SEC. 360F. Whenever any standard prescribed pursuant to section 358 with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this subpart shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

Overall, this indicates the federal regulation is indeed imposing substantial shocks on the manufacturers of diagnostic radiation-based medical devices.

At the federal level, the Atomic Energy Act of 1946 gave the Atomic Energy Commission (AEC) authority to regulate artificial radioactive materials, but its jurisdiction did not cover consumer goods or medical devices. In sum, neither prior state-level actions nor federal-level control have effectively addressed how diagnostic X-ray medical devices should be regulated with respect to their technical performance.

2.2 Legislative History of the RCHSA in 1968

In May 1967, GE initiated a large-scale, voluntary recall for approximately 90,000 color television sets due to high doses of leakage radiation.[15][16] The radiation emitted by these sets exceeded voluntary industry standards and there was no federal standards (Tran, 2006). On May 18, 1967, the National Center for Radiological Health commended that "there is no evidence in the hands of NCRH to suggest that any television receivers ... have excessively exposed viewers of television sets."

[15] See https://www.nytimes.com/1967/05/19/archives/general-electric-will-modify-90000-large-color-television-sets.html, last accessed February 14, 2025.

[16] There might be a concern that the documented increase in patenting was partially triggered by a surge in litigation risk due to the GE recall. To address this issue, I further searched for some qualitative descriptions of the consequences of this GE recall.

House Bill 10790 was introduced on June 13, 1967 as a result and later became the RCHSA in 1968. The hearings on House Bill 10790 initially concerned radiation emissions from television but quickly expanded to include other radiation concerns, especially medical and dental x-ray use (Tran, 2006). During the initial House Hearings, Congress realized that the radiation concern was beyond the GE televisions and thus expanded the scope of regulation to medical and dental X-ray use and methods.

President Lyndon Johnson expressed his approval to the passage of the RCHSA on February 6, 1968 as follows:

> It has been said that each civilization creates its own hazards. Ours is no exception. While modern technology has enriched our daily lives, it has sometimes yields unexpected and unfortunate side effects...Now modern science must be put to work on these hazards — particularly the hazards which confront the consumer. The [Radiation Control for Health and Safety Act] will give the Secretary of Health, Education, and Welfare authority to conduct intensive studies of the hazards and set and enforce standards to control them, [and] require manufacturers to recall defective equipment and devices."

On October 15, 1968, the 90^{th} Congress passed this bill and enacted the RCHSA, applying to any "electronic product" defined as "any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation."

According to Tran (2006), admittedly, the bill was weakened by the lobbying efforts of the Electronic Industries Association (EIA), which was designed to control the licensing of the large number of radio patents so that each member could have access to all the relevant patents necessary to build radio transmitters, antennas and receivers. Yet, the FDA still has vast authority to "conduct research, to set safety standards, to monitor compliance, and to impose civil penalties" under the RCHSA. The primary goal of this Act is to "*establish and carry out an electronic product radiation control program designed to protect public health and safety from electronic product radiation.*" In this regard, there are two main provisions under the Act: *safety performance standards* and *correction of defects*.

2.3 Safety Performance Standards

Radiation safety performance standards under the RCHSA prescribe the maximum emission levels of radiation and mandate all corresponding manufacturers to conform such

federal standards Tran (2006). According to *21 CFR Part 1010*, "each standard may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products." Meanwhile, "each regulation must take effect no sooner than one year and no later than two years after the date on which a standard is issued."

Safety standards were set gradually. The first standards were imposed for television receivers and went into effect in January, 1970. The microwave oven standards were initiated in October, 1970 and the third set of standards applied to electronic equipment in high schools and college science classes. On August 15, 1972, the FDA issued performance regulations (*21 C.F.R. 1020.30*) targeting diagnostic X-ray products. The regulation prescribes more than 60 performance standards for X-ray systems and relevant components manufactured after August 1, 1974. The FDA also requires that such products should be certified by the manufacturer after that date as being in compliance with the standards.

According to *21 C.F.R. 1020.30*, the following components of diagnostic X-ray systems which are manufactured were covered: Tube housing assemblies, X-ray controls, X-ray high-voltage generators, fluoroscopic imaging assemblies, tables, cradles, file changers, cassette holders, and beam-limiting devices. The specific regulations include (1) certification by assembler, (2) identification of X-ray components, (3) limits of responsibility, (4) warning label, (5) leakage radiation from the diagnostic source assembly, (6) radiation from components other than the diagnostic source assembly, (7) beam quality, (8) aluminum equivalent of material between patient and image receptor, and (9) battery charge indicator. The applicable performance standards for CT was officially enacted on Aug. 31, 1984 under *21 C.F.R. 1020.33.*

It is noteworthy that in the context of X-ray devices, there are some room and indications for manufacturers to leverage new technologies to reduce radiation emissions. First, according to the 1972 performance standards, manufacturers shall provide "positive means" to "limit the maximum x-ray tube potential to that of the diagnostic source assembly," if "the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly. Second, based on the 1968 general provision, the FDA specified recommendations for "the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures," as an approach to radiation protection.

2.4 Correction of Defects

Another major provision of the RCHSA is correction of existing defects via a number of compliance and enforcement actions targeting manufacturers, which include annual reporting, recalls, seizures, civil penalties, and regulations of imported products.

Under the RCHSA of 1968, manufacturers of relevant electronic products shall "notify the Secretary of any defect or failure to comply if such products have left the place of manufacture." If any electronic product fails to comply with an applicable standard or to have a defect which relates to the safety of use of such product, the manufacturer of such product should "(1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedies, (2) replace such product with equivalent product complying with applicable standard prescribed and which has no defect relating to the safety of its use, or (3) make a refund of the costs of such product" (*Public Law 90-602, October 18, 1968*).

The FDA enforced the performance standards very strictly. Three key approaches were developed: First, the FDA would evaluate product quality control and testing programs based on regular reports within factories. The FDA also conducted inspections among X-ray equipment manufacturers as a supplementary source of information. Second, inspectors from both the FDA and states with FDA contracts would (randomly) survey X-ray units in hospitals, clinics, and other healthcare facilities, in order to determine whether a system is assembled and performing in accordance with an applicable standard. Third, the FDA also regularly tests X-ray systems and components in its own laboratory to determine whether one complies with the standard (FDA, 1975).

In the case where a defect is detected, if the manufacturer determines the radiation risk is low, one can request an exemption from a mandatory duty to notify consumers. The FDA also may notify a manufacturer if the FDA discovers any violation of the standards. If no exemption from public notification is granted, the manufacturer must correct the defects at its own expense or refund the purchase prices. The FDA shall seize non-compliance products if the manufacturer fails to institute a recall. Additionally, the FDA can impose civil penalties on manufacturers: the RCHSA authorizes a civil penalty of not more than $\$1,000$ for each defective product, with the maximum penalty for a single party for any violations limited to $\$300,000$. Notably, the FDA can impose civil penalties on both the corporation and individuals for the same set of violations.

Under the RCHSA of 1968, the FDA also regulated the importation of electronic products

by denying the entry of products that do not comply with federal standards. If a product denied entry cannot be brought into compliance, the corresponding manufacturer must export the product at its own expense. Otherwise, the FDA may seize and destroy the non-compliant products if the product imposed substantial radiation risk to consumers.

2.5 Effort to Educate the Public

According to descriptive evidence (e.g. Tran, 2006), while public education is not technically mandated by the RCHSA, the FDA's radiation control program attempted to educate consumers and healthcare providers. Yet, these efforts are proven to have relatively limited effects on raising public awareness of radiation protection among both healthcare providers and consumers.

Educational Tools for Medical Practitioners/Technologists: To improve physicians' radiological health practices, the FDA developed several educational programs. For example, *the Radiological Health Sciences Learning Laboratory* is an educational system in diagnostic radiology for medical students, radiology residents, and postgraduate physicians. However, only 30 of the nation's medical institutions have purchased the Learning Laboratory by the end of 1973. Another set of training programs on radiation protection has been developed since 1973. The series, "*Radiation Protection During Medical X-Ray Examinations*," is a self-contained training program intended to teach technologists how to protect patients and themselves from unnecessary exposure during X-ray examinations.

According to Friedell (1971), introducing the RCHSA to directly correct defects and lower radiation emissions on the manufacturers' end should not be the whole story.

> "It is the physician who must weigh benefits against hazards; to introduce some kind of regulatory mechanism into decisionmaking is dangerous. The benefits of ionizing radiation have been conservatively estimated. There should be an effort to educate, to provide more information, and to upgrade training and experience, but not to determine exactly how value judgment is to be made."

A report from the United States General Accounting Office (GAO) in 1975 also mentioned that "... There is a need for Federal policy statements that provide health personnel, including physicians and clinical personnel, with criteria on who should be selected for X-ray examinations and when such examinations would be justified. Such criteria would help reduce the public's exposure to unnecessary X-ray examinations."[17]

[17] See https://www.gao.gov/products/hrd-77-22, last accessed February 14, 2025.

To formally address the role of medical practitioners in radiation protection, the Consumer-Patient Radiation Health and Safety Act in 1981 provides for "the establishment of minimum standards by the Federal Government for the accreditation of education programs for persons who administer radiologic procedures and for the certification of such persons" and "insure that medical and dental radiologic procedures are consistent with rigorous safety precautions and standards."

Changing Consumers' Perception: Similarly, the FDA has initiated some public education programs and moved ahead to reduce unnecessary exposure to X-rays in the late 1970s. A public information program targeting pregnant women was in effect to emphasize the collective responsibilities of the referring physician, the patient, and the X-ray technologists. The program instructed physicians on the dangers of radiation to the human embryo, encouraged physicians to ask female patients routinely if they were pregnant, and encouraged patients to be proactive in protecting their fetuses from unnecessary radiation by taking such simple measures as informing their doctors of possible pregnancies.

However, as pointed out by Pelc (2014) and Galasso and Luo (2021), "historically, the main drivers for technological improvements have been the physicians' demand for improved *image quality, speed, and new clinical applications*" in radiology (especially for CT scanners) (Pelc, 2014), whereas "dose control (risk mitigation) had been a secondary consideration" (Galasso and Luo, 2021). Therefore, it's reasonable to conclude that the RCHSA per se did not largely shape consumers' perceptions of diagnostic radiation risk.

3 Data and Sample Construction

This section begins by describing various data sources I used to implement my empirical analysis. I then discuss how to characterize key patent attributes of interest, including "radiation reducing" and "radiation generation". Eventually, I provide some stylized facts to motivate the main analysis.

3.1 USPTO Patent Files

The first dataset that I used is the universe patent files from the United States Patent and Trademark Office (USPTO).[18] These records provide the year in which a patent was applied and granted, the technology class and the corresponding subclass to which a patent belongs, the detailed description of each patent, the names of the inventors and current as-

[18] All the files were directly downloaded from Google Patents https://patents.google.com/, last accessed February 14, 2025.

signees (if any) associated with each patent, and the number of forward citations received by each patent. For example, in Figure 2, I present the record for one patent under class A61B6.

To identify the treatment and control groups, I use the classification code provided by *Cooperative Patent Classification* (CPC), a detailed and universe scheme of classes and subclasses.[19] Patent classes generally describe the broad technical field of an invention, and patent subclasses typically include more detailed technical features under a class. Throughout this paper, I define a "patent subclass" using the corresponding class-subclass pair. The treated subclasses include all patents belonging to the subclasses under A61B6 (apparatus for radiation diagnosis, e.g., combined with radiation therapy equipment) and include the keyword "x-ray".[20] The primary control group includes all other subclasses relating to *non-radiation* diagnostic medical devices under the broad category A61B (diagnosis; surgery; identification).[21] I construct two alternative control groups with patent subclasses related to medical implants (A61F) and drugs (A61K), respectively.

The final sample is a panel recording patent counts filed per year under each subclass spanning 1961 to 1980, and the unit of analysis is thus subclass-year. I chose the sample period to capture the symmetric window around 1970 (a one-year lag relative to the enactment of the RCHSA). Meanwhile, this 20-year window covers other key relevant shocks to both my treatment and control groups: For example, the passage of the Social Security Amendments of 1965 (also known as the *Medicare and Medicaid Act*) and the Medical Device Amendments to the FD&C Act of 1976. To avoid some confounding factors introduced by other radiation regulations (e.g., the Consumer-Patient Radiation Health and Safety Act of 1981), I terminated the sample in 1980.[22]

Following extensive literature on innovation, I first use the patent count as the primary

[19] For detailed information about the CPC scheme, see https://www.cooperativepatentclassification.org/about, last accessed February 14, 2025.

[20] My results are still robust when excluding this keyword selection.

[21] To be specific, these control classes include A61B1 (instruments for performing medical examinations of the interior of cavities or tubes of the body by visual or photographical inspection, e.g. endoscopes), A61B3 (apparatus for testing the eyes; Instruments for examining the eyes), A61B5 (measuring for diagnostic purposes; identification of persons), A61B7 (Instruments for auscultation), A61B8 (diagnosis using ultrasonic, sonic or infrasonic waves), A61B9 (instruments for examination by percussion; pleximeters), A61B10 (other methods or instruments for diagnosis, e.g. instruments for taking a cell sample, for biopsy, for vaccination diagnosis; sex determination; ovulation-period determination; throat striking implements), A61B13 (instruments for depressing the tongue), and A61B16 (devices specially adapted for vivisection or autopsy).

[22] The Consumer-Patient Radiation Health and Safety Act of 1981, "directs the Secretary of Health and Human Services to promulgate: (1) minimum standards for the accreditation of educational programs to train individuals to perform radiologic procedures; (2) minimum standards for the certification of persons who administer radiologic procedures; and (3) Federal radiation guidelines concerning radiologic procedures." See https://www.congress.gov/bill/97th-congress/house-bill/2457/all-info, last accessed February 14, 2025.

measure of innovation quantity. To account for the heterogeneity in the quality of the innovation, I also calculate the number of patents weighted by the number of their forward citations under each subclass per year. Because of the delays in granting patents, I use a patent's application year rather than their grant year.

There are limitations to using patent counts to measure innovation. For example, patent counts do not directly measure changes in meaningful innovation. To address this issue, I follow standard practice in the prior literature and use the number of forward citations as a proxy for patent quality. Specifically, I exploited the information regarding the number of (cumulative) forward citations received by each patent until 2020. I took several methods to adjust the fact that patents typically would receive more citations in their early lifespan.

3.2 Comprehensive Universe of U.S. Patents Data

The other question that I aim to answer is who are the main contributors to any innovation changes after the RCHSA. This exercise requires information on the original assignee of each patent (if any). Only recently did the available patent data sets analyzed by economists facilitate this analysis. For example, the NBER patent database (Hall, Jaffe and Trajtenberg, 2001) begins to document information of individual inventors listed on patents generally issued from January 1, 1975. In my context, this feature imposes a challenge in distinguishing between individual inventors and firms.

Economists have developed novel databases extending to the earliest surviving records of the U.S. Patent and Trademark Office (USPTO) and derived rich information from these patent files. The Comprehensive Universe of U.S. Patents Data (CUSP) is one such example developed by Berkes (2018).[23] From the CUSP data, I collect information on the type of assignee and the number of cumulative forward citations received by each patent within the technology subclasses of my primary interest.

Following Babina, Bernstein and Mezzanotti (2023), I categorize all patents into two groups: independent patents and firm patents. The former group includes either unassigned patents, patents assigned to the inventor(s), or assigned to other entities (e.g., angel investors, public institutions, etc.). The latter, on the contrary, includes patents that are assigned to firms and are produced by inventors employed by firms with in-house R&D labs who would have been contractually obliged to assign their inventions to their employers at the time of the patent grant date (Babina, Bernstein and Mezzanotti, 2023; Lamoreaux and Sokoloff,

[23]Other historical patent datasets include Akcigit, Grigsby and Nicholas (2017), Sarada, Andrews and Ziebarth (2019), Petralia, Balland and Rigby (2016), Marco et al. (2015), etc. For an excellent review, see Andrews (2021).

2001; Lamoreaux, Sokoloff and Sutthiphisal, 2008; Nicholas, 2010).

Meanwhile, I supplement the primary USPTO data with the CUSP assignee data, merging on the unique patent number. The main goal of this analysis is to identify whether domestic or foreign firms file patents and examine whether domestic firms are more or less likely to respond to the RCHSA.

There are several reasons to implement this additional analysis. For example, there might be a number of confounding factors that differentially affect my primary treatment and control groups, such as some technological breakthroughs in diagnostic radiation technologies. Patenting by foreign firms helps to control for such trends taking place in a given technology area that is common to both the US and foreign. This way, we can tease out the impact of these global technical shocks. Meanwhile, it is also reasonable to argue that along with the safety standards, the product liability risk might increase, thereby driving up patenting activities. In this regard, controlling for patenting by foreign firms may alleviate the concern, because US plaintiffs typically face more complexities and additional legal costs (such as matters of personal jurisdiction, conflicts of laws, and more significant difficulties in enforcing judgment) that make foreign producers less concerned about liability risk (Klerman, 2011; Galasso and Luo, 2022).

3.3 Data from Kogan et al. (2017)

Another key dataset enabling me to implement some firm-level analyses is from Kogan et al. (2017), which contains U.S. patents from 1926 to 2019 linked to the Center for Research in Security Prices (CRSP)-Compustat merged data. It provides estimates of each patent's private value constructed from the response of assigned firms' stock market response to news about the patent issuance.[24] I also complement this dataset with firm-level financial information from the Compustat data and the CRSP data. In the appendix, I provided detailed of how to construct the KPSS-Compustat sample.

Besides the patent count and the number of forward citations, I leverage information from changes in stock prices for the firms in the CRSP-Compustat data following patent issuance to estimate the private value of obtaining a patent. More precisely, the private value of each patent is given by the change in the firm's stock return attributable to the value of the patent in the three days after the patent issues times the firm's market capitalization on the day before the announcement that the patent issued. To calculate how much of the firm's

[24]The dataset is available here: https://github.com/KPSS2017/Technological-Innovation-Resource-Allocation-and-Growth-Extended-Data, last accessed February 14, 2025.

stock return is attributable to the value of the patent, they filter each firm's stock returns to remove movements in the stock price that are unrelated to news of patent issuance. Finally, they adjust the filtered stock returns to account for the fact that the probability that the patent will issue is already priced into the firm's market capitalization before the patent issuance.

3.4 National Hospital Discharge Survey

The last dataset, the National Hospital Discharge Survey (NHDS), was a national survey "*designed to meet the need for information on characteristics of inpatients discharged from non-Federal short-stay hospitals in the United States*" and was conducted annually from 1965-2010.[25] Ideally, information about a variety of medical procedures is expected from the 1968, 1969, and 1970 waves. However, such information was not published to the public and was only available from Moien (1974). Thus, I turn to digitize key statistics for a collection of nonsurgical medical procedures: room and care service,[26] laboratory services,[27] pharmacy services,[28] radiology,[29] operating and/or recovery room,[30] professional services,[31] and all other services.[32] In the case of RCHSA, the treatment group includes all radiology services, and the control group comprises all other medical services except professional services, which include services provided by radiologists. The key outcome of interest in this sample is the total number of discharges from short-stay hospitals per year by various groups (e.g., sex, age, location and type of hospital). In Figure 3 and Figure 4, I provide a snapshot of the publication where I obtained the NHDS data.

3.5 Characterizing Patent Attributes

To assess whether safety standards reshaped the direction of innovation (i.e., prioritizing certain features of a product), I conducted an in-depth analysis regarding the het-

[25]This data set is available here: https://www.cdc.gov/nchs/nhds/index.htm, last accessed February 14, 2025.

[26]The room and care charge include charges for room, food, nursing service, nursery, baby formula, and intensive care.

[27]The laboratory charge includes blood counts, serology, pathology, tissue examination, basal metabolism rate, electrocardiogram, electroencephalogram, and the like.

[28]The pharmacy charge includes items charged to drugs or pharmacies.

[29]The radiology charge includes items charged to diagnostic and therapeutic radiation, e.g., X-ray, cobalt, radium, and isotopes.

[30]use of the operating and/or recovery room is covered by this item.

[31]Professional services include charges for such items as a staff physician, anesthetist, radiologist, and pathologist.

[32]The other services are those items that are not assigned to previous categories, such as blood, oxygen, medical and surgical supplies, physical therapy, emergency room, and personal charges.

erogenous effects of the RCHSA by patent attributes. Building upon prior research which suggests a complementary relationship between product and process innovations (Athey and Schmutzler, 1995; Hullova, Trott and Simms, 2016), I carefully classify patents in the treatment group into two distinct categories: radiation-reducing patents and radiation-generating patents. It is noteworthy that as argued in Galasso and Luo (2021), radiation-reducing technologies can "take various forms, depending on the nature of the hazards, the magnitudes of the demand changes, and the technological possibilities" and therefore could be both process and product innovations.[33] Radiation-generating technologies, in contrast, refer to those new devices or key components of x-ray medical devices relying on radiation emission. In Figure 5 and Figure 6, two concrete examples are provided to illustrate the idea of *radiation-reducing* and *radiation-generating*, respectively.

This categorization allows for a comprehensive examination of the interactions between different types of innovation and enables me to test the theoretical predictions outlined in Section A2. Following Galasso and Luo (2021), I primarily rely on the Cooperative Patent Classification (CPC) system to classify patent subclasses related to reducing radiation risk. Based on the technical descriptions of each subclass, I identify three such RMT subclasses: `A616/10` ("application or adaptation of safety means"), `A61B6/54` ("control of apparatus or devices for radiation diagnosis"), or `A61B6/58` ("testing, adjusting or calibrating apparatus or devices for radiation diagnosis").[34] Another eight parent subclasses under `A61B6` are categorized as non-RMT patents: `A61B6/14` ("Applications or adaptations for density"), `A61B6/40` ("Applications or adaptations for density with arrangements for generating radiation specially adapted for radiation diagnosis"), `A61B6/44` ("Constructional features of apparatus for radiation diagnosis"), `A61B6/46` ("Applications or adaptations for density with special arrangements for interfacing with the operator or the patient"), `A61B6/48` ("Diagnostic techniques"), `A61B6/50` ("Clinical applications"), `A61B6/52` ("Devices using data or image processing specially adapted for radiation diagnosis"), and `A61B6/56` ("Details of data transmission or power supply, e.g. use of slip rings"). Based on their CPC subclasses, I then assign patents to RMT vs. non-RMT groups. One key feature to keep in mind is that the scope of "radiation reducing technologies" is broader in Galasso and Luo (2021) (in which the authors term them as "risk-mitigating technologies").

[33] For example, an assembly-line redesign that is more effective at identifying defects or using checklists during surgeries to reduce medical errors.

[34] Note I coded these RMT patents at the one-dot level, parent subclasses, instead of the more specific two/three-dot level, children subclasses. As described in Galasso and Luo (2021), this aggregation is reasonable "because a parent subclass contains residual patents that cannot be easily categorized into a specific children subclass and, therefore, may include broader patents that involve features of various lower-level children subclasses."

One limitation of this CPC-based approach, as highlighted by Berkes (2018), is that the CPC system does not provide information on the principal technological category of a patent. In other words, there may be an overlap between RMT patents and non-RMT patents, leading to potential double-counting in analyzing the impacts on different innovation types. For example, a patent that has both RMT and non-RMT characteristics might be counted in both categories, potentially inflating the innovation effect in both areas.

One patent (US3304423A), for example, "pertains to an X-ray shield and film holder for use in taking dental X-rays." In this regard, its primary purpose is to protect patients and operators from radiation risk. Yet the shield itself also "facilitates the aiming of the cone of an X-ray machine" and thus could be classified as non-RMT (i.e., improves features of radiation-generating equipment). In the Appendix Table A8, I re-estimate my primary results using alternative samples at the class-year level and ensure my results are valid.

3.6 Motivating Evidence

Figure 10 displays some motivating evidence on diagnostic x-ray device patents and other broad categories of patents during the historical episodes I study. The total number of patents are all normalized to the 0-1 scale (1960-1990).[35] The dashed vertical line encompasses the year associated with the regulatory shock in X-ray patenting. The solid line denotes the evolution of patent counts under A61B6. The dashed line represents the case for all non-radiation diagnostic device patents. It is clear that from 1968 to 1976/77, there were substantial increases in the rate of A61B6 patenting, while changes in the rates of patenting in non-A61B6 diagnostic devices were not that striking.

Interestingly, we can also observe a sharp decline in the patenting rate of diagnostic X-ray medical device patents since 1976/1977. One potential explanation for this drop is the passage of the Medical Devices Amendments (MDA) of 1976, consolidating and expanding existing Federal authority over medical devices into a comprehensive system of regulating the safety and effectiveness of medical devices in proportion to the degree of risk that they pose. This classification regime based on medical devices' risks may trigger increased approval costs (or say, approval delay in commercialization), thereby deterring entry and chilling innovation. The decline in patenting rates in diagnostic X-ray devices might also be attributed to the temporary nature of this innovation wave. Firms initially responded to new safety standards, focusing their innovation efforts on compliance and prioritizing the development emphasizing safety features. However, as these standards became more established and integrated, the necessity for ongoing innovation in radiation reduction

[35] I also normalized all values to the mean and derived similar patterns.

faded out over time. This observation underscores the need to consider the dynamic and evolving nature of innovation in response to regulatory changes, somewhat consistent with prior work from Finkelstein (2004).

Another interesting feature is that note the first CT scanner was introduced in late 1972, while the surge in `A61B6` patent counts began in 1968/1969. Therefore, though people can argue the increase in Figure 10 reflects how the market responded to a technological breakthrough, the timing here (the entry of CT vs. the 1968 RCHSA) suggests there might be something else going on. Details regarding this confounding factor are provided in Section 6.5.

4 Empirical Strategy

This section outlines the primary empirical specifications for analyzing the effects on patent counts, attributes, and quality. Then I acknowledge and address some challenges in establishing causal evidence.

4.1 Specification for Patent Counts

To identify the causal effects of RCHSA on patent counts, I first use a baseline difference-in-differences (DID) specification. This identification strategy is in the same spirit as the empirical innovation literature (see, for example, Finkelstein (2004) and Galasso and Luo (2022)).

$$log(Count_{sct+1}) = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{1}$$

where s denotes patent subclasses, c represents aggregate patent classes, and t indexes years. $log(Count_{sct+1})$ is the key outcome of interest, the logarithm of patent counts filed under each subclass-class pair sc in year $t+1$. In an alternative specification, I also use the raw patent count as the outcome to address the issues highlighted in Chen and Roth (2024). Treat_{sc} is an indicator of whether the patent subclass-class pair is under `A61B6`, and $Post1969_t$ indicates whether the RCHSA was in effect (after 1969) in year t. ρ_{sc} and η_t are patent subclass and year fixed effects, respectively. Therefore, β would identify the impact of the RCHSA on patenting activities associated with diagnostic medical equipment based on x-rays. $\beta > 0$ implies that innovation activities increase post the RCHSA, whereas $\beta < 0$ implies that the RCHSA imposes a negative effect on treated patents under `A61B6`.

It is worth noting that one alternative specification is to split the post-period into two parts: the 1969-1973 period and the 1974-1980 period. In this way, it is plausible to test whether it is the initial 1968 shock or the imposition of specific technical standards (1972) that drove the patent count up/down. However, I prefer to use the specification listed in Equation (1) for two reasons: First, this specification can capture the *expected* effects of the RCHSA; second, in 1973, the commercial computed tomography (CT) scan was officially marketed in the US. A spline design would not necessarily separate the effects from RCHSA and CT during the 1974-1980 period. In Section 6.5, I also address how to tease out the confounding impact of this technology shock in detail.

I also used Poisson regression, the preferred statistical model for counting data, to check the robustness. The specification is as follows:

$$E[Count_{sct+1}|X_t] = exp(\alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct}) \tag{2}$$

Choosing the appropriate control group, which serves as the counterfactual development of patent counts for diagnostic radiation medical devices, is a critical and delicate task that significantly influences the interpretation of my estimates. The control group might be "contaminated" by enacting the RCHSA for several reasons.

First, medical device firms that patent and produce diagnostic x-ray devices and other products in the control group should be considered. If diagnostic X-ray devices and other medical products share technical similarities in production, a surge in `A61B6` patenting induced by the regulation can generate positive spillovers on unregulated patents. For example, if a new component of diagnostic X-ray devices can also be applied to other non-radiation devices, firms may be more incentivized to develop the technology for both types of products simultaneously. As a result, firms can increase patenting activities in both `A61B6` and other technological classes in the control group. A positive coefficient (β) thus indicates a relative increase in `A61B6` patenting. In contrast, if a medical device firm reallocates its resources from non-radiation devices to diagnostic x-ray devices, such a *substitution* effect would generate a decline in patenting in the control group, indicating a change in the direction of innovation overall.

Second, whether the treated and control patents in my setting are *complementary* or *substitute* also hinges on the demand-side environment characteristics. If this policy shock induced healthcare facilities to increase the use of radiation-based diagnostic equipment due to the quality assurance effect, one may expect a decline in the demand for some substitutes of X-ray medical devices (e.g., other non-radiation diagnostic devices). This demand-pull

spillover can incentivize manufacturers to shift resources toward radiation-based devices, dampening innovation in the control group. If certain medical products complement the use of X-ray devices, the quality assurance effect can thus generate *positive* spillovers. In either case, the interpretation of my results can be biased.

4.2 Specification for Patent Attributes

Besides the patenting rates described above, I am also interested in whether the RCHSA affected innovation activities with some key patent attributes. These heterogeneous effects are crucial to understanding the mechanisms by which firms (or other entities) respond to stricter quality regulations. I employ the difference-in-differences method as outlined in Equations (3) and (4) to implement this exercise.

$$log(\textit{Count with an Attribute}_{sct+1}) = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{3}$$

$$E[\textit{Count with an Attribute}_{sct+1}|X_t] = exp(\alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct}) \tag{4}$$

The only distinction relative to Equations (1) and (2) here is that instead of calculating the number of all patents filed under subclass in year t, I focus on the number of patents exhibiting the attributes of interest (e.g., risk mitigation) within a specific patent subclass sc in year t within a patent subclass sc in year t.[36]

With this specification, it is important to note that interpreting the magnitude of the DID estimates warrants caution. The β coefficients in Equations (3) and (4) capture changes in the number of patents with specific attributes in response to stricter safety standards, relative to the patent counts of other non-diagnostic medical devices. Since the control group patents are irrelevant to radiation risk mitigation, any observed changes associated with β reflect *absolute* increases or decreases.

4.3 Specification for Patent Quality

It is crucial to keep in mind that a rise or drop in patent counts does not necessarily represent changes in *meaningful* innovation. For example, it can be challenging to determine whether policy-induced innovation leads to welfare improvements, especially in terms of reducing health risks. To address this, I adopt a standard approach in the literature and

[36]This approach is in the similar spirit to Galasso and Luo (2021), who directly compared patent counts of RMTs with patent counts of non-RMTs in response to a set of over-radiation accidents involving CT scanners in late 2009.

use forward citations as a proxy for patent quality. As briefly mentioned in 4.1, I construct two measures: (1) age-adjusted forward citations received per patent and (2) the private market value associated with patent issuance from publicly traded firms.

When using age-adjusted forward citations as the metric of patent quality, I check the heterogeneous effects on patent counts across the *distribution* of patent quality. To do so, I first remove the effects of *application year* and *patent-class* effects and identify the (filtered) citation distribution to which each patent belongs. I collapse all raw forward citation data to the class-year cell and then characterize the median of citation counts for each patent class in year t. In other words, I compare the number of citations each patent receives relative to its cohort (i.e., all patents applied under the same patent class and within the same calendar year). I further determine if the number of citations received by each patent is below or above this class-level median within the cohort (measured by the year of application) and separate the below-median observations and the above-median observations for each patent subclass every year. Eventually, I collapsed these data into the subclass-year cell. This method results in two distinct samples for each patent subclass: a "high quality sample" and a "low quality sample." These samples allow a detailed examination of how RCHSA affected patent counts at different levels of patent quality. Once patents are allocated to these citation-based categories, the effect of the RCHSA on patent counts separately for the "below-median" sample and the "above-median" sample, employing the same specifications outlined in Equations (1) and (2).

I also construct the share of high-quality patent counts for each subclass-year cell and estimate the following regression specification:

$$Share_{sct+1} = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{5}$$

$$\mathbf{1}_{Share_{sct+1}>0} = \alpha + \beta Treat_{sc} \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{6}$$

where $Share_{sct+1}$ is the intensive margin — the share of high-quality patents, and $\mathbf{1}_{Share_{sct+1}>0}$ is the extensive margin, indicating whether the propensity to innovate is positive within a subclass-year cell. Using these alternative metrics ensures that we capture the *relative* changes in the number of high-quality patents filed under each subclass per year developed after the RCHSA.

When turning to the private market value as the dependent variable, I use the KPSS-Compustata sample, where the unit of observation is firm-class-year. The corresponding

empirical specification is:

$$log(\textit{private market value}_{isct+1}) = \alpha + \beta Treat_{sc} \times Post1969_t + \theta_i + \rho_{sc} + \eta_t + \epsilon_{isct} \tag{7}$$

where i denotes firm, sc represents patent subclass, and t indexes year. In addition to controlling for subclass fixed effects (ρ_{sc}) and year fixed effects (η_t), I have the flexibility to incorporate firm fixed effects (θ_i) due to the panel nature of the current sample. Consequently, the key coefficient β captures the causal effect of the RCHSA on the one-year lagged market value among publicly traded firms.

4.4 Threat to Identification

Admittedly, my identification strategy described above has several concerns and limitations. In this subsection, I discuss strategies to address each of these issues.

Parallel Trends Assumption: The key assumption of a stylized DID framework states that in the absence of the policy shock, there should be no differences in patenting rates between the treatment and control group. To test this assumption, I employ an event study specification shown in Equation (8):

$$log(PatentCount_{sct+1} + 1) = \alpha + \sum_{i=-10}^{10} \beta_{t+i} Treat_{sc} \times year_{t+i} + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{8}$$

where $year_{t+i}$ is a set of indicators denoting whether a year is the i^{th} year before or after the enactment of the RCHSA. In this specification, the baseline year is 1970 and the coefficient associated with one year prior to the treatment has been normalized to zero. This event-study approach offers several advantages over a standard difference-in-differences (DID) model. It provides a more flexible and transparent depiction of the data, ensuring that the parallel trends assumption is satisfied in the context of this study. Additionally, it accounts for any dynamic effects that may arise due to the RCHSA.

Confounding Factors: It is possible that other concurrent shocks could affect the patenting activity of my treatment and control groups differently. If the subclass and year-fixed effects cannot fully capture such confounding factors, one would expect a correlation between $Post1969_t$ and the error term ϵ_{sct}.

For example, there might have been technological breakthroughs or other large-scale policy changes for some specific technologies that drove up the growth of patent counts in either the treatment or the control group after 1969. One such example is the introduction of

computed tomography (CT) technology in the early 1970s, which revolutionized medical imaging.[37] To address this issue, I investigated the robustness of my findings by excluding the subclass associated with CT, specifically A61B6/03, from the treatment group. Moreover, my event study analysis showed an increase in patenting activities under A61B6 one year right after the RCHSA. The timing of these effects indicates even in the absence of CT, we could observe the positive effect on innovation. I also re-scale my analysis to the class-month-year analysis and directly restrict the sample period to 1965-1971.[38] Eventually, I used a triple difference-in-differences specification, where foreign firms serve as the additional control group, to ensure any technology breakthrough could be controlled. Taken together, all four pieces of evidence demonstrate the robustness of my results, thereby alleviating concerns due to the introduction of CT.[39]

5 Results

This section first presents my main estimates for the overall effect on patent counts associated with diagnostic X-ray medical devices. In Section 5.2, I then discuss how two key patent attributes, radiation reduction and radiation generation, are affected by more stringent safety standards. Finally, in terms of patent quality, I present estimates in Section 5.3.

5.1 Effects on Patent Counts

I describe my main results on patent counts in Table 1. Estimates are derived from the specification listed in Section 4.1. Panel A reports the coefficient estimates based on raw patent counts, and Panel B shows all results when using the number of patents weighted by the number of their forward citations, an alternative measure of patent quantity that considers the innovation's quality.

In the first three columns, I use the baseline OLS model to quantify the effects on patent counts, measured as the natural logarithm of raw/citation-weighted patent counts.[40] Shift-

[37] The first CT was invented in 1972 for head scanning. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8555965/, last access February 14, 2025.

[38] I choose the starting point as 1965 to mitigate the concern that including observations prior to 1965 might introduce more confounding factors due to Medicare (in effect since 1965).

[39] It is possible that the middle-run or long-run effects of the RCHSA can be mixed with those associated with the entry of CT. For example, if CT largely changed the competition pressure faced by medical device manufacturers, it is challenging to clearly distinguish the impacts of the 1968 regulation and the technological shock.

[40] In the appendix (Table A6), I present additional robustness checks using the raw patent counts to address issues raised by Chen and Roth (2024).

ing to the last three columns, a Poisson model is used to address the skewness of my count data. Throughout these columns, three distinct control groups are included to test the robustness of my findings: "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" refer to medical implants (under patent class A61F), and "Pharma" refers to medicinal preparations containing organic active ingredients under class A61K.[41]

As illustrated by the estimates in Panel A of Table 1, there is a notable, significant increase in patenting rates across all specifications: the RCHSA resulted in a statistically significant increase of 79.9% (= exp(0.587)-1) in the number of patents filed relating to diagnostic x-ray medical devices, compared to other non-radiation diagnostic medical equipment. Equivalently, the RCHSA led to 1.41 additional patents per subclass every year (the pretreatment average number of patents under A61B6 is 1.77 per subclass every year). This indicates that the imposition of more stringent (enforceable) product safety standards has indeed generated a positive effect on overall patenting activities within my particular context. Panel B of Table 1 provides the results for citation-weighted patent counts. The effect is slightly larger: having the RCHSA in place indicates a statistically significant increase in the quality-adjusted innovation measure by at least 123.89% (= exp(0.806)-1).

To address the concern of spillovers across patent classes or technology types, two sets of exercises are implemented. Firstly, throughout the main analysis, I exclude two patent classes (A61B5 and A61B8) in the control group composed of non-radiation diagnostic medical device (NR-DME) patents. This is because, according to the USPTO, these two classes are most likely to share *technical similarities* with A61B6, thereby more likely to be exposed to spillovers under the RCHSA. When including them in the NR-DME control group, the magnitude of my estimates shrank substantially: the RCHSA led to an increase in the patenting rate of diagnostic medical devices by 52.81% (=exp(0.424)-1) or equivalently, 0.88 more patents per subclass every year. This change in the magnitude suggests some positive spillovers imposed by the RCHSA on A61B5 and A61B8; the point estimate 0.424 reflects a *relative* increase in radiation-based medical device patents.

Further, I consider "pharmaceutical ingredient patents" as the least *contaminated* control group. This is based on the argument that both the supply-side spillovers or any demand-side spillovers are less likely to affect the development for ingredient patents for drugs. The observed difference in magnitude may then encapsulate several spillover effects on other conceptually unaffected patents.[42] At first glance, comparing the estimates in column (3)

[41]Note that I did not choose the final drug patents because such patents can directly target specific diseases, thereby serving as complements/substitutes of A61B6.

[42]Here, regarding the least "contaminated" control group, it means drugs may share fewer technical similarities with diagnostic radiation medical devices on the supply side. On the demand side, it's also reasonable

and column (6) reveals a smaller increase in patenting rates when using non-radiation diagnostic medical equipment as the control group. This evidence suggests that the RCHSA can impose some *positive* spillovers on the conceptually "clean" group. The channels at play are at least two-fold. On the supply side, firms can pool resources in innovation activities and research and development (R&D), such as skilled labor, financial resources, equipment, technologies, etc. The innovation triggered by the RCHSA among radiation-based medical devices may further stimulate technological development for others. On the demand side, shifts in consumer risk perception following the RCHSA may lead radiologists and physicians to be more cautious about over-radiation, resulting in a greater hesitancy to prescribe relevant medical practices. Patients might also overestimate the radiation risk linked to such devices and opt for their substitutes (e.g., non-radiation diagnostic equipment). In either scenario, the expected expansion in market size for these non-radiation substitutes has the potential to drive an upsurge in innovation.

Meanwhile, the RCHSA appears to have a negative spillover effect on innovation in medical implants. This effect can be attributed to two primary mechanisms: the substitution effect in production and the complementary effect on the demand side. The substitution effect suggests that the RCHSA can chill innovation in specific medical implants or redirect innovation efforts toward x-ray diagnostic products. This reallocation of resources could occur if a substantial portion of resources is invested into one area, consequently crowding out the resources available for the development of other technologies. For example, Cesium Iodide crystals are scintillators - special materials that light up when they're hit by X-rays or other radiation. In traditional X-ray machines, large CsI crystal arrays are used in the detector panels. These same crystals, when manufactured in miniaturized form, could be integrated into implantable radiation sensors.

On the demand side, if medical implants and X-ray diagnostic devices complement each other, a decrease in demand for X-ray devices would lead to a drop in demand for medical implants. This, in turn, could significantly reduce the market size for implants and hinder innovation activities. Consider the case of orthopedic implants, like artificial hip joints. These implants rely heavily on X-ray imaging throughout their lifecycle - from initial placement to ongoing monitoring. When doctors use such an implant, they typically need X-ray imaging at several stages: pre-surgery planning, surgery for precise positioning, post-surgery verification, regular follow-up monitoring, etc. Imagine that a typical hospital reduce one's purchases of X-ray equipment by 30% following the regulation (e.g., because the manager/doctor realized the hazard of medical radiation). It would impose

to argue that drugs are less likely to be prescribed alongside diagnostic X-ray medical practices as a substitute or complementarity.

negative effects on the utilization of orthopedic implant: First, surgeons would have less access to X-ray imaging, making them more hesitant to perform implant procedures. Second, the reduced ability to monitor implants post-surgery could make doctors more conservative in recommending implant procedures.

Figure 11 then plots results based on my event-study specification. Overall, the trend of these point estimates closely corresponds with the evidence presented in Figure 10. Prior to the passage of the RCHSA at the end of 1968, there were no discernible differences in patenting rates between the treatment and control groups.[43] When safety standards were in effect, one can see an immediate and significant rise in the patenting rate of X-ray machines. It is worth noting that in the 1960s, the average application-grant lag in patenting was approximately 2.14 years for diagnostic X-ray machines. Therefore, this jump in patent counts cannot be attributed to an anticipatory effect, whereby companies rushed to patent their existing technologies emphasizing safety features in anticipation of the regulation.

Another noteworthy feature of these event-study estimates is that starting from 1976, the positive innovation effects began to fade out over time. As mentioned in Section 3.6, it might be attributed to either the enactment of the 1976 Medical Device Amendments or the dynamic nature of medical innovation. Regarding this phase-out feature, I will elaborate on more details when discussing the mechanisms in the next subsection.

5.2 Effects on Patent Attributes

Apart from the direct effects on patent flows/counts, I argue in Section A2 that the RCHSA could distinctively change the development of new technologies emphasizing different attributes. In particular, heterogeneous effects based on patent attributes have critical implications for firms' strategies and underlying mechanisms. Empirical evidence regarding this theoretical prediction is presented in this subsection.

5.2.1 Radiation-Reducing Technologies

In Panel A of Table 2, I summarize my estimates for the impact on radiation-reducing technologies following the RCHSA. In the first three columns, the key outcome of interest is the probability of having any patent applied under a subclass in year t; the dependent variable in the last three columns is the natural logarithm of raw patent counts. In line with the main result for the overall patenting rate in Table 2, I choose three control groups: non-radiation diagnostic medical devices, medical implants, and pharmaceutical ingredients.

[43] From onward, I define my primary control group as including all patents related to non-radiation diagnostic medical equipment.

As shown in column (1) - column (3) of Panel A, the number of patents with the radiation-reducing feature significantly increased, both statistically and economically. Across all specifications, this result is consistent and indicates in response to the stricter safety standards, the raw count of patents emphasizing radiation risk reduction and consumer protection increased by 64.2% (= exp(0.496)-1) (column 1 in Panel A) relative to other non-radiation diagnostic medical equipment. This is equivalent to an increase by 0.7 patent per subclass every year (the pretreatment patent count is 1.04 per subclass-year). This finding is consistent with my theoretical prediction: radiation-reducing technologies were developed to comply with the regulatory requirements and to address the increased compliance costs imposed by the RCHSA. Later in Section 6, I will elaborate on this main channel in greater details and provide more empirical evidence.

When considering the interpretation of these estimates, it's interesting to note that the magnitude of my estimates is similar when using NR-DME and pharmaceutical ingredient patents as the control group. Meanwhile, the estimate is larger when using medical implant patents as the control group, again suggesting the negative spillovers on these medical technologies. This pattern aligns well with my results shown in Table 1.

5.2.2 Radiation-Generating Technologies

As shown in Panel B of Table 2, the enactment of the RCHSA also induced a statistically significant increase in patent flows associated with *radiation-generating* technologies under the broad patent class `A61B6`. This increase amounted to 72.1% (= exp(0.543)-1) relative to all other non-radiation medical device patents. Once again, comparing these estimates across different control groups suggests that the RCHSA had spillover effects on other technologies, including non-radiation diagnostic medical equipment and medical implants.

Upon examination of estimates related to radiation-generating devices and radiation-reducing technologies, it is interesting to note a similarity in magnitude (i.e., 0.496 vs. 0.543 when using non-radiation diagnostic medical device patents as the primary control group). These findings show that under the RCHSA, technologies reducing radiation exposure are developed together with new X-ray devices simultaneously. Here I argue this pattern indicates that radiation-reducing technologies and radiation-generating technologies are complementary in production. Put differently, the increased density of radiation-reducing feature would largely reduce the marginal cost of producing devices generating X-ray for diagnosis. More details and examples would be discussed in Section 6.

Following the specification outlined in Equation (8), again, I provide evidence against the concern that pre-existing trends drove increases in X-ray medical device patenting since the

passage of the RCHSA. All the coefficient estimates associated with those pre-treatment indicators are not statistically different from zero. Meanwhile, the dynamic effects presented in Figure 15 also closely resemble those shown in the case of radiation-reducing technologies (Figure 13): the patenting rate only temporarily and slightly rose one year after the enactment of the RCHSA and then dropped (although not statistically significant). It was not until four years after the passage of the RCHSA (approximately 1973) that one could observe another wave of new technologies. Such similarities in patent flow between innovation emphasizing safety features and production innovation further indicate there's a good chance that these technologies are complementary in production.[44]

5.2.3 Innovation Complementarity in Production

Why would one expect stricter safety standards can induce an increased rate of patenting among technologies emphasizing radiation-generating? As highlighted in the theoretical framework in Section A2, this pattern could be explained by the complementarity of innovations: When firms adopt radiation-reducing technologies as a strategy to avoid defective products and reduce compliance costs, the marginal benefit of producing new devices relying on radiation generating also rises, thereby spurring product innovation.

To fix ideas, consider an example emphasizing both features: on December 28, 1968, General Dynamics Corporation filed a patent, namely US3567941A (the patent file is presented in Figure 7).[45] According to the abstract, this is

> "A readily conveniently table nonelectrical radiographic device for exposing X-ray sensitive film by utilizing a radiation source which *emits electromagnetic radiation* at or near the X-ray region (such as pure thulium 170 as the preferred source) as a gamma ray emission source and which incorporates *multiple safety features* integrally interrelated in such a manner as to enable a relatively untrained operator to utilize the machine or exchange power sources."

The device described above apparently encompasses both the radiation-reducing feature and the radiation-generating trait, thereby being assigned under two distinct subclasses (A61B6/06 and A61B6/107). If the number of patents with both of these characteristics increases following the RCHSA, it is possible that the two features are positively correlated and complimentary to each other in the production process. After examining patent files

[44] Admittedly, I would not fully rule out the possibility that the second wave of new radiation-based technologies is a mix of several institutional factors, including the imposition of detailed safety standards, the introduction of CT scanners, and the change in market structure in the mid-run.

[45] The patent file is available here: https://patentimages.storage.googleapis.com/a3/36/9a/13a0f52673f1ad/US3567941.pdf, last accessed February 14, 2025.

under A61B6, I have identified 86 patents that possess these particular features and have depicted their patenting trend in Figure 17. This suggests a strong connection between the two features.

In Table 3, I provide more empirical evidence supporting this complementarity channel. The outcome of interest is the number of patents filed under patent class c in year t. Instead of including all `A61B6` patents in the treatment group, I restrict my attention to this subset of patents encompassing dual features (both radiation-reducing and radiation-generating) and categorize them as the treated class. In the first three columns, I report my point estimates with the OLS model in the first three columns and results using a Poisson model in the last three columns. Across all columns, it is quite evident that the RCHSA indeed led to a rise in counts of patents with both radiation-reducing features and radiation-generating traits by at least 56.6%. These results show that introducing stricter product safety standards can simultaneously inflate the patenting rate for both innovation types, underscoring the complementary nature of these two types of innovations.

It is worth noting that radiation-reducing technology *per se* can be both new products and new features integrated into existing products, adding vertical differentiation ("process innovation") (Galasso and Luo, 2021). As a result, it is reasonable to argue that instead of reflecting the innovation complementarity, the simultaneous increase in both features comes from changes in the structure of the final product market. For example, if a surge in radiation-reducing products pushed up the demand for X-ray based device, the increase in risk-generating patents might simply suggest firms responded to this positive demand shock.

To alleviate the concern, I further implemented another exercise based on the type of radiation-reducing patents. The first type, A61B6/10, essentially refers to patents representing "adaption of safety means." It generally technologies like apron, shield, and other instruments to directly protect consumers from unnecessary radiation. Consequently, such apparatus are more likely to be manufactured and commercialized independently. In contrast, the second type, A61B6/54 and A61B6/58,[46] include components controlling apparatus or devices for radiation diagnosis. This type usually embedded within radiation-generating devices, thereby less likely to be valued as a final product. Building on this technological distinction, I re-run the regressions and use the second type of patents as the treatment group. Results in Table 4 compare the point estimates. In the first two columns, the treatment group includes all patents under `A61B6/10`, `A61B6/54`, and `A61B6/58`. The

[46] `A61B6/54` patents refer to "control of apparatus or devices for radiation diagnosis." `A61B6/58` includes "testing, adjusting or calibrating thereof."

last two columns show the results using only A61B6/54 patents and A61B6/58 patents as the treatment group. Based on these estimates, we can see the increase in patent counts primarily come from the second type of radiation-reducing technology, suggesting that such new technologies are more likely to be embedded in those radiation-generating devices. Again, it provides evidence that new methods are developed to fix radiation issues associated with existing devices.

Another relevant concern for this innovation complementarity argument is that a firm could develop a radiation-reducing/generating patent and sell it to other manufacturers. Put it differently, the inventor does not necessarily have the production capacity. In this case, the incentive to comply with stricter regulation and develop new safety technologies is not obvious among such inventors. Unfortunately, in the patent dataset, there is no way to directly tel or infer if the assignee is also the manufacturer of a medical device.

To address this concern, I leverage the panel data for publicly traded firms and present some firm-level evidence. The advantage of such firm-level analysis is that compared to small firms/entities, publicly traded ones are more likely to own one's R&D department and production lines. In other words, there is a good chance that public firms are both the inventor and manufacturer of medical devices.

In Table 5, I focus on a subset of publicly traded firms in the Compustat-KPSS sample, satisfying the following two conditions: (1) the firm has a prior patenting history in medical devices emitting radiation, and (2) the firm has data available throughout the sample period, 1960-1980. Overall, I find among these firms that are most likely to have "defective products," the patenting rate for radiation-reducing technologies increased significantly. At the same time, the patenting rate for radiation-generating technologies also experiences a rise with a similar magnitude. This additional evidence further demonstrates the complementarity channel at the firm level.

5.3 Effects on the Quality of Innovation

Beyond the quantity of innovation activities, I also test if the safety regulation affects the quality of innovation. Essentially, the efficacy of such regulations in promoting innovation hinges on whether they foster high-quality patents that stimulate *radical innovation* or merely generate minor patents that yield limited impacts, that is, *incremental innovation*.

5.3.1 The Distribution of Patent Quality

A standard measure of patent quality is the number of forward citations received by each patent (Pakes and Griliches, 1980). Yet, this metric is not free of concern. One notable limitation is namely the first-mover effect: the first papers/patents in a field will receive citations at a rate enormously higher than papers/patents published later, regardless of their actual content, quality, and value (Newman, 2009, 2014). To account for this bias, I follow the method proposed by Galasso and Luo (2022) and check the heterogeneous effects on patenting rates across the entire distribution of citations.[47]

The basic idea is straightforward: we aim to "normalize" citation counts by the average number of citations received by all patents in the focal patent's application year. To this end, I first allocate each patent to its respective citation distribution within its cohort (i.e., all patents applied under the same patent class in the same year) and classify whether it falls into the category of low quality (below the median of citations) or high quality (above the median of citations). I then aggregate all low-quality and high-quality patents at the subclass-year level, respectively. This way, I constructed two primary samples whose unit of observations is subclass-year. In the low-quality sample, each observation corresponds to the count of low-quality patents filed under subclass *sc* in year *t*. The high-quality sample, in contrast, includes the count of high-quality patents applied under a subclass per year.

Results based on this metric are shown in Table 6. Across all columns, the dependent variable is the natural logarithm of patent counts. To account for the highly skewed distribution of my data, a Poisson model is applied. I present my estimates in the first two columns, using all `A61B6` patents within the treatment group. Interestingly, higher safety standards appear to favor innovation among high-quality patents, with an increase of 88.6% in the patenting rate. When moving to patents emphasizing the reduction of radiation risk and hazards, the magnitude of changes in patenting rates among low-quality patents is almost identical to that of their high-quality counterparts. In the last two columns, we can again observe that the rise in patent counts among the high-quality ones is slightly more prominent. Taken together, this exercise reveals at least two patterns: First, the innovation effect is universal across the industry (i.e., all diagnostic X-ray medical devices are affected). Second, stricter safety standards favor high-quality patents, especially those emphasizing radiation generating.

[47] Alternatively, I estimate the impacts of the RCHSA on the number of forward citations per patent and the citation-weighted patent counts (now shown in this paper): Neither of these estimates is statistically significant. These insignificant results might be partially due to the structure of my citation data and thus reinforce the necessity to consider the "*first-mover*" effect in measuring innovation quality.

Table 7 summarizes my results regarding the impact on the share of high-quality patents. The dependent variable is the likelihood of having at least one high-quality patent in a subclass-year cell in odd-numbered columns, while the even-numbered columns show the log of the share of high-quality patents. Overall, these point estimates imply the propensity to have high-quality patents rose significantly when the RCHSA was in effect (by 17.4 percentage points).

5.3.2 Private Market Values

When analyzing companies listed on American stock exchanges, I utilized the patent market value from Kogan et al. (2017) as a measure of patent quality. This metric uses the excess stock returns for patenting firms on the date of the patent's issuance date recorded in the USPTO official gazette.

In Table 8, I separately provide the coefficient estimate for all `A61B6` technologies, radiation-reducing technologies, and radiation-generating technologies. These results all point to the fact that in response to the RCHSA, the quality of patents filed by publicly traded firms improved. To be concrete, the market value increased by 2.3%, 1.1%, and 2.1%, respectively. Taken together, my empirical findings based on both the forward citations and private market value highlight imposing safety standards has the potential to bolster patent quality.

5.4 Who Invented?

Recall the premise of my theoretical framework: firms respond to regulatory pressure by innovating. In this subsection, I present supporting evidence for this theoretical argument. To start, I directly check whether the main contributor to this surge in innovation is firms or independent inventors.

By reading the inventors' and assignees' names of each patent of interest in the CUSP, I manually separated these patents into two groups: independent patents and firm patents. As briefly mentioned in Section 3.2, independent patents refer to those either without any assignee, assigned to (original) inventors, or assigned to other individuals (i.e., investors). By contrast, I define all patents initially assigned to firms as *firm* patents. This category typically includes patents from inventors employed by firms with in-house $R\&D$ labs and are obliged to assign the invention to their employers by contract.

$$Firm_{i,sc,t+1} = \alpha + \beta Treat_{sc} \times After1969_t + \theta_{sc} + \mu_t + \epsilon_{i,sc,t} \tag{9}$$

Equation (9) lists the main specification in this analysis. The dependent variable is an indicator for whether the inventor is a firm. I control for both patent subclass fixed effects and year fixed effects. Put differently, I aim to check the composition effect of the RCHSA with this specification.

The main results are presented in Table 9. Column (1)-(3) report the point estimates for β with the treatment group as all `A61B6` patents, `A61B6` patents emphasizing safety features, and `A61B6` patents capturing the trait of "radiation generation," respectively. Throughout all the columns, one can tell it is firms that primarily contribute to the policy-induced innovation activities. The probability of being a *firm* patent increased by 17.8 percentage points if a patent is under any subclass of `A61B6`. This pattern is consistent among `A61B6` patents emphasizing safety features and addressing radiation generation.

I also re-run the regression specified in Equation (1) but focus on firm patents and individual patents separately. Table 9 then summarized these results. In column (1), (2), (4), and (5), the regression specification is the baseline DID model; in column (3) and column (6), a triple DID is applied:[48]

$$\begin{aligned} log(Counts_{f,sc,t+1}+1) =& \alpha + \beta_1 Treat_{sc} \times After1969_t \times Firm_f + \beta_2 Treat_{sc} \times After1969_t + \\ & \beta_3 Treat_{sc} \times Firm_f + \beta_4 Firm_f \times After1969_t + \theta_{sc} + \mu_t + Firm_f + \epsilon_{f,sc,t} \end{aligned} \tag{10}$$

Results for the baseline DID model indicate that we can observe an upward surge in innovation activities among firms along both the extensive and intensive margins (column 1 and 4). Conversely, a decline in the outcome of interest is consistently observed (column 2 and 5) among individual patents. The point estimates from column 3 and column 6 reinforce these patterns: Compared to individual patents, the increase in patenting rate is more evident among firm patents.

In summary, the distinction between the responses of firms and individual inventors in innovation underscores two key points: First, firms are indeed actively involved in developing and patenting more relevant technologies following the RCHSA, which is in line with the theoretical argument I presented. Second, the lack of response or even negative response from individual inventors suggests that the RCHSA might impose some adverse effects on (local) angel investors. For example, a more stringent and rigid regulatory environment can reshape local investors' risk perception toward new projects for radiation-related

[48] To implement this triple DID analysis, I reconstruct my primary sample: I append the sample composed of all individual patents to the one that including all firm patents. In other words, I have another balanced panel whose unit is patent-subclass.

products. If such investors exhibit more concerns about radiation risk in general, a decline in the supply of external funding might hinder innovation from independent inventors. This argument is consistent with a prior agenda claiming that (local) angel investors are the key source of financing/marketing for independent inventors (Babina, Bernstein and Mezzanotti, 2020; Nicholas, 2010).

6 Mechanisms

This section provides empirical findings to shed light on alternative mechanisms associated with the rise in innovation. Results from subsection 6.1 indicate that the surge in patent rates is not primarily due to the risk of legal action arising from defective products. In Subsection 6.2, I demonstrate that the RCHSA did not significantly boost consumers' demand for x-ray-based medical devices. Section 6.3 leverages historical qualitative evidence to rule out the possibility that increased approval costs resulted in the positive innovation effect. Section 6.4 presents suggestive evidence that this rise in innovation also cannot be primarily attributed to potential changes in product market structure following the regulation. Section 6.5 and Section 6.6 argue concurrent technological breakthroughs and other policies also cannot explain the rise in innovation, respectively. Taken together, my results indicate that regulatory compliance costs are the key mechanism at play.

6.1 Regulatory Compliance Costs

To start, I provide some qualitative evidence about the increasing compliance costs imposed by the RCHSA. According to United States. Department of Health and Welfare (1973), enforcement and compliance actions were taken immediately after the passage of the RCHSA.

> " ... Fifty-eight manufacturing plant inspections were made during 1972 involving 45 microwave oven manufacturers, 12 television receiver manufacturers, and one cold-cathode demonstration tube manufacturer ... At the end of 1972, there were 28 active compliance investigations involving defects, noncompliance with a performance standard, or test program disapproval ... 7 cases involve dental X-ray equipment, 4 involve medical X-ray equipment investigation ..."

> " During the past year (1972), eight compliance actions were initiated involving medical and dental X-ray equipment. In one compliance case, a pinhole radiation leak was discovered in the tube housing of a diagnostic X-ray machine,

creating the possibility of unnecessary exposure to patient or operator. Six compliance cases were initiated against the importers and distributors of a dental X-ray machine. In another compliance case, a fluoroscopy table was found to have an unacceptable failure rate, which could expose a patient to up to 2-1/2 times the required radiation. The manufacturer is replacing the defective diode in all machines in order to correct the problem."

In light of these descriptions, the FDA was indeed taking actions to go against the radiation risk associated with defective devices and components. The expected compliance costs are thus substantial to manufacturers.

To provide extra quantitative evidence, recall in Table 5, I revisited my primary results in Table 2: In the treatment group, I only include patents under two subclasses `A61B6/54` ("control of apparatus or devices for radiation diagnosis") and `A61B6/58` ("testing, adjusting or calibrating apparatus or devices for radiation diagnosis"), which both directly emphasize *controlling and lowering radiation emissions*, instead of protecting patients with *external safety apparatus* (e.g., shield under `A61B6/10`). In Figure 8 and Figure 9, two examples of the `A61B6/54` patent and the `A61B6/58` patent are presented.

As shown in Table 4, the patenting rate increased by 68.9% (= exp(0.524)-1) among subclass `A61B6/54` and `A61B6/58` (column (3)), relative to that of other diagnostic medical device patents. The magnitude of these estimates is quite similar to that of my main results (shown in column (1)). This additional evidence demonstrates manufacturers are incorporating "new means", which can directly reduce radiation emissions, to lower compliance costs in response to the regulation.

The third exercise I took to demonstrate the validity of this channel, is to investigate whether publicly traded firms with prior history in patenting radiation-generating devices. The basic idea is that such firm face larger compliance costs because their existing radiation-based products have a higher chance of generating radiation. Again, in Section 5.2.3, I have shown that such firms with higher radiation leakage risk are indeed responding to the regulation by patenting more safety technologies and radiation-generating devices simultaneously.

6.2 Litigation Risk of Defective Products

The first alternative channel through which the RCHSA increased firms' innovation incentives is by amplifying litigation risk associated with defective products. It is noteworthy that when referring to litigation risk, I refer to cases arising from *private litigation* due to

product liability (Viscusi and Moore, 1993). The concern here is two-fold: first of all, the initial GE recall in 1967 not only triggered the enactment of the RCHSA, but also scaled up litigation risk associated with all electronic products emitting radiation. Second, the RHSA *per se* can substantially change the legal environment, thereby inducing a spike in liability risk.[49]

In terms of the relationship between litigation risk and innovation, several prior studies provide some insights. For example, Viscusi and Moore (1993) argue that when the litigation risk is sufficiently low, the correlation between innovation intensity and litigation risk is positive. Galasso and Luo (2022) found that in the context of medical implants, liability risk can percolate throughout a vertical chain and impose a significant chilling effect on downstream innovation. Rogers (2023) documented the fact that when being exempted from litigation risk, firms would respond positively in innovation.

6.2.1 Private Litigation Targeting X-ray Medical Devices

To empirically explore this mechanism, I collect information from Westlaw on the number of federal/state cases involving GE as one of the defendants and general X-ray medical devices.[50] In particular, I searched the database using two keywords in the full text: General Electric (and other variations of the company's name) and X-ray medical device(s). I primarily focus on lawsuits in the following categories: personal injury/health care/pharmaceutical personal injury/product liability; personal injury/product liability; personal property/product liability; and contract/product liability.

Figure 18 plots the number of litigations involving X-ray medical devices due to product defects. There was no discernible change in case counts around the focal point of 1967, suggesting that the surge in patenting activity observed in Section 5 may not be tremendously driven by an increase in product liability litigation.[51]

6.2.2 Patenting Activities between Domestic and Foreign Firms

To demonstrate litigation risk (if any) did not have a tremendous impact on innovation, I also compare changes in patenting activities between domestic and foreign firms. Concep-

[49] For example, the 1960s and 1970s were decades of "tumult in products liability law." Courts were transforming a negligence regime into a strict liability regime based on product "defect" rather than manufacturers' or retailers' "fault." State jurists sought to extirpate from strict product liability several concepts grounded in negligence or fault-based liability" (Bell, 2019).

[50] See https://legal.thomsonreuters.com/en/westlaw, last accessed February 14, 2025.

[51] Using the timing and number of lawsuits as a proxy for litigation risks is in the similar spirit of Galasso and Luo (2022), who plot the evolution of lawsuits against DuPont in Appendix Figure A1.

tually, one might expect if liability risk were the sole driving factor, the RCHSA would impose little effect on the innovation efforts addressing safety enhancements among foreign firms. This argument is built on some narrative evidence drawn from prior legal studies. For example, Klerman (2011) argues that

> "Product liability law in many foreign jurisdictions is less consumer-friendly than in the United States, and contingent fees are seldom allowed. As a result, the costs of suing abroad and the low probability of fully compensatory damages mean that injured consumers are likely not to sue at all if the only available forum is outside the United States. This, of course, reduces the incentive of foreign manufacturers to design and produce safe products. In addition, it gives foreign companies a competitive advantage over American firms and encourages U.S. firms to relocate abroad."

Overall, it suggests that "even though foreign producers selling products in the US generally face the same product liability rules as domestic producers, US plaintiffs face complexities and additional legal costs (e.g., matters of personal jurisdiction, conflicts of laws, and greater difficulties in enforcing judgment) that make foreign producers less concerned about liability risk (Galasso and Luo, 2022)."

In the meantime, recall in Section 2, I briefly described that "any relevant electronic product offered for importation into the United States which fails to comply with applicable performance standards or to which is not affixed a certification in the form of a label or tag in conformity with section 358(h) shall be refused admission into the United States." In this regard, it suggests the innovation incentives for some foreign manufacturers may also get inflated following the RCHSA.

Table 12 reports my primary empirical evidence. In Panel A and B, I summarize the estimates for U.S. and foreign firms separately. The dependent variable is the number of patents filed by U.S./foreign firms in a subclass-year cell. In column (1) and column (3), the results are based on the baseline DID specification. Consistent with the above theoretical argument, domestic firms are more inclined to patent both radiation-reducing and radiation-generating technologies following the RCHSA. Examining the magnitudes associated with the estimates (0.551 vs. 0.557), we can re-assure that radiation-reducing and radiation-generation technologies are quite likely to be complementary in production. Meanwhile, it is interesting that even accounting for uncertainties in the domestic legal environment, the innovation effect on foreign firms is statistically significant and positive. It thus suggests a large part of the rise in innovation activities could be attributed to the regulation *per se*.

Another advantage of comparing patenting activities between domestic and foreign firms is that it enables me to better control for potential confounding factors affecting my treatment and control groups differentially. For example, if there were technological progress for radiation-based diagnostic medical devices during the reference period, one may raise concerns about the validity of my identification strategy. To address this issue, I incorporate the country of patent assignees as the additional variation in a triple DID model. Put differently, foreign firms serve as the control group and account for some common trends in patenting X-ray diagnostic medical technologies. The results in Table 12 indicate that relative to foreign firms, US firms are more likely to respond to the RCHSA in patenting both radiation-reducing and radiation-generating technologies (by 57.3% and 34.3%).

6.2.3 Patenting Activities between GE and Non-GE Firms

Last but not least, I directly assess whether the patenting activities of GE significantly differ from those of other firms. The basic assumption is that the initial GE recall in 1967 might have imposed more litigation risk on GE *per se* relative to its competitors in the market.

Table 13 presents the estimated effects on patent counts by technology for GE and non-GE domestic firms. In the first two columns, the treatment group includes all patents under class `A61B6`. In column (3) and column (4), the treatment group is defined as a subsample of `A61B6` patents emphasizing safety features. The last two columns in Table 13 represent the case where the treatment group is composed of all `A61B6` patents addressing radiation-generating technologies. Point estimates in the odd-numbered columns are based on a sample consisting of patents filed by GE. Results from the even-numbered columns represented the case for all non-GE firms.

Based on what we can observe in all odd-numbered columns in Table 13, little evidence shows that GE responded positively in innovation following the RCHSA. By contrast, patent counts increased significantly (by 65.9% for radiation-reducing technologies and by 57.1% for radiation-generating technologies) within non-GE domestic firms.

The above empirical findings are clearly not aligned with the hypothesis that increased litigation risk encouraged GE *per se* to prioritize investing in innovation. More interestingly, one possible channel to rationalize the decline in GE's patenting rate is that if most products of GE have met the minimum performance standards under the RCHSA, GE could stand to benefit from these standards and reduce investments in innovation. This is because higher safety standards protected GE from competing or at least helped GE avoid higher compliance costs.

6.3 (Expected) Market Size Expansion

According to Leland (1979), imposing minimum quality standards would mitigate asymmetric information between buyers and suppliers. This *quality assurance effect* improves the average quality available to consumers *ceteris paribus*, thereby increasing their willingness to pay for these regulated goods and services. In the presence of this positive demand shock for medical procedures involving equipment based on X-rays, firms' incentives to innovate will increase in response to this (expected) expansion in market size (Schmookler, 1966).

To investigate whether changes in consumer demand contributed to the increased patenting activity, I construct a novel dataset by digitizing information from the National Hospital Discharge Survey (NHDS), as described in Section 3. Specifically, I use the number of short-term hospital discharges per year as a proxy for demand and define the treatment group as the radiology service. To estimate the effect of changes in demand on patenting activities, I employ the following regression model:

$$y_{imt} = \alpha + \beta Treat_m \times Post1969_t + \psi_i + \theta_m + \mu_t + \epsilon_{imt} \tag{11}$$

where y_{imt} is the natural logarithm of the total number of discharges related to service type m under the demographic/hospital/regional group i in year t. $Treat_m$ is an indicator equaling to one if the medical procedure is the radiology service, and $After1969_t$ denotes whether the year includes and after 1969. ψ_i is a set of group-specific fixed effects (i.e., age group, gender, region, or hospital size). θ_m and μ_t are the medical procedure fixed and year fixed effects, respectively.

Table 14 shows the tentative evidence. The dependent variable is the natural logarithm of the number of discharges, and through column (1) to column (3), I separately estimate Equation (11) with three samples based on patients' age and sex, the size of hospitals, and the region where a hospital is located. Point estimates from Table 14 all indicate that when imposing the RCHSA of 1968, the number of short-stay hospital discharges involving radiology services did not change significantly, suggesting that relative to other types of medical procedures, stricter safety regulations targeting diagnostic x-ray medical devices imposed little effects on the utilization of radiation-based medical devices.

Admittedly, I should acknowledge the exercise above only suggests in the *short run*, the regulation did not trigger a substantial, immediate increase in consumers' demand. It is less determined how equilibrium outcomes would change. In future work, one could collect

more detailed data regarding technology diffusion and adoption and find other variation to answer to carefully examine whether and how safety regulations shaped the diffusion of technologies among both consumers and healthcare providers.

6.4 Approval Uncertainties

Besides regulatory compliance costs, the passage of the RCHSA may also introduce another type of fixed cost on firms' end: approval costs, or say, costs stemming from approval uncertainties (Stern, 2017). For example, the presence of more stringent safety performance standards can mechanically results in longer periods for the FDA to review and approve products. Faced with the prospect of higher approval costs, firms can strategically shift their innovation efforts and prioritize the development of technologies and features that directly address safety features outlined in these standards. By doing so, firms are able to streamline the approval process, minimize delays, and reduce fixed costs.

However, this theoretical hypothesis is not in line with the historical institution for medical devices during the 1960s and 1970s. As highlighted in Section A2 in the Appendix, the FDA had little power of pre-marketing approval or subsequent disapproval in the case of medical devices prior to 1976 (Finck, 1974). In particular, general medical device manufacturers did not go through the pre-marketing approval of any new device produced. The manufacturer is not mandated to show that a new device is effective, safe, and reliable for its purported use. Instead, the historical regime centers on *ex-post* regulations: the FDA relied on complaints or its own discoveries before the regulatory authority could be invoked.

6.5 Technological Breakthrough

Another noteworthy explanation for the surge in radiation device patents is the technological breakthrough during the 1970s. In a 1963 article published in the *Journal of Applied Physics*, Allan Cormack proposed a method to improve tomographic imaging: computed tomography (CT) technology. Rather than use X-rays to make photographs, Cormack suggested that physicians measure X-rays after they passed through a body to see how much radiation had been absorbed. Cormack also "made measurements of a phantom composed of aluminum and Lucite and produced plots of attenuation coefficient along proviles through the object" Schulz, Stein and Pelc (2021). It turns out to be the first experimental demonstration of computer assisted tomography and was published in 1964. For this piece of work during the 1960s, "attempts were made to interest hospital physicists in the results,

but to no avail" Schulz, Stein and Pelc (2021). A group at Siemens tried to conduct work on what was eventually called CT. Yet, given technological obstacles to being able to achieve spatial resolution of a fraction of a millimeter, the entire project was terminated.

In the meantime, Godfrey Hounsfield made primary contributions to the development of commercial CT scanners. Hounsfield first came up with the theoretical idea during a vacation trip in the late summer 1967. A physician who bemoaned the drawbacks of conventional radiography and first introduced him to human anatomy as an example of the problem of "reading through a box" Schulz, Stein and Pelc (2021). From November 1967 to July 1968, Hounsfield did his research work on CT without funding. The proposal received DHSS funding and EMI funding on October 28, 1968.

By August 1970, the specifications of the clinical prototype of CT scanners were finalized and the entire system were completed over a year later. During Hounsfield's talks showing results from the system, limited enthusiasm was received among radiologists as people did not fully appreciate the benefits. The first clinical scan of CT took place on October 1, 1971 and included great details. The corresponding early clinical data were presented at the British Institute of Radiology conference in April 20, 1972 and later shown to the public in New York on May 15, 1972, attracting the attention of medical community in the US. As a result, Hounsfield was featured in all three major television networks. In December 1972, EMI displayed and secured trade for these CT scanners at the annual meeting of the Radiological Society of North America (RSNA). EMI was also able to secure reimbursement for CT procedures from Medicare after demonstrating the effectiveness of its head scanner.

Given the description above, it is reasonable to argue that the entry of CT head scanners created a shock to manufacturers, leading to a wave of follow-on innovations in X-ray medical devices. The upward surge in `A61B6` patent counts thus could be partially attributed to this technology-specific breakthrough. However, note that my event-study results in Figure **??** and Figure **??** show that there was a significant rise in patenting rates for both the radiation reducing technology and radiation-generating technology in one year right after the RCHSA. In other words, the timing of effects helps alleviate concerns that the invention and entry of CT technology primarily drives my results.

It is worth noting that during this period, there was no substantial evidence showing that the medical application of such CT research was feasible. I searched for historical, narrative evidence and found no specific news mentioning CT or Hounsfield's early-stage research during the late 1960s.[52] It is thus relatively safe to say that the 1968 RCHSA preceded the

[52]To be specific, I checked Newspaper Archives https://newspaperarchive.com/, last accessed February 14, 2025. I search for keywords including "radiation" "CT scanner" and so on.

major developments in CT technology. The concern that CT scanner largely explained the short-run surge, again, is addressed by the timing.

Here I implemented a third exercise to prove the robustness of my results. Instead of using a subclass-year panel, I reconstructed my sample, and the unit of observations is now at the class-month-year level. Put differently, this new sample tracks information for the number of patents filed under each broad patent class within each month of the year.[53] I then estimate the following regression model:

$$y_{cmy} = \alpha + \beta Treat_c \times Post1968_{my} + \theta_c + \mu_m \times \psi_y + \epsilon_{cmy} \tag{12}$$

where c denotes patent classes, m indexes months, and y indexes years. $Treat_c$ is an indicator for whether a patent belongs to `A61B6` and $Post_{my}$ means whether a month-year pair is after 11/1968. In this specification, I include a set of "month-year" fixed effects and patent class fixed effects. This way, I can capture changes in the patenting rate at a higher frequency.

In the meantime, I also complement the above analysis with a two-part spline specification with knots in June 1969 and January 1973, which summarizes the event-study estimates and improves the precision of estimation relative to the event-study specification.

$$y_{cmy} = \alpha + \beta_1 Treat_c \times Post1968_{my} + \beta_2 Treat_c \times Post1973_{my} + \theta_c + \mu_m \times \psi_y + \epsilon_{cmy} \tag{13}$$

where β_1 and β_2 capture the impacts on innovation, following the RCHSA and the entry of CT, respectively.

For these two exercises, I directly drop all patents under subclass `A61B6/03` to check the robustness of my main results. I also exclude patents under the parent subclass `A61B6/02` in this round of robustness checks to account for the fact that a parent subclass may contain residual patents that cannot be easily categorized into a specific children subclass.

Table 15 presents these results. Across columns, coefficient estimates in Panel A suggest that, on average, the RCHSA was associated with an increase in patent counts of `A61B6` (excluding CT patents) by 25.5%, or 0.366 per month. Rescaling this number to the annual level, it indicates having the RCHSA in place, there was an increase of 4.392 in patent counts under `A61B6` per year, similar to our main results (an increase of 4.184 per year

[53] Collapsing data at the "subclass-month-year" level would include too many zeros.

an the patent class level). In Panel B, I repeat the exercise but extend the reference period to 1975: Again, I find the positive effect associated with the passage of the RCHSA is not absorbed by an indicator for the entry of CT technology, thereby ruling out the possibility that my treatment group was substantially contaminated by this additional shock. In Panel C, all the magnitude, direction, and significance of my estimates are quite similar to those shown in Table 1.

Finally, I exploit an institutional feature to rule out the possibility that the technology breakthrough is the primary driver of the new patenting activities. This is based on the justification that the introduction of CT scanners was a global shock to all manufacturers, including both domestic ones and foreign ones. In other words, if the technological breakthrough led to the increase in patent counts, one would expect the surge should be universal among all firms. Yet, recall in Table 12, under the RCHSA, domestic firms still came up with more patents for both radiation-reducing technologies and radiation generating devices. As a result, the entry of CT cannot solely explain what have been documented.

6.6 The Medical Device Amendments of 1976

It is worth noting that the Medical Device Amendments to the FD&C Act in 1976 is another important policy shock that may affect the causal interpretation of the estimates.[54] The 1976 Act was enacted to ensure the safety and effectiveness of medical devices and introduced a risk-based classification system for all medical devices. The Act also established regulatory pathways for new medical devices prior to their marketing and introduced several key post-market requirements. There is a potential concern that including the post-MDA period may lead to differential effects on innovation incentives for treated and control subclasses due to institutional changes. To address this concern, I changed the reference period and restricted my sample to 1960-1975, one year prior to the 1976 Amendments. At the same time, I drop all patents under `A61B6/03`.

Based on the coefficient estimates presented in Table 16, it appears that, on average, the RCHSA resulted in a 44.9% increase in patenting (or an increase of 0.64 patents per year) in the `A61B6` subclass. This represents a slight decrease in the estimated effect size relative to the results in Table 1, which suggested an increase of 58.7% (or say, 0.85 more patents per year). Thus, this exercise reassures that the potential confounding effect of the MDA is not a serious concern in my setting.

[54] See https://www.govinfo.gov/content/pkg/STATUTE-90/pdf/STATUTE-90-Pg539.pdf, last accessed February 14, 2025.

7 Welfare Implications

To shed more light on the welfare implications of imposing stricter product safety standards, I discuss how to quantify some of the benefits associated with the RCHSA in 1968.

Ideally, painting a comprehensive picture of welfare analysis in contexts like mine would require various calculations. To name a few, benefits include but are not limited to (1) the consumer surplus gained from accessing additional medical devices (Grennan and Town, 2020), either because fewer harmful products are developed or because the new products are safer (Galasso and Luo, 2021), (2) a direct reduction in the incidence of adverse health events (e.g., cancer, death, hospitalization) linked to radiation risk (Lin, 2010; Verdun et al., 2008), and (3) the increased market value resulting from innovation (Kogan et al., 2017). Regarding costs, it may encompass the increased medical expenditure, conditional on safety regulation inflating the price of radiation-based healthcare services (Rogers, 2023). Leveraging my key findings in this paper, I provide some calculations to assess the potential welfare gains of the RCHSA.

Market Value of Innovation: To start, recall that in the main analysis based on Kogan et al. (2017), I documented the increase in private market value associated with policy-induced patents among publicly traded firms. I first attempt to capture this added value as a component of the welfare gains attributable to the regulation.

It is important to note that I am calculating the *net* added market value, which incorporates both costs and benefits for three primary reasons. First, compliance often necessitates substantial investment in R&D, testing, and regulatory approval, imposing direct costs on firms that can offset perceived gains in market value. Second, if only a few firms succeed in securing patents due to regulatory barriers, they may gain increased market power.[55] In this case, part of the observed increase in market value may stem from monopoly rents rather than genuine innovation-driven benefits. Third, regulation-induced innovation may crowd out alternative, potentially more valuable, research efforts, leading to a reallocation of resources rather than a net expansion of technological progress.

I exploit the estimates by Kogan et al. (2017) on the increase in market value attributed to the issuance of a patent. According to Kogan et al. (2017), the median value of a patent is equal to $1.24 million in 1969 dollars. Meanwhile, my estimates from Section 5 and Section 6 show the presence of the RCHSA has led to an increase in counts by 1.4 per subclass among publicly traded firms annually. At the same time, the increase in private market value per patent among publicly traded firms is 2.3%. Collectively, it sug-

[55] Though in the appendix Section A.6, I showed that this market power story is less likely to happen.

gests that the increased private value of these patents is approximately $1.81 million (= 0.4*1.24*2.3%+1.77*1.24*2.3%+1.4* 1.24, in 1969 dollars).

One issue worth reiterating is the market value linked to each patent is derived from all U.S. public firms Kogan et al. (2017). To ensure the precision of the above calculation, I further confirm that there is no statistically significant difference in patenting activities between publicly traded and private firms following the RCHSA in the sample period.

Value of A Statistical Life (VSL): As posited by Linet et al. (2012), "the 600% increase in medical radiation exposure to the US population since 1980 has provided immense benefit, but potential future cancer risks to patients." Notably, most of the increase is from diagnostic radiologic procedures. Prior epidemiologic studies have long established the link between diagnostic X-rays and the increased cancer risk among patients. For example, Stewart et al. (1956), Stewart, Webb and Hewitt (1958), MacMahon (1962), and Wakeford (2008) found modest excesses of pediatric leukemia in offspring of mothers undergoing diagnostic x-rays during pregnancy. Boice Jr et al. (1991), Howe and McLaughlin (1996), and Ron (2003) documented increased breast cancer risks among women with tuberculosis monitored using fluoroscopy and women with scoliosis evaluated with repeated X-rays.

Building on historical data and the economic framework in Viscusi, Huber and Bell (2014), I estimate the value of a statistical life (VSL) associated with the Radiation Control for Health and Safety Act (RCHSA). This estimation is based on the following assumptions:

(1) Each patent related to radiation-reducing technologies is assumed to correspond directly to a fully developed and adopted medical device, without adjusting for commercialization barriers, regulatory delays, or market adoption rates.

(2) The incidence rate of radiation-induced cancers remains constant over time, with approximately 1,800 cases per year, as reported by the FDA (1970).

(3) The present value of an expected cancer case occurring with a one-decade latency period is $1.81 million in 1969 dollars, as estimated in Viscusi, Huber and Bell (2014).

As shown in Table 2, following the implementation of the RCHSA, the number of patents relevant to radiation reduction increased by 0.7 per subclass per year, with three subclasses identified as focusing on radiation-reducing technologies. Taking these factors together, I estimate the cumulative VSL associated with the RCHSA at $6.84 billion per year (calculated as $0.7 \times 3 \times 1.81$ million $\times$ 1,800, in 1969 dollars).

8 Conclusion

Striking a balance between safeguarding consumers and advancing medical technology poses a multifaceted challenge, especially within the medical device industry. In this paper, I empirically assess how imposing stricter safety performance standards affected the development of new technologies through a lens of history. Exploiting the passage of the Radiation Control for Health and Safety Act (RCHSA) in 1968 as a quasi-experiment, I find patents related to diagnostic X-ray medical devices experienced a drastic increase in quantity (by at least 42.4%), as well as quality. These positive effects hold for both technologies emphasizing radiation protection and new devices relying on radiation, which are likely to be complementarities in production.

To disentangle the mechanisms at play, I conducted a variety of empirical tests. My findings, together with narrative evidence, suggest it is the presence of regulatory compliance costs that drives up firms' innovation incentives, rather than increased liability risk, higher approval uncertainties, expanded market size, or substantial changes in product market competition. To elaborate, a rise in compliance costs under stricter safety standards induced firms to prioritize cost-saving innovation, thereby resulting in a surge in new technologies mitigating radiating risk. This influx of radiation-reducing technologies, in turn, intensifies the marginal benefits of developing new X-ray-based medical devices and further fosters product innovation.

My paper provides novel and complementary evidence to the sparse empirical work investigating the interplay between product quality regulation and innovation. In particular, it emphasizes that facing a highly stringent regulatory regime, firms can take innovation as a strategy to combat increased costs and mitigate risk. It also highlights the delicate nature of designing policy instruments to address product safety and quality: in a context wherein technologies themselves can interact, even regulations targeting a single dimension can create unexpected impacts on other technology classes.

This paper emphasizes at least three priorities for future research. Beyond quantifying firms' innovation strategies and activities, it is also crucial to assess how such safety regulations affect the diffusion and adoption of relevant technologies. For example, besides altering consumers' perceived quality, stringent safety regulations could bolster healthcare facilities' incentives to adopt X-ray medical machines if the profitability of adopting *safer* devices outweighs its costs. Measuring effects along this margin is important because the overall welfare effects of product quality regulation hinge on whether consumers can directly access these induced new technologies. Further, reconciling various channels, which

are outlined in both prior work (Viscusi and Moore, 1993; Galasso and Luo, 2022; Rogers, 2023) and mine, within a structural model offers another promising but challenging avenue for future research. Eventually, another compelling direction is exploring additional mechanisms that explain the relationship between regulation and innovation. For example, it would be intriguing to investigate whether industrial regulations influence coordination among firms, especially if detailed firm-product level data can be leveraged. This could offer new insights into the ways firms collaborate in response to regulatory pressures, further enriching our understanding of how regulations shape firms' strategies.

In terms of external validity, my case study highlights wide-ranging implications for contemporary policy levers, particularly in the context of emerging AI-based medical products. Such historical evidence from X-ray regulation demonstrates how well-designed safety standards can promote both product safety and technological innovation because of *technological complementarity*. Meanwhile, it also emphasizes that for medical device regulations, an one-size-fits-all approach may be misleading (because of the complicated interactions between technologies). Policymakers should be cautious in designing/implementing regulatory reforms, ensuring that these safety mandates are tailored to the specific characteristics of different technology classes. A rigid regulatory framework that fails to consider these technological interactions may inadvertently stifle innovation. Future research should also keep advancing our understanding of these dynamics and investigating how different regulatory approaches shape innovation activities.

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Tables and Figures

Table 1. Effects of the RCHSA on Patent Counts (1960-1980)

	OLS			Poisson		
	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma
Panel A. raw counts						
$Treat_c \times Post1969_t$	0.587***	0.674***	0.557***	0.607**	0.805***	0.728***
	(0.122)	(0.120)	(0.119)	(0.200)	(0.236)	(0.203)
Panel B. citation-weighted						
$Treat_c \times Post1969_t$	0.806***	0.998***	0.845***	0.501**	0.471**	0.298*
	(0.221)	(0.203)	(0.185)	(0.199)	(0.238)	(0.178)
# of clusters	67	94	127	67	94	127
# of obs.	1,407	1,974	2,667	1,407	1,974	2,667
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period (1960-1980). The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the outcome of interest is constructed based on the raw patent counts, and in Panel B, the outcome is constructed using the citation-weighted patent counts. All standard errors are clustered by patent subclasses.

Table 2. Effects of the RCHSA on Patent Attributes

	OLS			Poisson		
	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma
Panel A. Radiation-Reducing						
$Treat_c \times After1969_t$	0.496***	0.583***	0.466***	0.602***	0.799***	0.722***
	(0.108)	(0.105)	(0.104)	(0.221)	(0.254)	(0.223)
# of clusters	54	81	114	54	81	114
# of obs.	1,134	1,701	2,394	1,134	1,701	2,394
Panel B. Radiation-Generating						
$Treat_c \times After1969_t$	0.543***	0.630***	0.513***	0.754**	0.951***	0.874***
	(0.170)	(0.168)	(0.167)	(0.295)	(0.320)	(0.296)
# of clusters	59	86	119	59	86	119
# of obs.	1,239	1,806	2,499	1,239	1,806	2,499
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The treatment group in this set of regressions includes all `A61B6` patents emphasizing radiation-reducing. The dependent variable of all regressions in columns (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Pharma" means all pharmaceutical ingredients under the category `A61K`. In Panel A, the treatment group is constructed based on the CPC code and includes all diagnostic medical devices emphasizing "radiation reduction"; in Panel B, the treatment group includes all diagnostic X-ray medical devices generating radiation beam. All standard errors are clustered by patent subclass.

Table 3. Effects of Radiation Control on Patent Attributes (Dual Features)

	OLS			Poisson		
$Treat_c \times Post1969_t$	0.730**	0.752***	0.566**	1.259***	1.433***	1.403***
	(0.288)	(0.266)	(0.267)	(0.404)	(0.389)	(0.391)
# of obs.	126	147	273	126	147	273
control group	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is class-year. The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Pharma" means all pharmaceutical ingredients under the category `A61K`.

Table 4. Effects of Radiation Control on Embedded Radiation-Reducing Technologies

	Including A61B6/10		Excluding A61B6/10	
	OLS	Poisson	OLS	Poisson
$Treat_s \times Post1969_t$	0.496***	0.602***	0.524***	0.880***
	(0.108)	(0.221)	(0.146)	(0.254)
# of clusters	54	54	53	53
# of obs.	1,134	1,134	1,113	1,113
subclass FE	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office (USPTO) during the reference period (1960-1980). The unit of observation is patent subclass-year. The dependent variable of all regressions is the annual patent counts filed under a patent (sub)class in year t. All standard errors are clustered by patent subclass. In the first two columns, the treatment group includes all patents under three subclasses: `A61B6/10`, `A61B6/54`, and `A61B6/58`. The last two columns include patents from `A61B6/54` and `A61B6/58`. `A61B6/10` patents refer to "safety means specially adapted therefor." `A61B6/54` patents refer to "control of apparatus or devices for radiation diagnosis." `A61B6/58` includes "testing, adjusting or calibrating thereof."

Table 5. Evidence of Innovation Complementarity

	Dependent Variable: log(patent counts+1)	
	Radiation-Reducing	Radiation-Generating
$Treat_c \times Post1969_t$	0.134^{***}	0.102^{*}
	(0.048)	(0.058)
firm FE	Yes	Yes
class FE	Yes	Yes
year FE	Yes	Yes
# of obs.	1,134	1,134

Note: Data are drawn from the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is at the firm-class-year level. The dependent variable of both regressions is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t.

Table 6. Effects on Patent Counts across Patent Quality Distribution

	Dependent Variable: log(patent counts+1)					
	All		Radiation Reducing		Radiation Generating	
$Treat_{sc} \times Post1969_t$	0.706^{***}	0.473^{***}	0.533^{***}	0.334^{***}	0.664^{***}	0.346^{**}
	(0.123)	(0.134)	(0.052)	(0.087)	(0.155)	(0.170)
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
sample	high-quality	low-quality	high-quality	low-quality	high-quality	low-quality
# of clusters	68	68	54	54	59	59
# of obs.	1,428	1,134	1,134	1,239	1,239	1,239

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO and CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office (USPTO) during the reference period. The unit of observation is patent subclass-year. The dependent variable of all regressions is the annual patent counts filed under a patent (sub)class in year t. All standard errors are clustered by patent subclass.

Table 7. Effects of the RCHSA on Share of High-Quality Patents

	All		Radiation Reducing		Radiation Generating	
	$\mathbf{1}_{\text{share}>0}$	log(share+1)	$\mathbf{1}_{\text{share}>0}$	log(share+1)	$\mathbf{1}_{\text{share}>0}$	log(share+1)
$Treat_{sc} \times Post1969_t$	0.174***	0.047*	0.114***	-0.016	0.174***	0.058
	(0.049)	(0.028)	(0.038)	(0.018)	(0.062)	(0.040)
# of clusters	68	68	54	54	59	59
# of obs.	1,428	1,428	1,134	1,134	1,239	1,239
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO and CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The dependent variable of all regressions is the share of high-quality patents filed under a patent subclass in year t. All standard errors are clustered by patent subclass.

Table 8. Effects on Innovation Quality among Publicly Traded Firms

	Dependent Variable: log(average market value)		
	All `A61B6` Tech	Radiation Reducing	Radiation Generating
$Treat_c \times Post1969_t$	0.023***	0.011***	0.021***
	(0.006)	(0.004)	(0.006)
class FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
firm FE	Yes	Yes	Yes
# of obs.	22,965	22,965	22,965

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO and CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is firm-subclass-year. The dependent variable of all regressions is the annual patent counts filed by firm i under a patent (sub)class in year t. All standard errors are clustered by patent subclass.

Table 9. Effects on the Composition of Inventors (Firms vs. Independent Inventors)

	Dependent Variable: $1_{\text{Firm Patent}}$		
	All A61B6 Patents	Radiation Reducing	Radiation Generating
$Treat_{sc} \times After1969_t$	0.178***	0.278***	0.185***
	(0.028)	(0.081)	(0.032)
subclass fixed effects	Yes	Yes	Yes
year fixed effects	Yes	Yes	Yes
Observations	10,641	9,148	9,786

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of observation is individual patents. The dependent variable of all regressions is an indicator of whether the patent was assigned to firms. All standard errors are clustered by patent subclass.

Table 10. Effects on Patent Counts (Firms vs. Individual Inventors)

	Dependent Variable: log(patent counts+1)					
	Radiation Reducing			Radiation Generating		
$Treat_{sc} \times Post1969_t$	0.778***	-0.165***	-0.165***	0.709***	-0.032	-0.032
	(0.142)	(0.056)	(0.055)	(0.190)	(0.053)	(0.052)
$Treat_{sc} \times Post1969_t \times Firm_f$	-	-	0.942***	-	-	0.740***
	-	-	(0.160)	-	-	(0.168)
$Firm_f$	-	-	0.255***	-	-	0.255***
	-	-	(0.057)	-	-	(0.057)
# of clusters	52	52	52	59	59	59
# of obs.	1,092	1,092	2,184	1,239	1,239	2,478
sample	firm	individual	full	firm	individual	full
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the log of patent counts filed under a patent class in year t. All standard errors are clustered by patent subclass.

Table 11. Effects on the Composition of Inventors (Domestic vs. Foreign Firms)

	Dependent Variable: log(Patent Counts+1)			
	Radiation Reducing		Radiation Generating	
Panel A. domestic firms				
$Treat_{sc} \times After1969_t$	0.609***	0.551***	0.611***	0.557***
	(0.143)	(0.139)	(0.196)	(0.197)
# of private litigation	-	0.022**	-	0.020***
	-	(0.010)	-	(0.007)
Panel B. foreign firms				
$Treat_{sc} \times After1969_t$	0.155**	0.138*	0.316**	0.280**
	(0.067)	(0.073)	(0.136)	(0.120)
# of private litigation	-	0.007	-	0.013
	-	(0.007)	-	(0.008)
# of clusters	52	52	59	59
# of obs.	1,092	1,092	1,239	1,239
subclass fixed effects	Yes	Yes	Yes	Yes
year fixed effects	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the USPTO in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the log of the annual patent counts filed under a patent class in year *t*. The sample in Panel A includes all patents filed by domestic firms; Panel B includes all patents filed by foreign firms. All standard errors are clustered by patent subclass.

Table 12. Effects of the Radiation Control on Domestic vs. Foreign Firms

	Dependent Variable: log(Patent Counts+1)					
	Radiation Reducing			Radiation Generating		
$Treat_{sc} \times Post1969_t$	0.609***	0.155**	0.155**	0.611***	0.316**	0.316**
	(0.143)	(0.067)	(0.066)	(0.196)	(0.136)	(0.134)
$Treat_{sc} \times Post1969_t \times$ *Domestic*	-	-	0.453**	-	-	0.295**
	-	-	(0.182)	-	-	(0.126)
sample	domestic	foreign	full	domestic	foreign	full
# of clusters	52	52	52	59	59	59
# of obs.	1,092	1,092	2,184	1,239	1,239	2,478
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the CUSP sample, including all patents granted and applied for at the USPTO in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed under a patent subclass in year *t*. All standard errors are clustered by patent subclass.

Table 13. Effects of the RCHSA on Patent Counts (GE vs. Non-GE Firms)

	Dependent Variable: log(patent counts+1)					
	All Tech		Radiation-Reducing		Radiation-Generating	
$Treat_{sc} \times Post1969_t$	-0.021	0.410***	0.019	0.506***	-0.024	0.452**
	(0.073)	(0.124)	(0.167)	(0.117)	(0.090)	(0.183)
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
sample	GE	non-GE	GE	non-GE	GE	non-GE
# of clusters	66	66	52	52	59	59
# of obs.	1,386	1,386	1,092	1,092	1,239	1,239

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is subclass-year. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed under a patent subclass in year t. All standard errors are clustered by patent subclass.

Table 14. Effects of RC on the Utilization of Medical Services (1968-1970)

	(1) Demographic Groups	**(2)** Hospital Sizes	**(3)** Regional Groups
$Treat_c \times Post1969_t$	0.098	0.089	0.077*
	(0.077)	(0.088)	(0.044)
service type FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
age × gender FE	Yes	No	No
hospital size FE	No	Yes	No
region FE	No	No	Yes
# of obs.	120	108	72

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from NHDS sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. I digitized key statistics for a variety of medical procedures. The unit of analysis is group-type (of medical procedures)-year. The dependent variable of all regressions is the natural logarithm of the annual number of discharges within a group (age, gender, region, or type of hospital). "Demographic Groups" denotes that the data are collected based on patients' age and gender, "Hospital Sizes" represents the sample is grouped by the size of hospitals, and "Regional Groups" means the data are assembled based on where a hospital is located.

Table 15. Robustness Check: The Entry of CT Scanners

	NR-DME	Medical Implants	Drugs
Panel A: 1/1965-12/1971			
$Treat_c \times Post1969_{my}$	0.227**	0.290**	0.252**
	(0.113)	(0.118)	(0.107)
class FE	Yes	Yes	Yes
month×year FE	Yes	Yes	Yes
# of obs.	504	756	1,092
Panel B: dropping `A61B6/03`			
$Treat_c \times Post1969_{my}$	0.561***	0.674***	0.557***
	(0.122)	(0.120)	(0.119)
subclass FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes
Observations	1,344	1,974	2,667

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. All standard errors are clustered by patent subclass in Panel C.

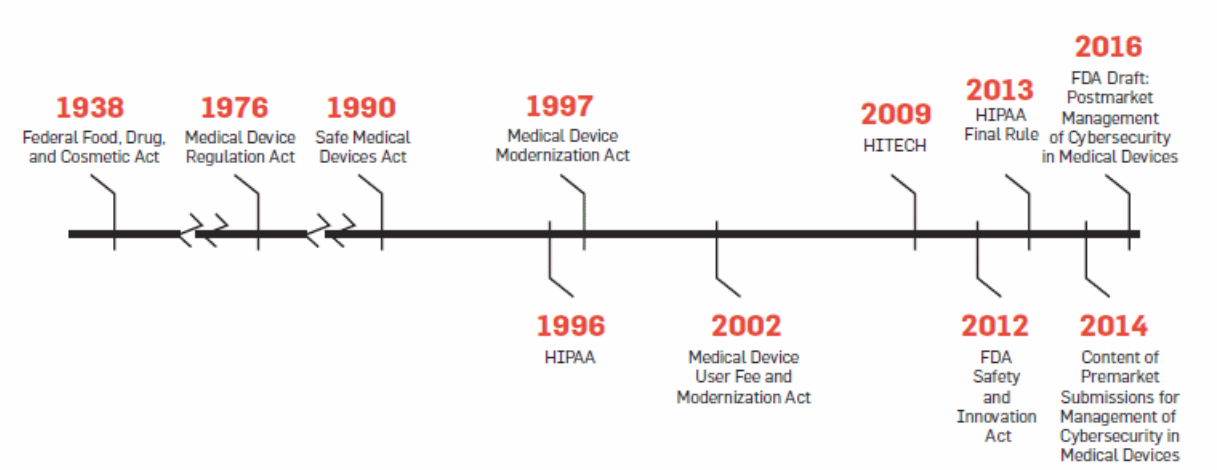
Table 16. Robustness Check: Medical Device Amendments to the FD&C Act in 1976

	OLS			Poisson		
	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma
$Treat_c \times Post1969_{my}$	0.371***	0.462***	0.386***	0.447***	0.612***	0.533***
	(0.116)	(0.116)	(0.112)	(0.164)	(0.187)	(0.170)
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	1,056	1,504	2,032	1,056	1,504	2,032

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

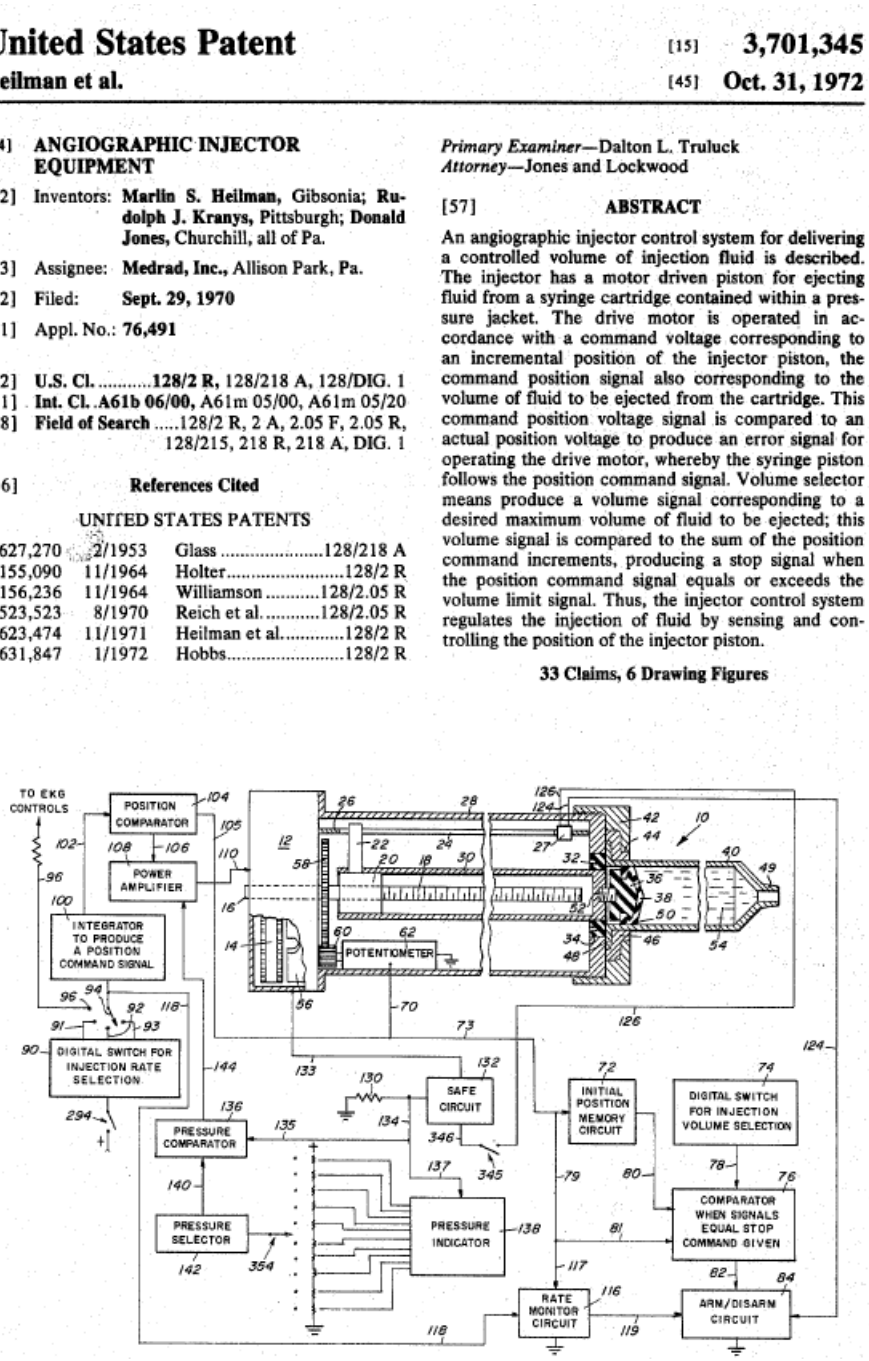
Note: Data are drawn from the USPTO sample. The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Pharma" means all pharmaceutical ingredients and chemical substances under the category `A61K`. All standard errors are clustered by patent subclass.

Figure 1. Timeline of Key Legislation and Regulation for Medical Devices



Note: This figure is from Burns, Johnson and Honeyman (2016), summarizing a collation of key legislation and regulatory actions governing medical devices in the U.S.

Figure 2. Example of A61B6 Patent Files



United States Patent

Heilman et al.

[15] **3,701,345**

[45] **Oct. 31, 1972**

[54] **ANGIOGRAPHIC INJECTOR EQUIPMENT**

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[22] Filed: **Sept. 29, 1970**

[21] Appl. No.: **76,491**

[52] **U.S. Cl.** .....**128/2 R**, 128/218 A, 128/DIG. 1

[51] **Int. Cl. A61b 06/00**, A61m 05/00, A61m 05/20

[58] **Field of Search** .....128/2 R, 2 A, 2.05 F, 2.05 R, 128/215, 218 R, 218 A, DIG. 1

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Primary Examiner—Dalton L. Truluck
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[57] **ABSTRACT**

An angiographic injector control system for delivering a controlled volume of injection fluid is described. The injector has a motor driven piston for ejecting fluid from a syringe cartridge contained within a pressure jacket. The drive motor is operated in accordance with a command voltage corresponding to an incremental position of the injector piston, the command position signal also corresponding to the volume of fluid to be ejected from the cartridge. This command position voltage signal is compared to an actual position voltage to produce an error signal for operating the drive motor, whereby the syringe piston follows the position command signal. Volume selector means produce a volume signal corresponding to a desired maximum volume of fluid to be ejected; this volume signal is compared to the sum of the position command increments, producing a stop signal when the position command signal equals or exceeds the volume limit signal. Thus, the injector control system regulates the injection of fluid by sensing and controlling the position of the injector piston.

33 Claims, 6 Drawing Figures

Note: This figure presents the raw patent file US3701345. It describes an angiographic injector control system for delivering a controlled volume of injection fluid. Three key sections are included in the file: abstract, claims, and detailed description.

Figure 3. A Snapshot of the NHDS

Table 4. Total charges and percent distribution for discharges from short-stay hospitals by type of hospital service, according to geographic region and bed size of hospital: United States, 1968-70—Con.

[Excludes Federal hospitals, deliveries, and newborn infants]

Geographic region and bed size	All discharges	Room and care	Laboratory	Pharmacy	Radiology	Operating and/or recovery room	Professional services	Other services
1968	Charge in millions of dollars							
All hospitals	13,154	7,732	1,500	966	693	795	146	1,322
Region								
Northeast	3,798	2,351	459	193	211	219	60	305
North Central	4,113	2,377	469	322	214	247	16	468
South	3,307	1,850	367	314	177	192	38	369
West	1,937	1,154	205	136	90	138	32	182
Bed size								
6-99 beds	1,973	1,082	220	227	117	103	13	214
100-199 beds	2,453	1,387	295	206	144	139	26	256
200-299 beds	2,491	1,536	252	141	122	164	26	250
300-499 beds	3,977	2,361	457	267	200	260	58	374
500-999 beds	1,822	1,030	244	116	100	120	17	195
1,000 beds or more	438	336	32	9	11	10	6	34

Note: This is a table from the National Hospital Discharge Survey (1968-1970). It shows the total discharge and percent distribution of discharges from short-stay hospitals by type of hospital service.

Figure 4. A Snapshot of the NHDS

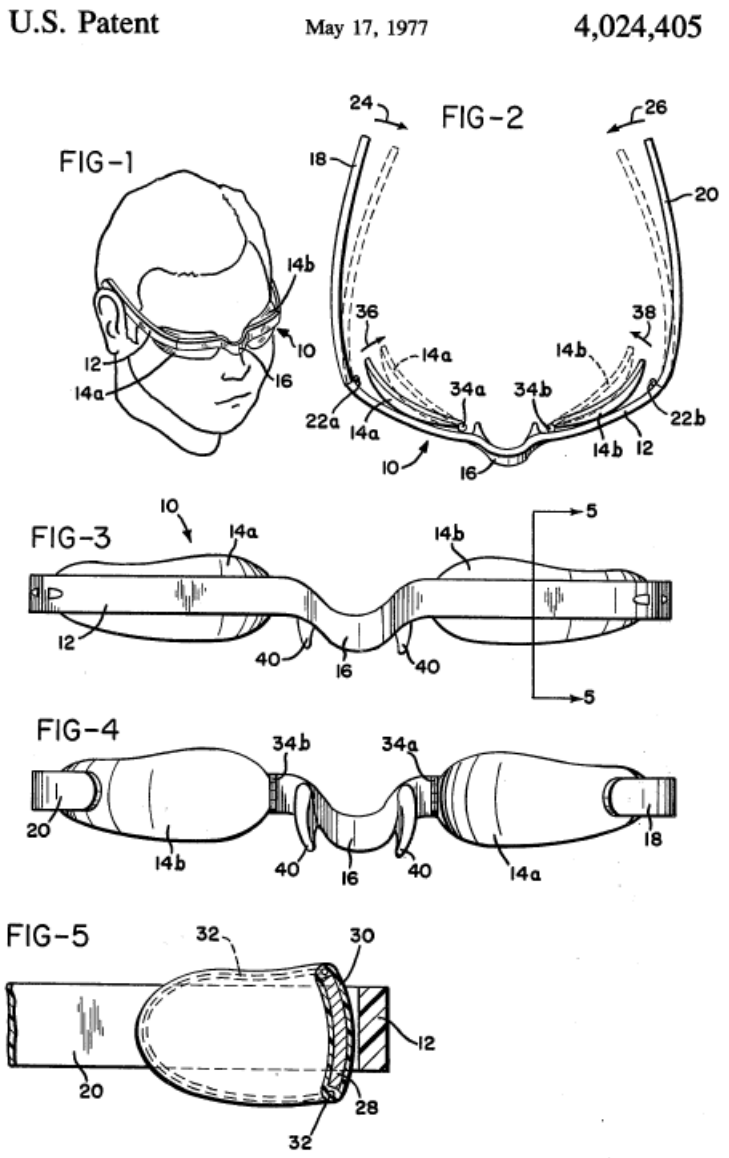
Table 1. Number and percent of discharges form short-stay hospitals, by sex and age of patient and type of hospital service: United States, 1968-70—Con.

[Excludes Federal hospitals, deliveries, and newborn infants]

Sex and age	All discharges	Room and care	Laboratory	Pharmacy	Radiology	Operating and/or recovery room	Professional services	Other services
1968								
Both sexes[1]	Number in thousands							
All ages[3]	24,531	24,471	23,100	22,049	15,164	10,458	2,756	21,479
Under 15 years	4,112	4,102	3,881	3,485	2,090	2,012	396	3,346
15-44 years	8,326	8,301	7,660	7,302	4,549	4,021	811	7,213
45-64 years	6,410	6,386	6,076	5,870	4,398	2,682	685	5,732
65 years and over	5,678	5,676	5,478	5,387	4,123	1,740	864	5,181
Male								
All ages[3]	11,370	11,351	10,603	10,071	7,280	4,513	1,310	9,826
Under 15 years	2,291	2,284	2,164	1,929	1,173	1,115	216	1,866
15-44 years	3,313	3,308	3,008	2,855	2,042	1,403	362	2,817
45-64 years	3,138	3,133	2,924	2,824	2,180	1,166	332	2,769
65 years and over	2,623	2,623	2,503	2,459	1,883	828	400	2,370
Female								
All ages[3]	13,102	13,061	12,441	11,925	7,848	5,922	1,437	11,601
Under 15 years	1,809	1,806	1,706	1,545	913	891	178	1,470
15-44 years	4,998	4,979	4,639	4,433	2,498	2,613	450	4,383
45-64 years	3,257	3,239	3,138	3,033	2,209	1,512	348	2,951
65 years and over	3,037	3,035	2,957	2,913	2,226	906	462	2,795

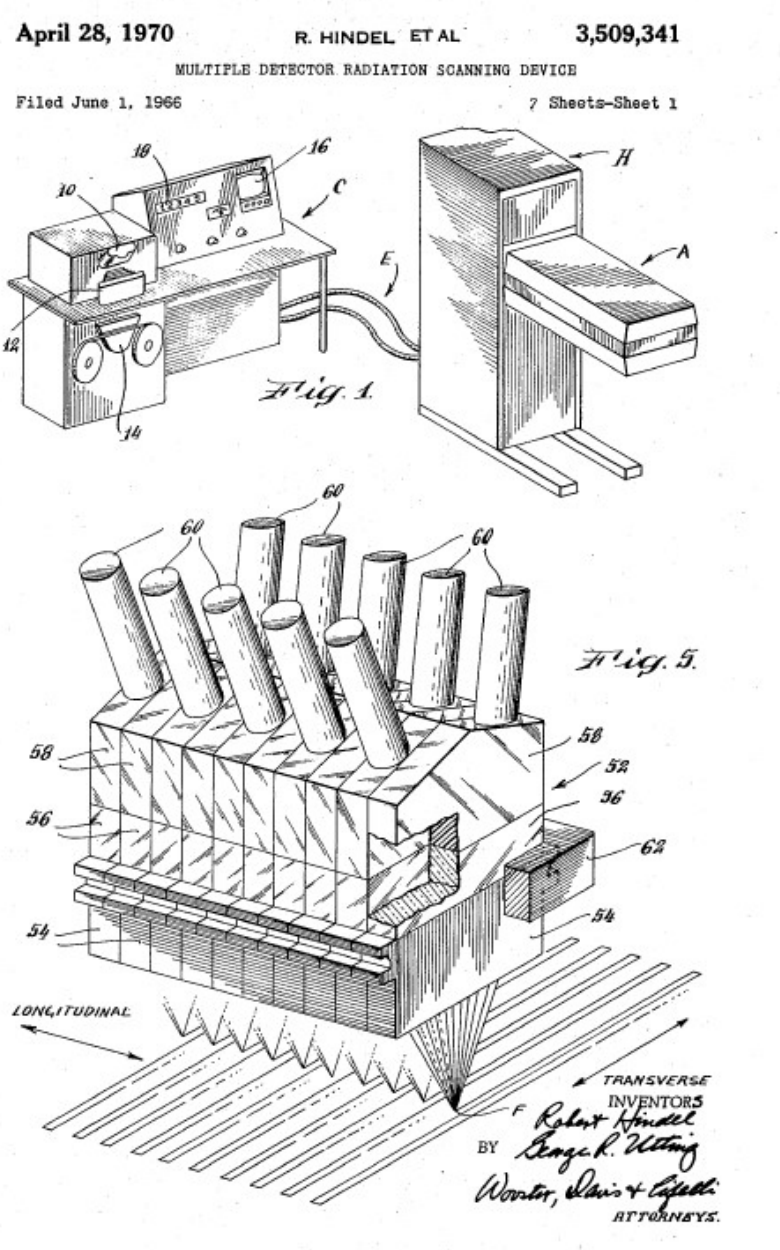
Note: This is a table from the National Hospital Discharge Survey (1968-1970). It shows the total discharge and percent distribution of discharges from short-stay hospitals by type of hospital service.

Figure 5. An Example of Radiation Reducing Technology



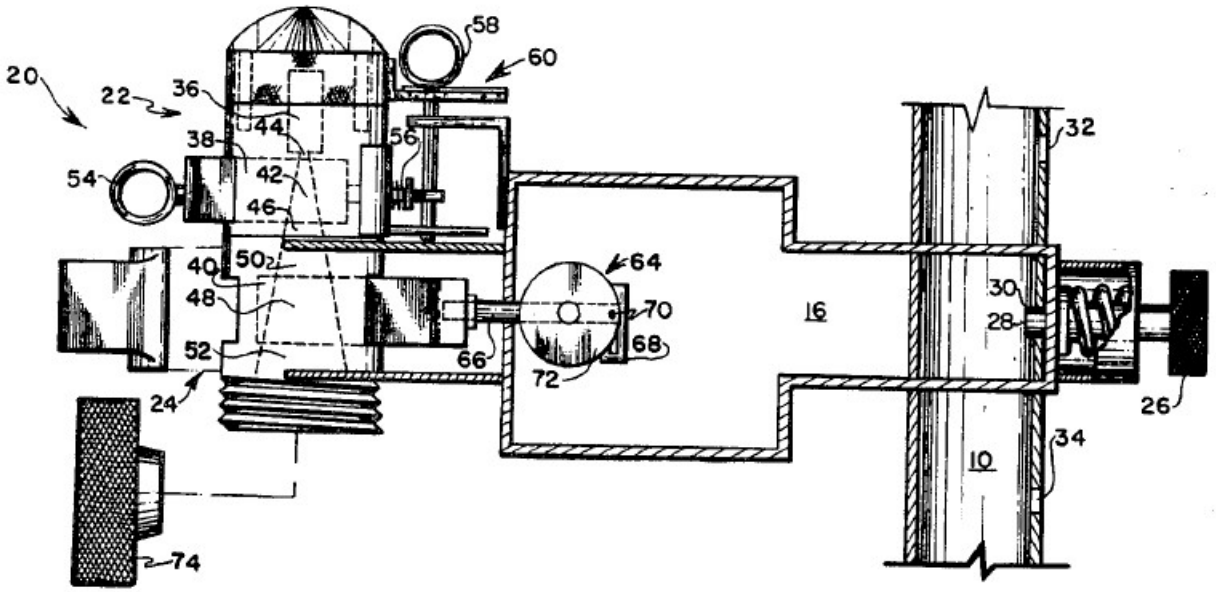
Note: This is drawn from the patent file of US4024405. An X-ray eye shield useful in protecting eye tissue from radiation during dental radiography. The eye shield has a radiolucent frame and radiopaque lens cups which prevent passage of X-ray radiation.

Figure 6. An Example of Radiation Generating Technology



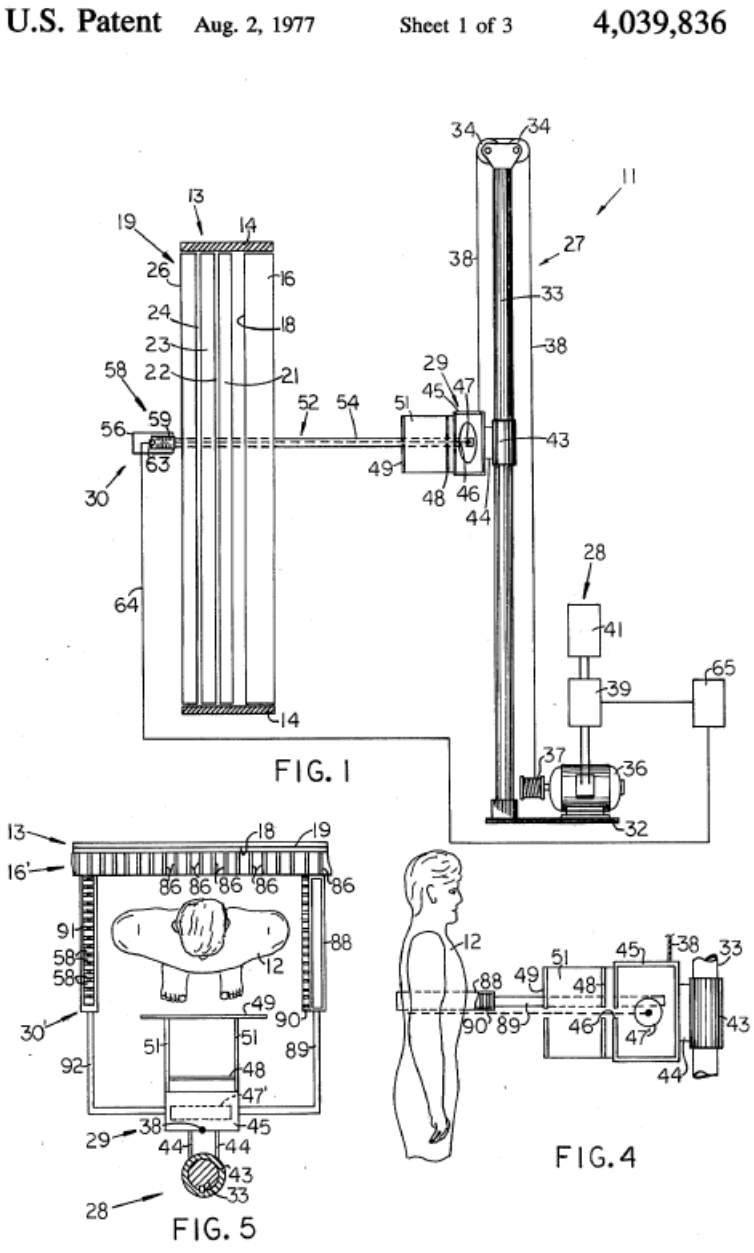
Note: This is drawn from the patent file of US3509341. This is a multi-channel scanner for mapping radioisotope distribution within a human body. The device employs a movable arm housing a scanning head enclosing a linear array of relatively large scintillation crystals. It is categorized as A61B6/4258 (Arrangements for detecting radiation specially adapted for radiation diagnosis characterised by using a particular type of detector for detecting non x-ray radiation, e.g. gamma radiation) and captures the idea of radiation generating.

Figure 7. Example of Patents with Dual Features



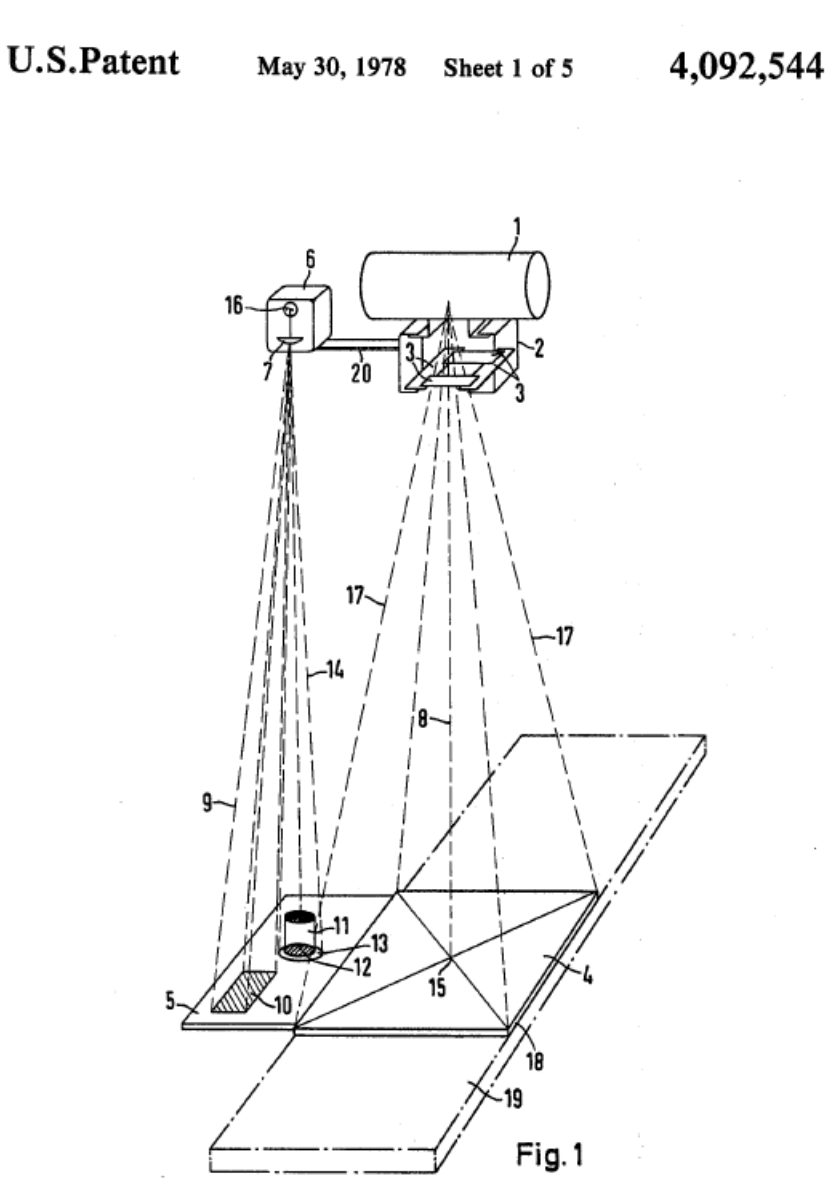
Note: This is an example of patents showing both "radiation reducing" and "radiation generating" features.

Figure 8. Example of Patents Under A61B6/54



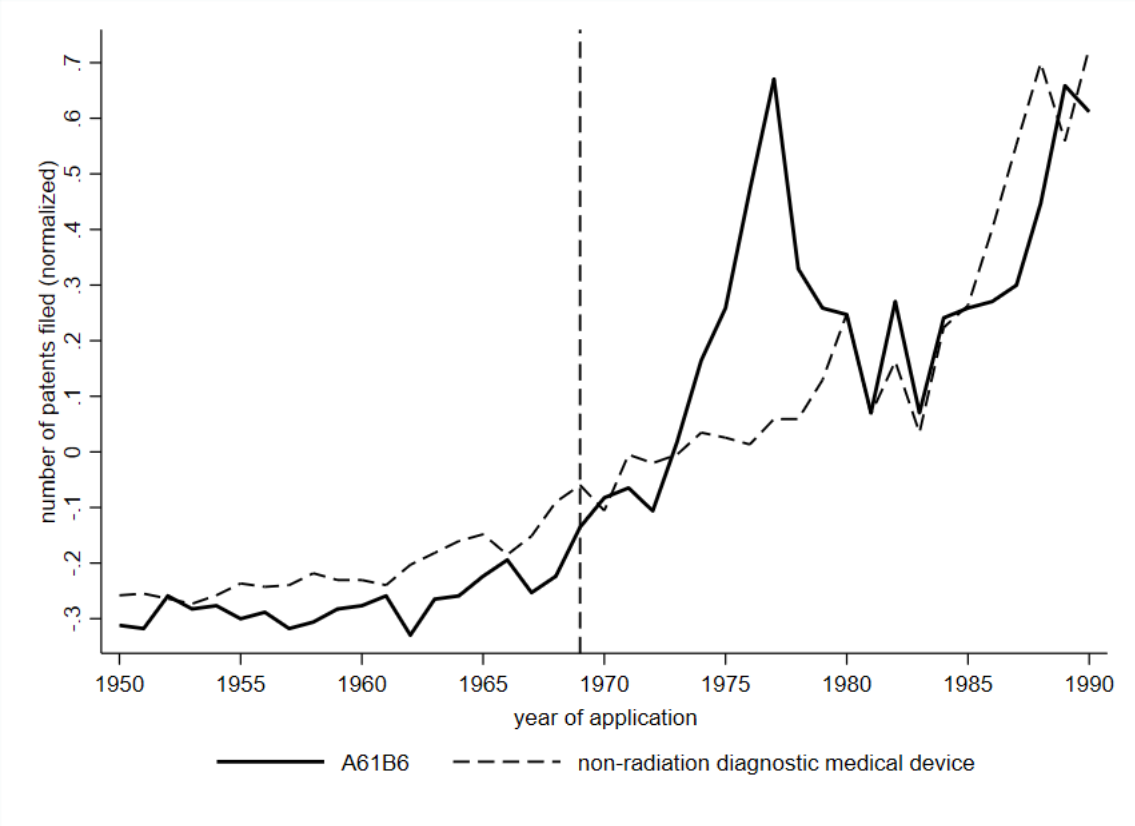
Note: This is drawn from the patent file of US4039836. This is an apparatus for X-raying having a source structure for providing X-rays. The feedback mechanism detects the thickness of the body areas of the patient through which X-rays are passing or the quantity of X-rays passing completely therethrough, and adjusts the motor speed such that the duration of exposure to X-rays of the patient's body area in the vertical dimension is directly proportional to the thickness of each area or inversely proportional to the quantity of X-rays passing therethrough. It was categorized under patent subclass A61B6/542 (Control of apparatus or devices for radiation diagnosis involving control of exposure).

Figure 9. Example of Patents Under A61B6/58



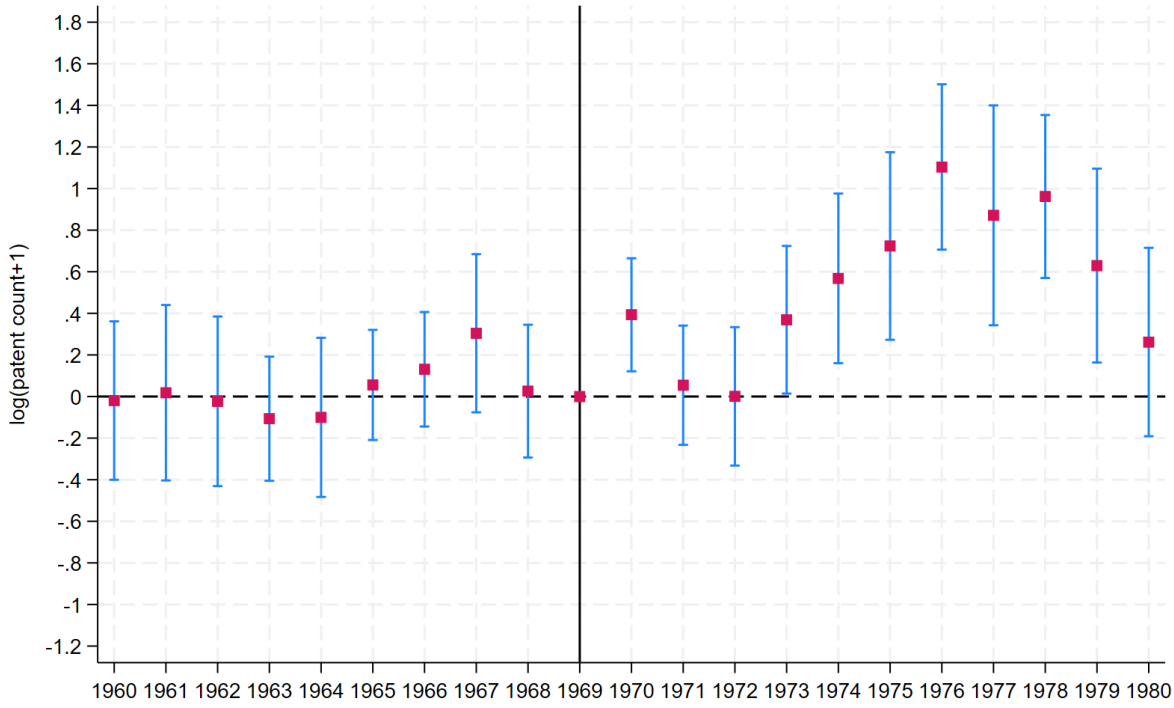
Note: This is drawn from the patent file of US4092544. This invention discloses an X-ray photography device having an X-ray tube associated with a primary diaphragm for defining or limiting the X-ray beam by partially blocking the same. It is classified as A61B6/587 (Alignment of source unit to detector unit).

Figure 10. Patenting Patterns for A61B6 vs. Non-Radiation Diagnostic Medical Devices



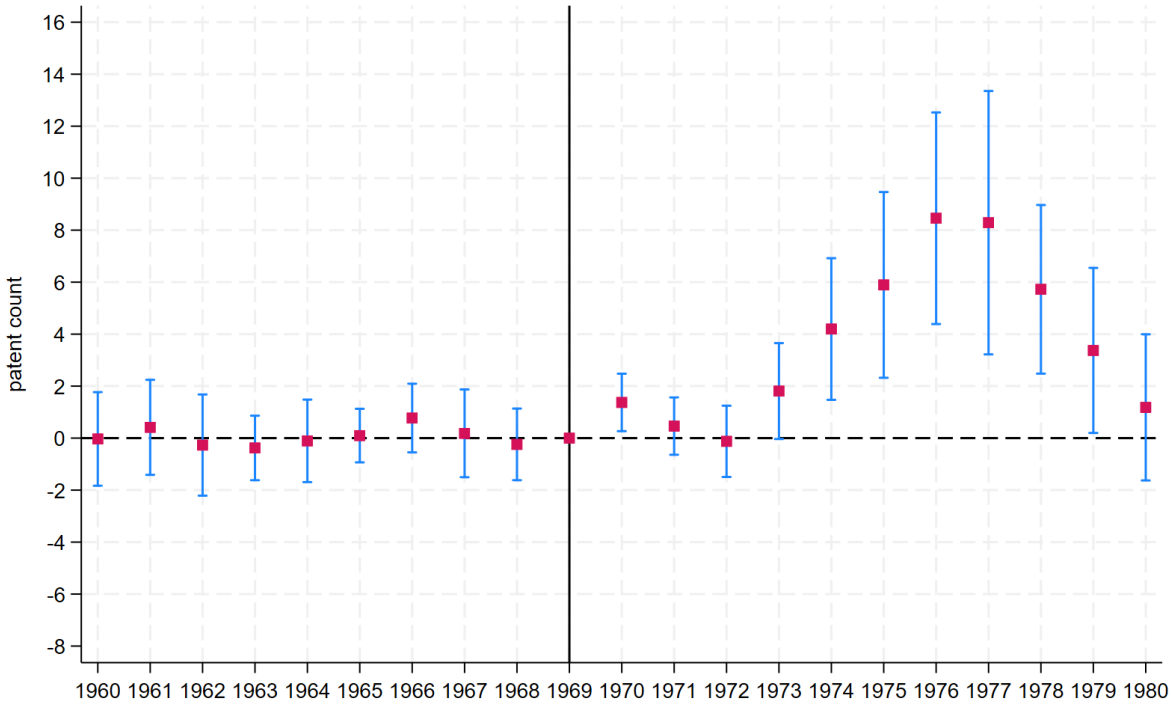
Note: Data are drawn from the USPTO data (1950-1990). The variable of interest is patent count in each class-year cell.

Figure 11. Event-Study Estimates for All A61B6 Patents



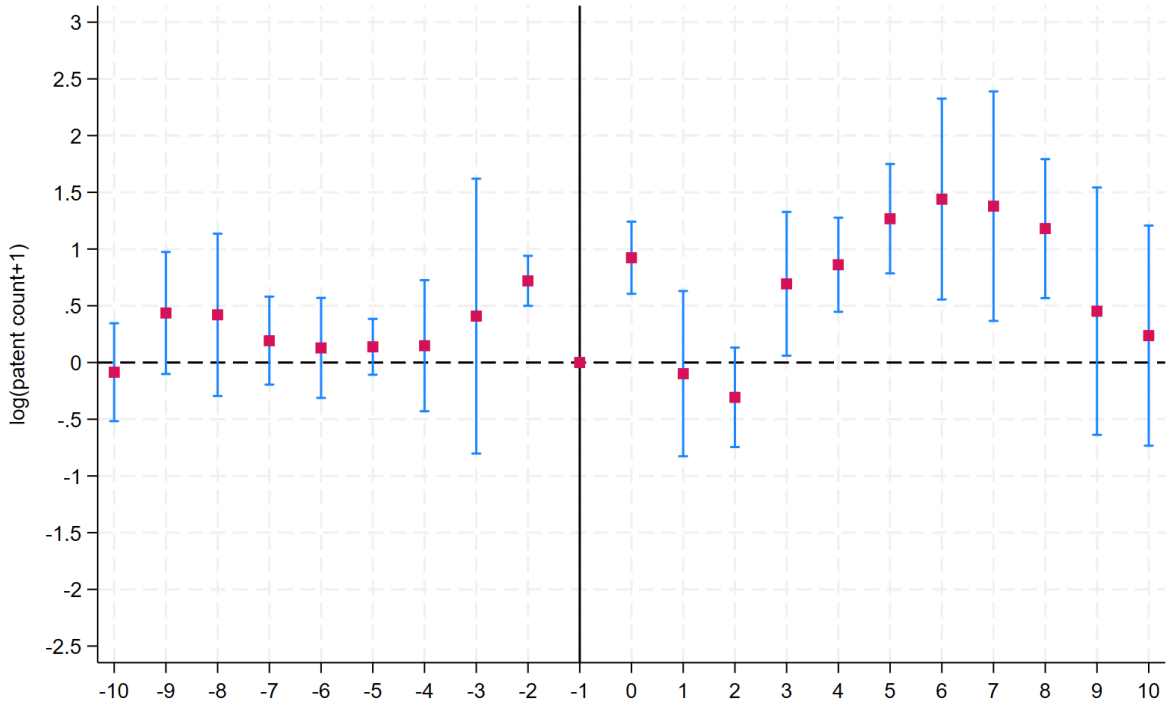
Note: Data are drawn from the USPTO sample Results are derived from the event-study specification in Equation 1. The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

Figure 12. Event-Study Estimates for All A61B6 Patents (Raw Count)



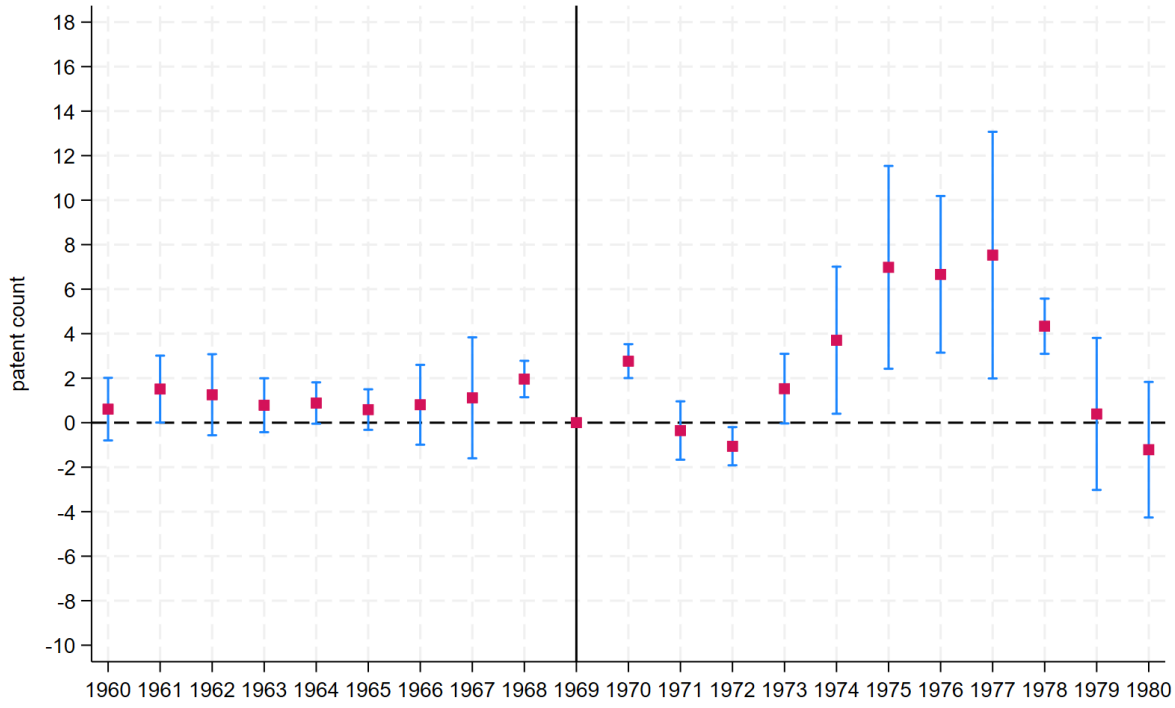
Note: Data are drawn from the USPTO sample Results are derived from the event-study specification in Equation 2. The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

Figure 13. Event Study Estimates for A61B6 Patents Emphasizing Radiation Reduction



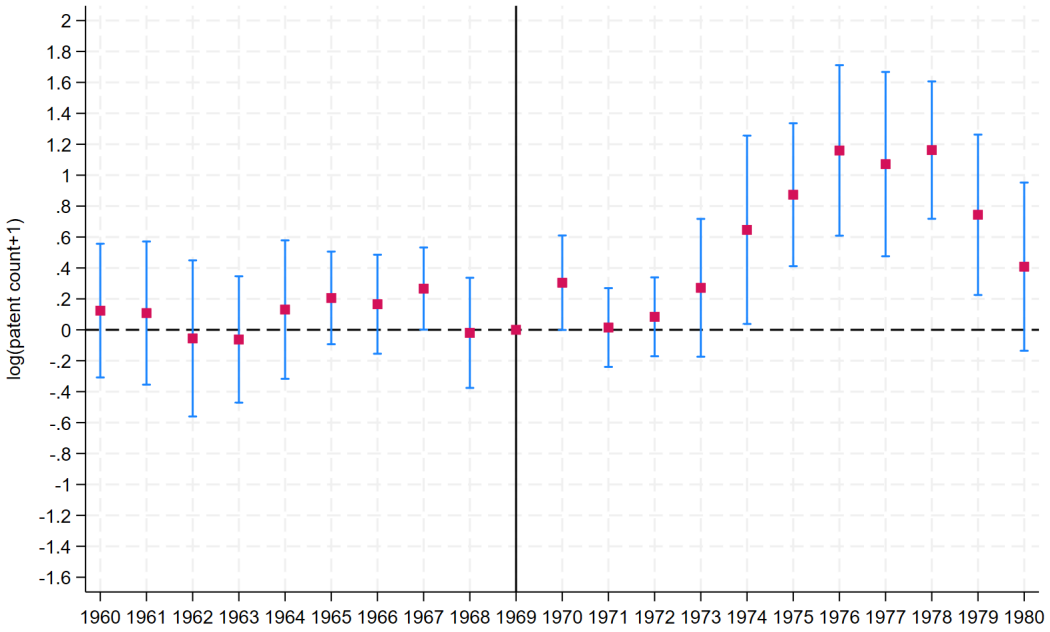
Note: Data are from the USPTO sample. The results are derived from the event study specification in Equation 3. The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

Figure 14. Event Study Estimates for A61B6 Patents Emphasizing Radiation Reduction (Raw Count)



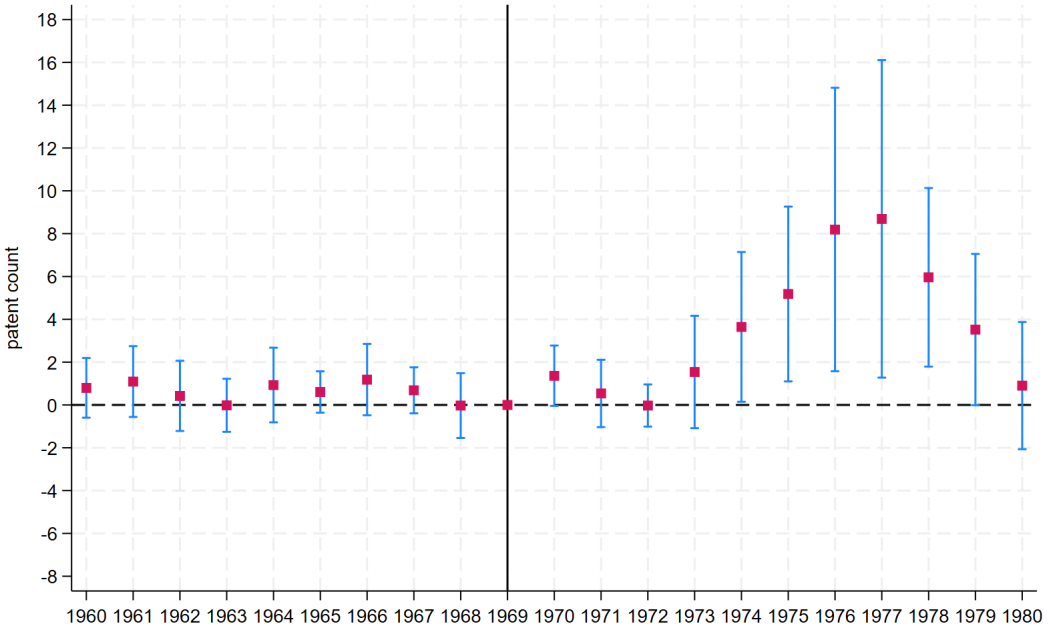
Note: Data are from the USPTO sample. The results are derived from the event study specification in Equation (4). The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

Figure 15. Event Study Estimates for A61B6 Patents Emphasizing Radiation Generation



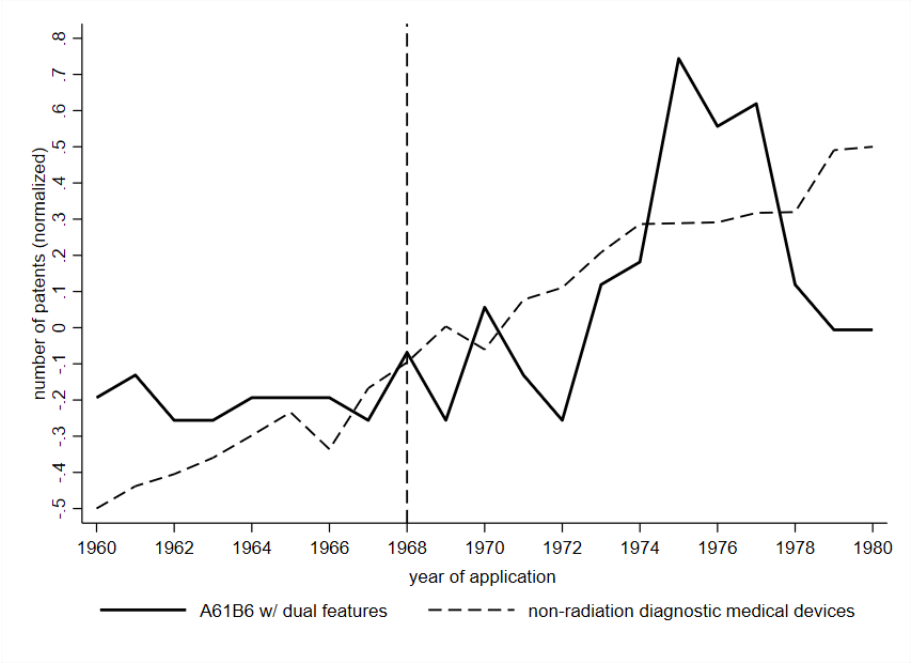
Note: Data are drawn from the USPTO sample. Results are derived from the event-study specification in Equation (3). The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

Figure 16. Event Study Estimates for A61B6 Patents Emphasizing Radiation Generation (Raw Count)



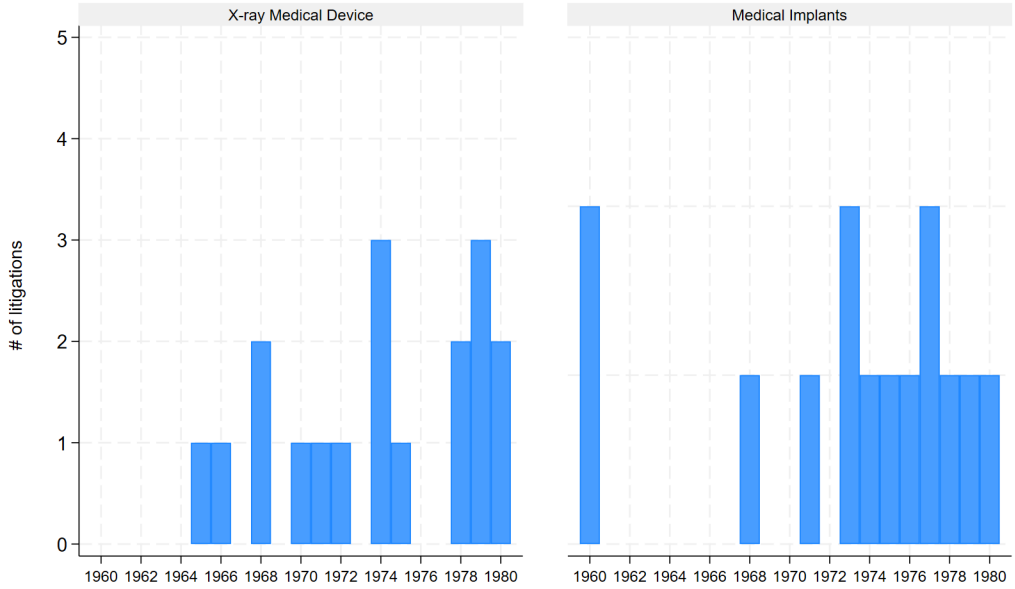
Note: Data are drawn from the USPTO sample. Results are derived from the event-study specification in Equation (4). The control group includes all non-radiation diagnostic medical device patents. All standard errors are clustered by patent subclass.

Figure 17. Patenting Trend of A61B6 with Dual Features



Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period.

Figure 18. Trends in the Number of Lawsuits towards X-ray Medical Devices



Note: Data are drawn from Westlaw. This figure plots the number of lawsuits involving X-ray medical devices and medical implants in the US from 1960 to 1980.

Online Appendices

This appendix provides supplementary information and analyses as follows: Section A.1 summarizes more institutional background contexts regarding the state-level radiation control programs and how the RCHSA interacted with other regulations/laws. Section A.2 outlines a conceptual framework in which I detail how the regulation can theoretically shape innovation activities. Section A.3 presents additional information on how to construct the sample of analysis. Section A.4 describes the classification of relevant patents used in the main analysis. Section A.5 includes a number of additional robustness checks and Section A.6 shows suggestive evidence to rule out alternative channels. Eventually, Section A.7 provides additional figures.

A.1. Additional Institutional Contexts

A.1.1. Details on State-Level Radiation Control

As of March 1, 1969, 47 of 53 "states" (including Puerto Rico, the Virgin Islands, and the District of Columbia) have passed legislation to authorize the control of ionizing radiation (Udall, 1984). Only 50% of these have adopted most of the provisions of the Council of State Governments' model regulations. As mentioned in Udall (1984),

> "Major inadequacies in a number of State programs include (1) lack of regulations or failure to update regulations to implement radiation control authority, (2) insufficient funds and personnel to conduct comprehensive control programs in the areas of ionizing and non-ionizing radiation, (3) no provision to license, certify, or set qualifications for operators of X-ray machines used in the healing arts, and (4) lack of uniformity in the control of health hazards from the use of radium and accelerator-produced radionuclides including **safety standards**, inspection-requirements, regulations, and enforcement."

In Figure A-1, I present the radiation protection regulations by state as of 1972. A-2 then shows the geographic distribution of such state-level protection programs. Though most states have some radiation controls, very little has been addressed to directly regulate the radiation risk faced by consumers.

Table 1. - Enabling Acts for Radiation Protection Regulations by State, as of June 30, 1972

State	Act/Year	Effective Date of Act	Responsible Agency or Remarks[a]
Alabama	Act 582/63	9/16/63	
Alaska	Chapter 66/57	3/18/57	Dept. of Environmental Conservation
Arizona	Chapter 30/64	7/15/64	Arizona Atomic Energy Commission
Arkansas	Act 8/61; as amended by H.B. 441/71	12/20/61; 4/28/71	Bureau of Environmental Health Services NOTE: To exclude any therapeutic instrument approved or licensed by the Federal Communications Commission from the definition of electronic products.
California	Chapter 1711/61; as amended by A.B. 2491/71	7/1/62; 11/8/71	NOTE: Radioactive Waste
Colorado	Chapter 156/57; S.B. 231/65; as amended by S.B. 108; as amended by S.B. 1	3/13/57; 4/23/65 6/1/67; 7/1/68	
Connecticut	Public Act 550/67	6/20/67	
Delaware	Chapter 74	4/26/68	
Florida	Chapter 290/61; S.B. 670/71	2/21/62; 6/18/71	NOTE: Nonionizing
Georgia	Act 936/64; as amended by H.B. 864; as amended by H.B. 1586	7/1/64; 4/3/68 4/8/68	Department of Human Resources
Hawaii	Chapter 18/51	5/2/51	
Idaho	Chapter 243/61; H.B. 519/72	5/2/61; 3/27/72	
Illinois	S.B. 515/59; as amended by S.B. 756/63; as amended by H.B. 1041/71	8/16/63; 7/10/71 7/10/71	NOTE: Extend license to users of radium and radioactive materials artifically-produced
Indiana	Chapter 77/59; as amended by Chapter 116/61 as amended by S.B. 601/71	3/4/61; 4/14/71	NOTE: Electronic Products
Kansas	Chapter 290/63; as amended by S.B. 236/72	7/1/63; 2/18/72	NOTE: Electronic Products
Kentucky	Section 152.120 (1A), 152.125, & 152.190, Ky. Rev. Stat.; as amended by S.B. 284/60; H.B. 404/72; as amended by H.B. 362/72	3/25/60 3/29/72; 3/30/72	NOTE: User Control X-ray and Electronic Products
Louisiana	Act 84/62; as amended by H.B. 1165	8/1/62; 7/31/68	Louisiana Board of Nuclear Energy
Maine	Chapter 403/61	3/2/62	
Maryland	Article 43; as amended by Chapter 88/60 as amended by S.B. 93	6/1/60 6/1/68	
Massachusetts	Chapter 633/60, Chapter 224/61; S.B. 1148	11/28/60; 612/61 10/9/68	Massachusetts Department of Labor and Industries
Minnesota	Chapter 361/57	4/11/57	
Mississippi	H.B. 499/64	4/24/64	
Missouri	S.B. 322/63	10/13/63	
Montana	H.B. 245/67	7/1/67	
Nebraska	L.B. 19/63; L.B. 1405/72	10/19/63; 4/8/72	NOTE: Create Regional Radiation Health Center to provide care and treatment of radiation casualties
Nevada	A.B. 495/63	7/1/63	
New Hampshire	H.B. 597/63; as amended by A.B. 207/71	7/2/63; 6/8/71	NOTE: Nonionizing and license fees for ionizing x rays
New Jersey	Chapter 116/58; as amended by S.B. 2901/71	7/8/58; 12/30/71	Dept. of Environmental Protection Agency NOTE: Nonionizing radiation
New Mexico	Chapter 185/59; as amended by H.B. 426/71	6/12/59; 4/8/71	Environmental Improvement Agency NOTE: Radioactive materials
New York	Section 201 & 255, P.H. Law, as amended by Chapter 628/60, and S.B. 4570/66 S.B. 6480.71; S.B. 4888/71 as amended by S.B. 7278/72; A.B. 8041/71; S.B. 8118/72 & A.B. 8381/72	4/18/60; 5/23/66 7/2/71; 6/17/71 4/5/72; 4/25/72 6/2/72; 6/2/72	NOTE: 1 chiropractor and x-ray technologist
North Carolina	Chapter 104-C, General Statute, as amended by H.B. 34/63	6/26/63	
North Dakota	S.B. 202/65; Chapter 446/65	7/1/65; 7/1/65	N. Dak. Water Conservation Commission
Ohio	H.B. 410/59	11/4/59	
Oklahoma	S.B. 26/63; as amended by H.B. 678/63 H.B. 1020	7/1/63; 6/18/63; 4/22/68	
Oregon	Chapter 664/61	8/9/61	
Pennsylvania	Act 578/65; as amended by S.B. 320	1/28/66; 9/30/68	Dept. of Environmental Resources
Puerto Rico	Act 79/65; as amended by H.B. 462	7/1/65; 3/26/67	
South Carolina	Act 302/67	5/1/67	
South Dakota	S.B. 162/67	7/1/67	
Tennessee	Chapter 66/59; as amended by S.B. 167/71	7/1/59; 4/16/71	
Texas	Chapter 72/61; as amended by S.B. 3271/71 and H.B. 733/71	4/17/61; 5/25/71 and 6/9/71	NOTE: User, chiropractic, and nonionizing legislation
Utah	H.B. 137/67	5/9/67	
Vermont	H.B. 59/67	7/1/67	
Virginia	Chapter 158/64; Chapter 314/68	3/3/67; 6/28/68	
Washington	Chapter 207/61; as amended by S.B. 15/65	6/30/61; 8/6/65	
Wisconsin	Chapter 325/63; as amended by Chapter 459/63	9/25/63; 1/4/84	
Wyoming	Chapter 153/55	2/19/55	Registration Statute

[a]Unless otherwise specified, statutes designate the State health department as the agency responsible for radiation protection with the authority to adopt regulations.

Figure A-1: Enabling Acts for Radiation Protection Regulations by State

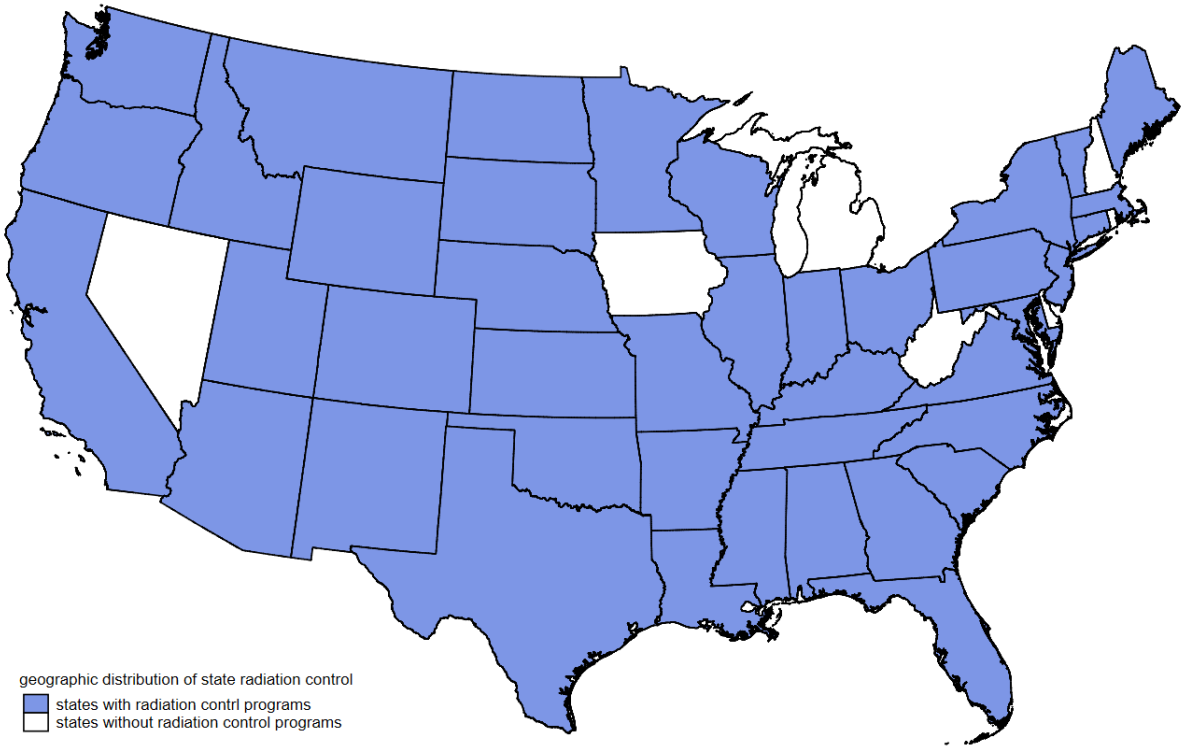


Figure A-2: State Actions for General Radiation Protection

A.1.2. Interactions with Other Regulations and Laws

Another feature to keep in mind is the RCHSA of 1968 can interact with other relevant regulations and laws. This subsection briefly summarizes these key interactions and explains why they should not largely influence the medical innovation. Institutional details are collected from Tran (2006).

The Nuclear Regulatory Commission (NRC) is also in charge of regulating radiation therapy devices. The objective of NRC is to "provide for the radiation safety of workers, the general public, patients, and human research subjects" (Tran, 2006). The FDA and NRC generally share data on radiation hazards and knowledge of incidents of patient exposure through an informal process. Under the 1976 MDA, the FDA has a broader range of regulatory options. Thus, the NRC usually defers to the FDA to take care of regulatory actions.

The Atomic Energy Act of 1954 assigned the AEC with the control of radiation risks and hazards. However, its scope of work only limited to taking care of the "public health and safety in connection with the construction and operation of nuclear facilities and the use of source, byproduct, and special nuclear material,"[56] thereby having little overlap with the RCHSA of 1968.

The Consumer Product Safety Commission (CPSC) regulates general consumer products, which include those emitting radiation but explicitly exclude medical devices. The only exceptions are televisions and microwave ovens, which come under the regulation of both the FDA and the CPSC. The Consumer Product Safety Act in 1972 aims to fix the issue related to "an unacceptable number of consumer products distributed in commerce presented an unreasonable risk of injury and that existing federal, state, and local control was inadequate" (915 U.S.C. § 2051). The CPSA was modeled after the RCHSA but followed stronger penalties and provided for criminal sanctions and seizure of noncompliant products. In the case of radiation emission, the CPSA typically defers to CDRH (in charge with the responsibility of carrying out the provisions of the RCHSA of 1968) regarding radiation emissions.

[56] See https://www.cia.gov/readingroom/docs/CIA-RDP80B01676R002800010001-2.pdf, last accessed February 14, 2025.

A.2. Conceptual Framework

In this section, I set up a conceptual model to illustrate the theoretical effects of safety regulations on innovation. This model builds on the framework in Viscusi and Moore (1993) and conceptualizes how a regulatory regime distorts firms' investments in product safety and product novelty. The major distinction from Viscusi and Moore (1993) is that instead of centering around costs from product liability, my model extends the discussion to more general costs relating to safety and quality regulations.

Several key features are incorporated in my model: First, a typical firm faces higher costs imposed by more stringent regulations. These regulation costs include and generalize several types: (1) direct costs from compliance and enforcement actions ("*compliance costs*"), (2) administrative and financial burdens from approval delays ("*approval costs*") (Pietzsch, Zanchi and Linehan, 2013; Stern, 2017; Rogers, 2023), and (3) litigation risk because of defective products ("*liability costs*") (Viscusi and Moore, 1993; Galasso and Luo, 2022). Second, to adapt to the regulation, a firm can develop new technologies emphasizing certain product safety features, termed as "*safety innovation*" in Viscusi and Moore (1993). Third, the intensity of product safety investment (including both the regular safety investment and safety innovation) could be correlated with marginal regulation costs. For example, a higher level of *ex-ante* product safety investment can substantially reduce the probability of facing a penalty and being seized or sued because of product defects, thereby lowering the corresponding marginal cost. Finally, innovation emphasizing safety features and innovation highlighting radiation generation can interact within this environment. This interaction is somehow in the same spirit of the complementarity between cost-saving innovation and demand-enhancing innovation. As indicated in Athey and Schmutzler (1995), cost-saving (process) innovation and demand-enhancing (product) innovation are complementary in terms of increasing the firm's net revenue. I extend the model of Viscusi and Moore (1993) to account for this complementarity in production.

One thing to keep in mind is that throughout the analysis, I assume (1) the market is perfectly competitive and (2) there's no substantial change in the market structure in response to the regulation. The simplification here is justified by two facts captured in my empirical analysis: First, the innovation effects of the RCHSA are universal regardless of firms' size. Second, qualitative evidence also indicates the market structure of this industry remains stable throughout the reference period. Consequently, I directly followed the assumption in Viscusi and Moore (1993) and applied it to the context of radiation control.

A.2.1. Set-up

In a perfectly competitive market, I construct the model in terms of the firm's unit profit function π and focus on two types of endogenous choices: safety investment (s) and product innovation (z).[57] In the context of radiation control, I consider a firm's safety investment encompassing two parts, *regular safety investment* (s_r)[58] and *safety innovation* (s_i), which can lower the risks of radiation. The latter component, as mentioned in Galasso and Luo (2021), has the feature of *cost-saving, process innovation*. For simplicity, I consider the total amount of safety investment to be the sum of *regular safety investment* and *radiation-reducing investment* (i.e., $s = s_r + s_i$, or alternatively as a linear combination of both). Following the framework proposed in Rogers (2023), I also model the regular safety investment as a mandated level of effort $\bar{s_r}$.

The unit price of the product is described by a nonlinear hedonic price function, consisting of a base product price p (for simplicity, I normalize it to zero), a premium αz for product novelty, and a damage cost function $\beta(s_r, s_i, R)$. Consumers value product novelty and thus will pay the premium (i.e., $\alpha > 0$). The unit damage cost function $\beta(s, R)$ is a decreasing function of safety investment (β_{s_r}<0, $\beta_{s_i} < 0$), and an increasing function with the stringency of the product safety regulation ($\beta_R > 0$). Without loss of generality, the damage cost function is a nonlinear function of the level of safety under various regulatory regimes.

The input to produce safety and product novelty is captured by $c(s, z)$. The input requirements increase at an increasing rate with respect to the value of each joint product (i.e., $c_{s_r} > 0$, $c_{s_i} > 0$, $c_z > 0$, $c_{s_r s_r} > 0$, $c_{s_i s_i} > 0$, and $c_{zz} > 0$). The unit cost of the input is r and can be normalized to 1.

A.2.2. Characterizing Firms' Decisions

A representative firm selects s_r, s_i, and z to maximize one's unit profits:

$$max_{s,z}\pi = \alpha z - \beta(s, R) - c(s, z) \tag{A1}$$

And the first-order condition would be

$$\frac{c_s}{c_z} = -\frac{\beta_s}{\alpha} \tag{A2}$$

[57] Alternatively, expanding the model to include a quantity choice would complicate the comparative statistic results by adding another equation to the system. The simplification directly follows Viscusi and Moore (1993).

[58] For example, regular safety investment can include product inspections and testing to guarantee a device meets the safety standards.

Equation A2 here captures the optimal mix of safety investment and product innovation, which hinges on both consumers' value of novel products and the marginal damage cost of safety investment.

A.2.3. Safety Regulation and Innovation

To better understand how safety regulations affect product innovation and safety innovation, it would be helpful to think about some comparative statistics exercises. In an extremely stringent regulatory regime (i.e., a large value of R), there would be a corner solution at which the firm undertakes no product innovation and directly maximizes its safety investment by reallocating resources. For example, consider the current regulatory approval process for high-risk medical devices in the U.S., the so-called "premarket approval" (PMA). It is necessary when a medical device developer wants to market a new high-risk device. Importantly, once the first model in a product code is approved through the PMA process, all subsequent devices in that product code must all be approved through the PMA process. The PMA is thus criticized as a complex and time-consuming process for manufacturers.[59] As shown in Stern (2017), this approval process is associated with longer approval delays among pioneer entrants. Small, financially constrained firms are less likely to enter new device markets.

For the general interior solutions, the effects of product safety regulations on the choice variables are characterized as:

$$\frac{ds}{dR} = \frac{c_{zz}\beta_{sR}}{D} \tag{A3}$$

and

$$\frac{dz}{dR} = -\frac{c_{sz}\beta_{sR}}{D} \tag{A4}$$

where $D = (c_{sz})^2 - c_{zz}(\beta_{ss} + c_{ss}) < 0$ is the determinant of the Hessian matrix at the maximum interior solution (s^*, z^*).

It is worthwhile to address some structural features of my model before deriving the theoretical predictions. From Equation (A3), it is clear whether the regulation can distort safety investment depends in part on the correlation between the intensity of safety investment and the marginal costs of regulation (β_{sR}). In essence, if investing more in product safety can efficiently decrease the marginal cost of regulation ($\beta_{sR} < 0$), firms will be more inclined to exert effort toward quality control or developing new safety technologies. By

[59] The average approval time for a new high-risk device is 18.1 months, although the average for a device that is first within a product code is longer, at 22.5 months (Stern, 2017).

contrast, in an alternative regime where the marginal cost of regulation is merely unrelated to the *ex-ante* safety investment ($\beta_{sR} = 0$), there is a good chance firms would not comply at all. For example, if the administrative hassles associated with pre-market approvals are sufficiently large (e.g., the approval process requires an extremely long fixed period, or firms have to file complex paperwork and documents, etc.), increasing *ex-ante* safety investment is less likely to reduce the marginal cost of regulation in any case.

Hypothesis 1. *More stringent safety regulations can spur safety innovation if product safety investment directly reduces the marginal cost of regulation.*

This testable hypothesis directly follows the assumption $\beta_{sR} < 0$ and Equation A3. Recall the institutional features of the RCHSA as described in Section 2: this act specified and mandated performance standards for relevant products, along with various compliance and enforcement actions (i.e., reporting, inspections, civil penalties, recalls, and seizures). Thus, I argue this correlation β_{sR} is plausibly negative in my context. Consequently, the effect of the RCHSA on the development of radiation-reducing technologies is likely to be positive.

Hypothesis 2. *More stringent safety regulations spur product innovation if and only if product innovation and safety innovation are complementary in production.*

As mentioned above, I model the regular safety investment s_r as a mandated level of effort ($\bar{s_r}$).[60] The total safety effort is thus $s = \bar{s_r} + s_i$ and the profit-maximization in equation (1) can be simplified as follows:

$$max_{s_i,z}\pi = \alpha z - \beta(s_i, R) - c(s_i, z) \tag{A5}$$

Based on Equation (A4), it is clear that whether the stricter safety regulation spurs or stifles product innovation hinges on the sign of g_{sz}, assuming $\beta_{sR} < 0$. Here g_{sz} captures the complementarity/substitutability between product innovation z and safety innovation s_i. For example, if the development of RMTs enables a firm to increase one's investment in product innovation at less cost (e.g., a reduction in the marginal expected damage cost), then $c_{s_iz} < 0$ and $\frac{dz}{dR} > 0$, indicating an increased number of patents for non-RMTs would be expected. By contrast, if the development of RMTs restrains the firm from allocating resources to other $R\&D$ projects of new products, then $c_{s_iz} > 0$ and $\frac{dz}{dR} < 0$, suggesting a decline in the number of non-RMT patents will follow the safety regulation.

[60] This simplification would be reasonable if more general, less-risky methods to improve products' safety profiles are preferred. In the case of X-ray medical devices, it is quite likely to hold. After all, applying new RMTs into production would require more time , relative to directly conducting pre-market quality controls.

My simple model thus emphasizes how product safety regulations shape innovation is eventually an empirical question. It hinges on at least two gradients: the features of a regulatory regime (β_{sR}) and the interaction between different technology types (g_{sz}). In the next section, I turn to data and empirically estimate these innovation effects.

Hypothesis 3. *Stricter safety regulations would facilitate both process and product innovations among firms with more relaxed resource constraints.*

A.3. Details of Sample Construction

In the primary analysis, I used several historical patent datasets to construct my samples of interest. I first collected patent data from *Google Patents*, which directly records information on successful applications for patents granted by the USPTO between 1960-1980. These data include the full text of the patent (title, abstract, claims, and description) as well as patent identification numbers, names of inventors/assignees (if any), CPC classification, and application and publication (issue) years.

There are two primary limitations of this original USPTO sample. First, the information on patent assignee only reflects the *current* assignees of a patent. Second, data on patent citations are missing. To fix these issues, I turn to the supplementary dataset, *the Comprehensive Universe of U.S. Patents* Berkes (2018), draw information on each patent's original assignee and the cumulative citations counts, and merge patent identification number to the USPTO data.

A.3.1. Other Historical Patent Data

Besides the CUSP (Berkes, 2018), there are several other historical patent datasets available. For example, HistPat (Petralia, Balland and Rigby, 2016) contains issued U.S. patents filed from 1790 to 1978, collected from USPTO-digitized patent images. I prefer to use the raw USPTO data, supplemented with the CUSP as the baseline patent data in this analysis, instead of the HistPat, for several reasons.

First, the fact that the HistPat only contains the data on patent issue dates rather than patent filing dates is a central limitation. Because what I am interested in is exploring how firms' patenting activities responded to the RCHSA, long lags between patent applications and patent grants can make my results more difficult to interpret. I thus extract information from the CUSP data, which includes both filing and issue dates for each patent.

Second, the HistPat data only covers patents filed by U.S. firms and independent inventors. However, as mentioned in Section 6, I am interested in investigating responses from both domestic and foreign firms following the RCHSA to control for unobserved technological breakthroughs uniformly affecting all entities. Note, as pointed out in , Andrews (2021), while both the CUSP and HistPat datasets are very accurate, the CUSP has a slightly higher error rate for the sample patents for patents according to the spot-checking. For this reason, I first merge the CUSP data to the primary USPTO sample on patent identification numbers, and then carefully and manually identify whether a patent was filed by foreign entities based on the nationality of its assignees.

Third, another limitation of the HistPat data is its relatively short time span (being terminated in 1978). Recall in Figure 10, I emphasized the innovation effect induced by the RCHSA appears to fade out over time. To directly and transparently examine this pattern, an event-study specification with detailed data on patenting in the subsequent period is necessary. To do so, I rely on the USPTO-CUSP sample to implement such exercises.

A.3.2. Constructing KPSS-Compustat Sample

The primary firm-level sample of interest is constructed in the following three steps. First, I merge all patent data under the broad category `A61B` from the KPSS data to the CRSP data using the unique stock ID (`permno`). This way, I identify 443 unique firms in total. Put differently, all firms have filed at least one `A61B` patent application from 1950 to 1990. Second, I manually merge the CRSP data of these 443 firms to the Compustat data using the 9-digit firm identifier (`CUSIP`) and construct the CRSP-Compustat sample, which includes 365 unique firms and 13,009 firm-year observations. Specifically, for each firm with a history of `A61B` patenting, I include its relevant data from the Compustat at the annual frequency. Finally, I collapse all patent data under `A61B` in the KPSS sample at the firm-class-year level and merge these collapsed data back to the CRSP-Compustat sample. The value zero is assigned to observation ($patent_{ict} = 0$) if the given firm i did not apply for any patent under the class c in year t.

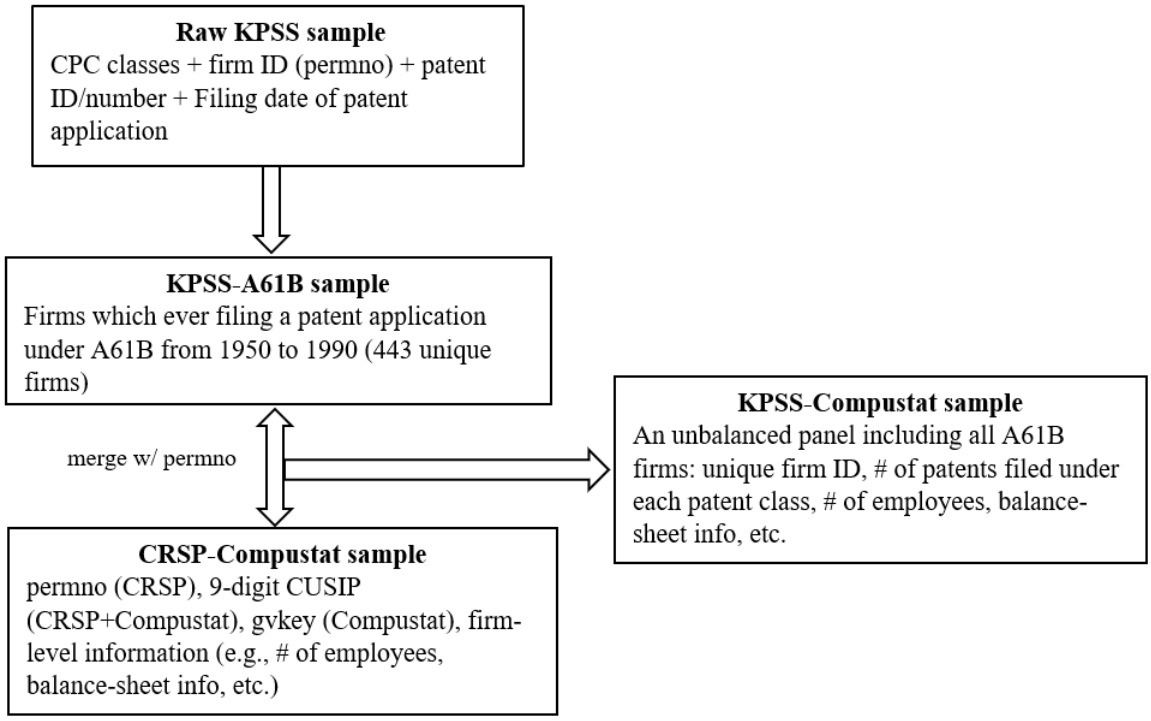


Figure A-3: Construction of the KPSS-Compustat Sample

A.4. Patent Classification

This section shows the details about what types of patents are included in my main analysis. In particular, Table A2 shows the primary control and treatment groups. Table A3 presents the description of patent classification for pharmaceutical components; Table A4 summarizes patents related to medical implants used as an alternative control group. Table A5 then lists patent classification relevant to radiation reducing and radiation generating, respectively.

Table A2. Description of Subclasses under A61B (Diagnosis)

A61B1	Instruments for performing medical examinations of the interior of cavities or tubes of the body by visual or photographical inspection, e.g. endoscopes; Illuminating arrangements therefor
A61B3	Apparatus for testing the eyes; Instruments for examining the eyes
A61B5	Measuring for diagnostic purposes; Identification of persons
A61B6	Apparatus for radiation diagnosis, e.g. combined with radiation therapy equipment
A61B7	Instruments for auscultation
A61B8	Diagnosis using ultrasonic, sonic or infrasonic waves (imaging of objects using sonar G01S 15/00)
A61B9	Instruments for examination by percussion; Pleximeters
A61B10	Instruments for examination by percussion; Pleximeters
A61B13	Instruments for depressing the tongue
A61B16	Devices specially adapted for vivisection or autopsy (similar devices for medical purposes, see the relevant groups for such devices ; autopsy tables A61G 13/0027)

Table A3. Description of Subclasses under A61F

A61F2	Filters implantable into blood vessels; Prostheses, i.e. artificial substitutes or replacements for parts of the body; Appliances for connecting them with the body; Devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g. stents
A61F3	Lengthening pieces for natural legs
A61F4	Methods or devices enabling patients or disabled persons to operate an apparatus or a device not forming part of the body
A61F5	Orthopaedic methods or devices for non-surgical treatment of bones or joints
A61F6	Contraceptive devices; Pessaries; Applicators therefor
A61F7	Heating or cooling appliances for medical or therapeutic treatment of the human body
A61F9	Methods or devices for treatment of the eyes; Devices for putting-in contact lenses; Devices to correct squinting; Apparatus to guide the blind; Protective devices for the eyes, carried on the body or in the hand
A61F11	Methods or devices for treatment of the ears or hearing sense; Non-electric hearing aids; Methods or devices for enabling ear patients to achieve auditory perception through physiological senses other than hearing sense; Protective devices for the ears, carried on the body or in the hand
A61F13	Bandages or dressings; Absorbent pads
A61F15	Auxiliary appliances for wound dressings; Dispensing containers for dressings or bandages
A61F17	First-aid kits

Table A4. Description of Subclasses under A61K

A61K6	Preparations for dentistry
A61K8	Cosmetics or similar toiletry preparations
A61K9	Medicinal preparations characterised by special physical form
A61K31	Medicinal preparations containing organic active ingredients
A61K33	Medicinal preparations containing inorganic active ingredients
A61K35	Medicinal preparations containing materials or reaction products thereof with undetermined constitution
A61K36	Medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicines
A61K38	Medicinal preparations containing peptides
A61K39	Medicinal preparations containing antigens or antibodies
A61K41	Medicinal preparations obtained by treating materials with wave energy or particle radiation
A61K45	Medicinal preparations containing active ingredients not provided for in groups A61K 31/00 - A61K 41/00
A61K47	Medicinal preparations characterised by the non-active ingredients used, e.g. carriers or inert additives; Targeting or modifying agents chemically bound to the active ingredient
A61K48	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
A61K49	Preparations for testing in vivo
A61K51	Preparations containing radioactive substances for use in therapy or testing in vivo
A61K2121	Preparations for use in therapy
A61K2123	Preparations for testing in vivo
A61K2236	Isolation or extraction methods of medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicine
A61K2300	Medicinal preparations characterized by the non-active ingredients used, e.g. carriers or inert additives; Targeting or modifying agents chemically bound to the active ingredient
A61K2300	Mixtures or combinations of active ingredients, wherein at least one active ingredient is fully defined in groups A61K 31/00 - A61K 41/00
A61K2800	Properties of cosmetic compositions or active ingredients thereof or formulation aids used therein and process related aspects

Table A5. Patent Attributes under A61B6

Attributes	CPC sub-class	Description
reducing radiation risk	A61B6/10	Application or adaptation of safety means
	A61B6/54	Aspects of radiation diagnostic devices concerning control of the device or parts of the device.
	A61B6/58	Means for assessing and adjusting the parameters of the device as a function of the system geometry.
(relying on) the generation of radiation	A61B6/14	Radiation diagnosis devices specially adapted for a dental examination, e.g. devices for panoramic imaging of the teeth.
	A61B6/40	Radiation diagnostic devices comprising a radiation source for generating radiation and arrangements for manipulating said radiation by shaping the radiation beam, displacing it or modifying its characteristics.
	A61B6/44	Diagnostic devices comprising structural or mechanical arrangements allowing a specific usage or property, e.g. movement, modularity.
	A61B6/46	Radiation diagnosis devices comprising input and/or output means structurally or functionally designed for allowing a specific interaction with the device user or the patient.
	A61B6/48	Diagnostic devices involving a specific use of ionising radiation to perform a particular type of diagnosis. Imaging techniques are independent of the device used for implementing them.
	A61B6/50	Clinical applications: Classification in this group depends on the body part or organ which is to be diagnosed.
	A61B6/52	Radiation diagnosis devices involving any kind of processing of data (raw data or diagnostic data) or image processing for enhancement purposes, e.g. artefacts reduction or resolution improvement.
	A61B6/56	Radiation diagnosis devices comprising: means for transmitting/receiving data to/from an external device or between components of the device, e.g. image transmission to a remote physician workstation for diagnosis; or means for supplying power to any component of the device, e.g. between stationary and moving parts.

Table A5. Patent Attributes under A61B6

Attributes	CPC sub-class	Description
the detection of radiation	A61B6/06	Diaphragms specially adapted for particular diagnostic applications, e.g. tomography. Devices adapted to modify the spatial confinement of the cross-section of the radiation beam, e.g. collimators, situated between the source unit and the patient.
	A61B6/08	Radiation diagnosis devices comprising means for assessing direction and/or extent of the radiation beam before acquisition.
	A61B6/10	This class covers the use of radiation diagnostic devices to determine the position of a surgical instrument during an operation.
the patient support	A61B6/04	Any means, e.g. tables, beds, chairs, suitable for positioning the patient in the diagnostic device.

A.5. Robustness and Extensions to Main Results

This section summaries additional results based on a number of robustness checks and extensions. Section A.5.1 lists some alternative identification specifications; Section A.5.2 presents some evidence regarding how this regulation imposed spillover effects on other technologies. In Section A.5.3, I discuss how I used a text-analysis-based method to check the robustness of my results. Finally, in Section A.5.4, I show the heterogeneous effects imposed by the regulation.

A.5.1. Alternative Identification Specifications

As pointed out by Chen and Roth (2024), taking logarithms on the data, including zeros, can lead to bias in the estimate. This issue can arise in the context of patent data. I took several exercises to address this issue and show my main estimates are robust.

In the first robustness check, the raw patent count applied per patent subclass every year is set as the main outcome as follows:

$$\text{Count}_{sct+1} = \alpha + \beta Treat_s c \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{A6}$$

Thus, the coefficient β is interpreted as the impact of the RCHSA on the number of patents applied under *A61B6*.

In the second analysis, I separately check the extensive margin of the patent application. The outcome of interest is an indicator of whether there was any patent applied within a subclass per year.

$$\mathbb{1}_{\text{count} > 0_{cst+1}} = \alpha + \beta Treat_s c \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{A7}$$

Finally, I took the inverse hyperbolic sine transformation of my patent data and tested the robustness of estimates based on this alternative specification. The motivation to use this transformation is that it allows for non-positive values and thus reduces the influence of outliers in a right-skewed distribution (Norton, 2022).

$$\mathbb{1}_{\text{count} > 0_{cst+1}} = \alpha + \beta Treat_s c \times Post1969_t + \rho_{sc} + \eta_t + \epsilon_{sct} \tag{A8}$$

I present my estimates based on these robustness checks in Table A6. In columns 1, 4, and 7, the control group is all non-radiation diagnostic medical devices. In columns 2, 5, and

8, I use medical implant patents as the control; in columns 3, 6, and 9, the control group includes all patents related to pharmaceutical ingredients.

In terms of results using raw patent counts (columns 1-3), we can observe that the estimate is significant and positive in column 1. It is worth noting that the magnitude is much higher; the number of patents applied per year increased by approximately 4 under the A61B1 subclass group. This is primarily due to the highly skewed nature of the patent data, indicating it's reasonable and necessary to rely on the inverse hyperbolic sine transformation and the Poisson regression to fix this issue. Along the extensive margin, we note there is a statistically significant increase in columns 5 and 6. It indicates that using alternative control groups, the positive innovation effects mainly reflect an increase in the likelihood of submitting a patent application. Eventually, in the last three columns, we also observe a strong, significant, and positive impact on innovation; the magnitude is also similar to my main results. Thus, these robustness exercises highlight my baseline estimates mentioned in Section 5 still hold.

Table A6. Effects of the RCHSA on Patent Counts (1960-1980)

	raw patent counts			extensive margin			IHS transformation		
	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma
Panel A. raw counts									
$Treat_c \times Post1969_t$	4.088***	3.039*	0.323	0.083	0.103*	0.111**	0.706***	0.701***	0.688***
	(1.270)	(1.675)	(2.064)	(0.058)	(0.057)	(0.052)	(0.146)	(0.132)	(0.141)
mean of DV (1960-1967)	0.508	0.564	0.599	41.43	71.43	51.62			
# of clusters	67	94	127	67	94	127			
# of obs.	1407	1974	2667	1407	1974	2667	1407	1974	2667
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period (1960-1980). The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the outcome of interest is constructed based on the raw patent counts, and in Panel B, the outcome is constructed using the citation-weighted patent counts. All standard errors are clustered by patent subclasses.

A.5.2. Testing Technical Spillovers to Other Medical Technologies

A key identification assumption in my case is that patents in the control group will not be affected by the regulation. In other words, there should not be spillover effects imposed by the RCHSA on the ideal control groups. As mentioned in Section 4, there are several concerns related to this assumption. In this section, I elaborate on how to interpret these spillovers.

Spillovers to Non-Radiation Diagnostic Devices: One potential spillover channel is through demand-side substitution effects. When stricter safety regulations under the RCHSA constrained the use of X-ray-based diagnostics (A61B 6), healthcare providers and insurers sought safer, non-ionizing alternatives, leading to increased market demand for safer alternatives, like ultrasound and optical imaging. This shift incentivized medical device firms to redirect R&D investments into these alternative diagnostic technologies, fostering postive innovation spillovers. As firms adapted to evolving market needs, they leveraged existing technological expertise and infrastructure to accelerate advancements in non-radiation imaging, creating positive externalities across related medical technology sectors.

To empirically capture this demand-side spillover, I exploit the fact that there are two patent classes closely relevant to A61B6. According to the CPC system,[61] A61B5 (Measuring for diagnostic purposes; Identification of persons) and A61B8 (Diagnosis using ultrasonic, sonic or infrasonic waves) are closely related to A61B6 but cover non-ionizing diagnostic technologies. For example, A61B5/055 (Magnetic resonance), A61B5/0059 (Optical imaging), A61B5/0093 (Opto-acoustic imaging) are all diagnostic medical devices using non-ionising radiation.

If demand-side substitution effects induced by the RCHSA led to positive spillovers, we would expect to observe a slight decline in the estimated magnitude of the increased patenting rate when including A61B5 and A61B8 patents in the control group. This attenuation occurs because these two categories, while not directly regulated, likely benefited from spillover effects driven by the shift in demand toward non-ionizing diagnostic technologies. In Columns (1) and (4) of Table A7, I implement this robustness check and confirm the presence of positive spillover effects. Compared to my main results excluding A61B5 and A61B8 ($\hat{\beta}$ = 0.587), the increase in patenting rate of diagnostic X-ray medical device increased only by 52.81% (= exp(0.424)-1). It thus indicates that besides patents directly relevant to ionizing radiation, these safe alternative technologies also got positively affected by the safety standards.

[61] See https://www.uspto.gov/web/patents/classification/cpc/pdf/cpc-definition-A61B.pdf, last accessed February 14, 2025.

Spillovers to Medical Implants: Another type of spillover can occur through the complementarity effect, as medical imaging and implantable devices can co-evolve due to their mutual dependence. For example, X-ray-based diagnostics were essential for implanting and monitoring pacemakers, requiring these devices to be radiation-resistant to function properly in an imaging-dominated medical environment (Fradley et al., 2021). Because pacemakers had to withstand routine exposure to ionizing radiation, firms invested in radiation-hardened electronics and shielding materials, reinforcing innovation spillovers between medical imaging and implantable device technologies. However, as low-dose radiation imaging became widespread due to regulatory changes, the strength of this technological complementarity declined, reducing the need for radiation-resistant designs and leading firms to redirect R&D efforts away from pacemaker development and toward alternative medical technologies.

Your argument is well-structured and effectively conveys the spillover effect, but one potential refinement could be to clarify the mechanism more explicitly—particularly how the use of medical implant patents as a control group affects the interpretation of the spillover effect. Here's a refined version with slight improvements in clarity and logical flow:

In Columns (2) and (5) of Table A7, I provide evidence for the spillover effect on medical implant patents. When using medical implant patents as the control group, the magnitude of point estimates increases slightly (0.674 in OLS and 0.805 in Poisson), suggesting that implant-related innovation was indirectly influenced by regulatory constraints on X-ray-based diagnostics. To further isolate this spillover effect, I use pharmaceutical patents as an alternative control group, as they are less technologically dependent on radiation-based imaging and therefore serve as a baseline largely unaffected by the RCHSA regulations. The contrast in results across different control groups strengthens the case that regulatory constraints on one technology can induce spillovers into adjacent fields, as firms redirect R&D efforts through shared resources, technological interdependencies, and knowledge diffusion across medical innovation sectors.

Table A7. Effects of the RCHSA on Patent Counts (1960-1980)

	OLS			Poisson		
	NR-DME	Implants	Pharma	NR-DME	Implants	Pharma
$Treat_c \times Post1969_t$	0.424***	0.674***	0.557***	0.453**	0.805***	0.728***
	(0.118)	(0.120)	(0.119)	(0.196)	(0.236)	(0.203)
mean of DV (1960-1967)	0.508	0.564	0.599	41.43	71.43	51.62
# of clusters	116	94	127	116	94	127
# of obs.	2436	1974	2667	2436	1974	2667
subclass FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period (1960-1980). The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the outcome of interest is constructed based on the raw patent counts, and in Panel B, the outcome is constructed using the citation-weighted patent counts. All standard errors are clustered by patent subclasses.

A.5.3. Robustness of the CPC Approach

In the primary analysis, I relied on the detailed CPC code to distinguish the treatment and control groups and identify key patent attributes. In this section, I discuss some limitations of this approach and potential ways to address them.

One limitation arises from the fact that the CPC system does not explicitly provide information on the principal technological category of a patent (as mentioned in Section 4.5.1). As a result, when using the patent subclass as the basic unit of analysis, there is a possibility of double-counting patents that are classified under multiple relevant subclasses. This could introduce measurement noise and lead to an overestimation of patenting activity in certain categories.

Additionally, the CPC classification system is subject to periodic updates, which may alter the scope and definition of certain subclasses over time. This is particularly relevant for diagnostic medical devices based on X-ray technology, as their classification could shift due to technological advancements or changes in industry standards. If the scope of A61B6 patents (radiation-based diagnostics) expanded or contracted over time, it could affect the comparability of patent counts across different periods.

To address these concerns, I first re-collapsed all patents to the *class-year* level and re-

estimated the innovation effects. Table A8 presents the results of this robustness check: relative to other non-radiation diagnostic medical equipment patents, patent count relating to diagnostic X-ray medical devices increased by 61.8%, or say 13.65 patents per year under the class A61B6. These estimates are consistent with the results in Section 5: there is a 42.4% increase (or equivalently 0.83 patents per subclass-year) among diagnostic X-ray medical device patents.[62]

Table A8. Effects of Radiation Control on Patent Counts (Class-Level Analysis)

	OLS			Poisson		
	NR-DME	Implants	Drugs	NR-DME	Implants	Drugs
$Treat_c \times Post1969_t$	0.618***	0.788***	0.654***	0.569***	0.814***	0.801***
	(0.159)	(0.157)	(0.141)	(0.116)	(0.117)	(0.118)
mean of DV (1960-1967)	22.09	25.33	39.52	22.09	25.33	39.52
# of obs.	168	189	273	168	189	273
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Standard errors in parentheses

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in column (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category A61F, and "Drugs" means all drugs and chemical substances under the category A61K.

Second, I employ a dictionary-based text analysis method to identify patents focused on radiation reduction technology. This approach calculates a "relevance score" for each patent, which measures the patent's emphasis on the feature of radiation reducing. There are four key steps in this text analysis process:

Step 1. Dictionary Construction: I begin by building a term dictionary through systematic review of technical literature and patent documents. Using Python's spaCy library for natural language processing, I first conduct text mining on a sample of known radiation-protection patents to extract frequent noun phrases and technical terms. These candidate terms are then filtered based on their relevance to radiation reducing technology, consulting technical documentation and field expertise to ensure appropriateness. Each term in our final dictionary receives the same weight, reflecting the assumption that their importance in indicating radiation reduction technology is identical.

[62] Under the patent class A61B6, there are 16 two-dot subclasses. Thus, the class-level increase is equivalent to 13.28 patents per class-year.

Key terms use in this directory are drawn from Galasso and Luo (2021): "safety monitor," "radiation shield," "radiation blocking," "dose control," "reducing electromagnetic radiation," "reducing radiation," "dose modulation," "exposure control," "radiation protection," "low-dose," "x-ray intensity," "radiation exposure," "x-ray exposure," "x-ray dose," "radiation attenuation," "x-ray emissions," "dose rate control," "radiation dose," "radiation minimization," "x-ray irradiation," "dosage detection," "radiation shielding," "dose distribution," "dose information," "x-ray reduction."

Step 2. Document Preprocessing: The second step involves the preprocessing of patent files to prepare them for analysis. I employ Python's text processing tools to load each patent document, and then segment the text into three distinct sections: abstract, claims, and description. This segmentation is crucial because I assume different sections carry different weights in the text analysis. Specifically, I assign the highest weight of 2.0 to the abstract, as it typically contains the most concentrated description of the patent's purpose. Claims receive a weight of 1.5, reflecting their legal and technical significance, while the description section receives a baseline weight of 1.0. After segmentation, I convert all text to lowercase and remove special characters to ensure consistent and accurate term matching across all documents.

Step 3. Term Frequency Analysis: In this step, I perform the term frequency analysis across each section of the patent document. This algorithm processes each section separately, using string matching functions to identify and count occurrences of dictionary terms. The system maintains separate counts for each term within each section, allowing one to apply the appropriate section weights later in the analysis. I also implement robust error handling mechanisms to manage variations in patent text formatting, ensuring consistent processing across large patent datasets. This step creates a frequency map that captures both where and how often each dictionary term appears in the patent.

Step 4. Score Calculation: In this step, for each term found in the patent, I multiply two key components: the term's frequency in a given section and the section weight as follows:

$$\text{relevance score} = \sum weight_s \times frequency_i$$

Where frequency_i represents how often term i appears in a patent text and weight_s reflects the corresponding weight assigned to each section of a patent file. For example, finding the word "shield" twice in the abstract would contribute 2 (frequency) × 2.0 (abstract weight) = 4.0 points to the final score. Similarly, finding "protect" once in the claims section would add 1 (frequency) × 1.5 (claims weight) = 1.5 points. The system then sums all these in-

dividual scores across all terms and sections to produce the final reducing score for the patent.

Step 5. Validation and Documentation: The final step ensures the reliability and reproducibility of the analysis, verifying correct section identification and term matching. It includes detailed logging features that track how each patent's score is calculated, documenting the contribution of each term and section to the final score. This step allows for verification of the analysis process and helps identify any unusual patterns or potential issues in the scoring.

Based on the text analysis of patent documents, I classify patents as radiation reducing one if their relevance score exceeds the mean score within the sample. Among our sample of 1,073 patents, there are 413 categorized as "radiation reducing technology," constructing the treatment group in this robustness check.

In Table A9, I present the result of this robustness check. Throughout the analysis, the control group includes all patents relevant to non-radiation diagnostic medical device. The key outcome in Column (1) is the probability of having any patent application within a subclass in year t. In Column (2), the outcome is log(patent+1) and the specification is an OLS model. In Column (3), this is a Poisson regression with the raw patent count as the dependent variable.

Estimates from all three columns suggest that there was an increase in patenting for diagnostic X-ray medical device relative to their non-radiation counterparts (though this increase is not statistically significant along the intensive margin in Column (2)). In terms of the magnitude, there is a slight decline in this text-analysis-based result, compared to my main estimates.[63] It might suggest there are indeed some patents capturing radiation-reducing feature but not categorized as so by the CPC system.

[63] Among all three specification, I slightly prefer the Poisson regression as it addresses the concern that

Table A9. Robustness Check Using Text Analysis Method

	application	log(patent+1)	Poisson
$Treat_c \times Post1969_t$	0.152**	0.149	1.199***
	(0.071)	(0.147)	(0.264)
mean of DV (1960-1967)	0.508	0.564	0.599
# of clusters	67	67	67
# of obs.	1407	1407	1407
subclass FE	Yes	Yes	Yes
year FE	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period (1960-1980). The dependent variable of all regressions in column (1) - (3) is the natural logarithm of the annual patent counts filed under a patent (sub)class in year t. The dependent variable of all regressions in columns (4) - (6) is the annual patent counts filed under a patent (sub)class in year t. "NR-DME" denotes non-radiation diagnostic medical equipment, "Implants" represents medical implants under the broad patent category `A61F`, and "Drugs" means all drugs and chemical substances under the category `A61K`. In Panel A, the outcome of interest is constructed based on the raw patent counts, and in Panel B, the outcome is constructed using the citation-weighted patent counts. All standard errors are clustered by patent subclasses.

A.5.4. Heterogeneity by Financial Constraint

In the main analysis, I have demonstrated that the safety regulation increased both the quantity and quality of innovation related to diagnostic X-ray medical devices. In the appendix, I turn to explore whether and how these effects depend on firms' financing constraints.

A voluminous literature emphasized the relationship between financial frictions and innovation (see, for example, Caggese, 2019). In a context like mine, financial frictions may arise in the phase of product development. For example, in the presence of stricter product safety standards, firms with better access to financial resources have more flexibility in choosing cost-saving innovation as an option to combat higher compliance costs. As noted in Miravete and Permoas (2006), whether product innovation and process innovation are complements or substitutes in production is determined by the supply-side environment. One such driver could be the availability of accessible resources: If a company has limited resources, it may have to trade off its investment in new products against improvements in process innovation. By contrast, if a large company has sufficiently relaxed resource constraints, it would be able to pursue both types of innovation simultaneously, leading to a complementary relationship between product innovation and RMTs. Drawing on firm-level data from Kogan et al. (2017), I examine the sensitivity of firms' patenting rates to firms' financing constraints as follows.

To start with, I first assess if the RCHSA *per se* directly distorted firms' financing performance, including capital intensity (*capital-labor ratio*), financial leverage (*debt/assets*), cash balances (*cash/assets*), cash flow (*cash flow/assets*), dividend payout (*current dividends/assets*), and sales. Along all the above dimensions, there is little evidence that the imposition of safety regulations significantly altered relevant outcomes. It thus suggests that the regulation did not significantly affect firms' financial performance, as well as their input mix.

In Table A10, I estimate a firm-level regression as follows to capture the heterogeneous effects:

$$y_{ict+1} = \alpha + \beta Treat_c \times Post1969_t + log(\#\text{of employees}) + \theta_i + \psi_c + \phi_t + \epsilon_{ict} \tag{A9}$$

where y_{ict+1} denotes the number of patents filed by firm *i* under class *c* in year *t+1*. The annual number of employees within a firm here is a proxy for firm size and has been included as a control. $Treat_c$ indicates whether a patent belongs to diagnostic x-ray medical equipment. $Post1969_t$ denotes whether the RCHSA is in place in year *t*. A number of fixed effects are also included: firm fixed effects (θ_i), class fixed effects (ψ_c), and year fixed effects (ϕ_t).

Table A10 presents how the RCHSA affected the patenting rate across the distribution of firms' dividend payout, which is often seen as an inverse proxy for the severity of financing constraints. In particular, I allocate assignees (firms) into four categories: whether the dividend payout of a firm is below the 25^{th} percentile, between the 25^{th} percentile and the 50^{th} percentile, between the 50^{th} percentile and the 75^{th} percentile, or above the 75^{th} percentile. Overall, I find the increase in patent counts is significant among firms with higher levels of dividend payouts.

Table A10. Effects of the RCHSA on Innovation (by Dividend Payout)

	Dependent Variable: log(patent counts+1)			
	below 25th	25th-50th	50th-75th	above 75th
$Treat_c \times Post1969_t$	0.005	0.023***	0.030***	0.020*
	(0.007)	(0.008)	(0.009)	(0.011)
# of obs.	4,945	5,300	5,400	5,510
class FE	Yes	Yes	Yes	Yes
firm FE	Yes	Yes	Yes	Yes

Standard errors in parentheses
* $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Note: Data are drawn from the USPTO sample and the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is firm-class-year. The dependent variable of all regressions is the natural logarithm of the annual patent counts filed by a firm under a patent class in year t.

A.6. Additional Mechanism: Competition

Besides the alternative channels discussed in the paper, another plausible explanation for the observed increase in patenting activities is changes in market structure following the RCHSA. In essence, stricter product safety regulations can substantially change product market competition in equilibrium (Atal, Cuesta and Sæthre, 2022), thereby distorting firms' incentives to innovate.

Setting higher (minimum) safety performance standards can directly influence product market competition (PMC) through at least two key channels, among many others: increasing fixed costs and driving up market size.[64] Following the theoretical models outlined in Budish, Roin and Williams (2015) and Atal, Cuesta and Sæthre (2022), I briefly summarize these two forces in turn.[65]

Increased Fixed Costs: On the supply side, one can conceptualize that a typical firm would face a two-stage decision when innovating: *invention* and *commercialization* (Budish, Roin

[64] Admittedly, another complexity regarding product market structure is that manufacturers may collude and endogenously set the minimum performance standards by forming trade organizations and lobbying the government. For example, if a trade organization successfully lowers the stringency of safety standards (i.e., reducing the extent to which the minimum quality standard dampens the quality competition), it then leaves room for firms to further collude and reduce competition.

[65] From the theoretical perspective, Marette (2007) argues under perfect information about safety for consumers, the standard is always compatible with competition: The absence of standard due to safety overinvestment by firms only emerges under competition in quantities and a relatively low cost of safety improvement. However, under imperfect information about safety among consumers, the standard often leads to a monopoly situation, essentially covering the cost of safety improvement. However, for relatively high values of this cost, a standard cannot impede the market failure arising from the lack of information.

and Williams, 2015; Rogers, 2023). In the first stage, firms develop ideas and invest in $R\&D$ till the new technology is patentable. In the second stage, firms decide whether the newly invented technology/product could enter the market. Higher safety performance standards can inflate fixed costs in both phases. To be concrete, during the invention phase, these standards may drive up regulatory pressure and mandate firms to comply with ("*regulatory compliance costs*").[66] At the point of entry or say, commercialization, higher performance standards would potentially result in approval delays, thereby triggering approval costs.[67] [68] Together, if these two types of fixed costs are too high, safety performance standards can lead to exit, deter entry, and stifle product market competition Atal, Cuesta and Sæthre (2022).

Expanded Market Size: Similar to the argument in Section 6.2, consumers demand new medical devices subject to friction due to asymmetric information: without the intervention of any product safety regulation, consumers cannot distinguish between high- and low-quality products. As a result, safety performance standards serve to resolve market failure, thus increasing consumers' willingness to pay for products under regulation.

In sum, the equilibrium effect of safety regulations on market structure hinges on several factors. A thorough analysis of the competition effect is beyond the scope of my paper and essentially requires a structural model (see for example, Atal, Cuesta and Sæthre, 2022). Building on these theories and taking into account changes in product market structure (if any), I now turn to discuss how safety regulations can indirectly affect innovation activities via competition.

Prior seminal work has emphasized an inverted-U relationship between competition and innovation (see, for example, Aghion et al., 2005): product market competition discourages *laggard* firms from innovating but encourages *neck-and-neck* firms to innovate.[69] Drawing

[66] The theoretical framework outlined in Section A6 builds on this line of argument.

[67] For example, firms may face financing costs if approval costs exceed their assets Buera and Shin (2013).

[68] Of course, in the current regulatory regime, the approval requirement of the FDA plays a key role in delaying product commercialization (Pietzsch, Zanchi and Linehan, 2012). However, it is noteworthy that in my context, wherein the current risk-based regulatory regime has not been introduced, these approval costs might be negligible. This is because the FDA's historical regulation for medical devices did not require manufacturers to register with the Secretary of the Department of Health, Education and Welfare. Put differently, the Secretary did not have any power of approval and subsequent disapproval before a medical device was marketed.

[69] As Aghion et al. (2005) argued, firms' innovation incentives hinge heavily on the difference between post-innovation and pre-innovation rents of firms. As a result, more competition can facilitate innovation when it reduces a firm's pre-innovation rents by more than it reduces its post-innovation rents, thereby enabling such firms to escape from competition. This *escaping competition* effect is more prominent in sectors where incumbent (or say, *neck-to-neck*) firms are operating at similar technological levels. In contrast, when innovations are made by laggard firms with low initial profits in the first place, increased competition pressure would primarily affect post-innovation rents and thus hinder innovation.

on this line of theoretical predictions, if higher safety standards reduced product market competition, one may expect the documented rise in patent counts to reflect a surge in innovation incentives of non-incumbent firms exclusively. In contrast, if the increase in market size is sufficiently large and intensifies competition pressure, the induced innovation could be primarily contributed by incumbent firms. That said, in either case, there should be a significant difference in innovation activities between incumbents and new entrants with stricter safety standards in place.

Admittedly, it's challenging to directly test this channel when product-firm-level data are unavailable. As follows, I provided two groups of suggestive evidence why the dramatic changes in innovation could not be fully explained by market structure changes in the short run. First, I draw on the description from Birnbaum (1984); second, I compare the differential effects of the RCHSA by firms' size. More specifically, I constructed two sets of incumbents in this industry: taking publicly traded firms as a proxy for incumbents and using a firm's prior patenting history to infer whether it's an incumbents one.

A.6.1. Narrative Evidence from Birnbaum (1984)

Birnbaum (1984) provided some descriptive evidence regarding the market structure of the medical diagnosis and medical therapy industry. For example, in March 1980, eleven semistructured interviews of up to two hours were conducted among congressional representatives and administrators from the Bureau of Radiological Health, the Bureau of Medical Devices, the National Electrical Manufacturers Association, the Health Industries Manufacturing Association, and the American Association for Medical Instrumentation. Additional questionnaire responses were collected from firms representing 62 percent of the medical diagnosis and medical therapy market segments. Based on these data, Birnbaum (1984) confirmed that seven firms accounted for 78% of the medical diagnostic market and 90% of the medical therapy market in 1980.

Meanwhile, Birnbaum (1984) also collected data on market share in 1974 from Hale and Hale (1978). Comparing data from both 1974 and 1980, Birnbaum (1984) further argued "*major changes in market leadership can be identified*" during the 1970s. Furthermore, the average growth rate of 23.3% over the 16 years, medical X-ray market grew in excess of the U.S. economy. One would even "*expect greater competition and volatility over market share earlier in the growth phase before 1974.*" Overall, this description appears to suggest that throughout the 1960s and 1970s, the medical X-ray industry did not experience a substantial decline in the extent of product market competition.

A.6.2. Innovation Activities from Publicly Traded Firms vs. Other Private Firms

Does the regulation affect firms deferentially based on their size? This heterogeneous effect can provide key implications for the competition channel argued in Section 6.5. If the innovation effects documented here were primarily driven by a change in market structure, one would expect it largely reflected responses from incumbent firms. This is simply because when facing increased competition pressure, incumbent firms are more likely to improve innovation efforts.

To test this channel, I use U.S. publicly traded firms identified in the KPSS-Compustat sample as a proxy for *incumbents*. Table A11 reports my estimated effects on patent counts filed by publicly traded firms (column (1) and column (4)) and other private firms (column (2) and column (5)), respectively. My first set of regressions is the baseline difference-in-differences analysis with patents filed by US publicly traded firms in a class-year cell as the dependent variable.[70] Results are reported in the first and the fourth columns of Table A11: relative to non-radiation diagnostic medical device technologies, both radiation-reducing and radiation-generating technologies experienced a significant and sizable increase after 1969. I repeat this exercise and focus on patents filed by other private firms in column (2) and column (5). Similarly, I documented a significant rise in patenting rate within these non-publicly traded firms. In the third and last column, I also report the main results using a triple difference-in-differences specification. That said, for each class-year cell, I crate two observations, one for patent counts for publicly traded firms and the other for other private firms as the assignee. The total number of observations is thus twice as many as that in column (1) (2) (4) and (5). The key coefficient associated with the triple interaction term ($Treat_c \times Post1969_t \times KPSS$) captures the differential effect of the RCHSA on innovation between incumbents and entrants.

A.6.3. Innovation Activities from Firms with Prior Patenting History

In addition, I follow Gross (2023) and use a firm's patenting history to infer if it's an incumbent. Concretely, a firm will be defined as an "incumbent" if it has filed at least one patent application between 1950 and 1967.[71] Of course, this approach is not free of concerns. For example, since there is no way to track the history of a firm's entry, exit, and mergers/acquisitions, it is indeed quite hard to tease out potential selection bias.

Table A12 summarizes these results by technology types: in column (1) and column (3), the

[70] When aggregating patent counts at the subclass-year level, the distribution of data for publicly traded firms is highly skewed. Therefore, I choose to aggregate data at the class-year level.

[71] For example, if a firm ever filed a patent under class `A61B6`

point estimates represent the impact on innovation among all incumbent firms; coefficient estimates for entrants are listed in the even-numbered columns. In sum, we can observe both incumbents and entrants are more engaged in innovation following the RCHSA. Together with results from Table A11, it implies that the RCHSA did not shape technology progress for incumbent firms and new entrants in a substantially different way. These findings contrast with the hypothesis that changes in competition are a primary driver of innovation in my context.

Table A11. Effects on Patent Counts (Publicly Traded vs. Other Private Firms)

	OLS			Poisson		
$Treat_c \times Post1969_t$	1.351***	0.818**	0.818***	1.476***	0.903***	0.903***
	(0.303)	(0.314)	(0.287)	(0.210)	(0.256)	(0.270)
$Treat_{sc} \times Post1969_t \times KPSS$	-	-	0.533	-	-	0.573
	-	-	(0.410)	-	-	(0.361)
# of obs.	126	126	252	126	126	252
sample	incumbent	entrants	full	incumbent	entrants	full
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Note: Data are drawn from the USPTO sample and the KPSS-Compustat sample, including all patents granted and applied for at the United States Patent and Trademark Office in the reference period. The unit of analysis is class-year. The dependent variable of all regressions in column (1)-(3) is the natural logarithm of the annual patent counts filed under a patent class in year t. The dependent variable in column (4)-(6) is the patent count filed under each patent class in year t.

Table A12. Effects of the RCHSA on Patent Counts (by Prior Patenting History)

	propensity to patent			log(patent counts+1)		
$Treat_c \times Post1969_t$	0.017**	0.018***	0.018***	0.023**	0.017***	0.017***
	(0.008)	(0.004)	(0.004)	(0.010)	(0.003)	(0.003)
$Treat_{sc} \times Post1969_t \times Incumbent$	-	-	-0.001	-	-	0.006
	-	-	(0.009)	-	-	(0.010)
mean of DV (1960-1967)						
# of obs.	7,550	15,415	22,965	7,550	15,415	22,965
sample	incumbent	entrants	full	incumbent	entrants	full
firm FE	Yes	Yes	Yes	Yes	Yes	Yes
class FE	Yes	Yes	Yes	Yes	Yes	Yes
year FE	Yes	Yes	Yes	Yes	Yes	Yes

Note: Data are drawn from the KPSS-Compustat sample. The unit of analysis is firm-class-year. The dependent variable of all regressions in column (1)-(3) is an indicator for whether a patent has been filed by firm i under a patent class c in year t. The dependent variable in column (4)-(6) is the natural log of patent count filed by firm i under each patent class c in year t.

A.7. Additional Event-Study Estimates

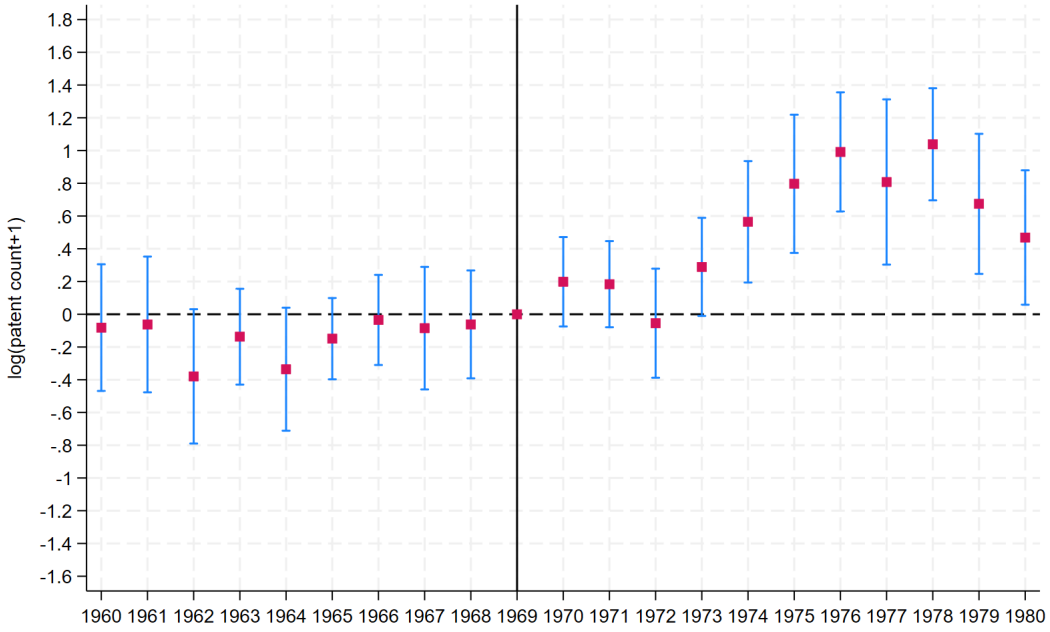


Figure A-4: Event Study Estimates (with Medical Implants as the Control Group)

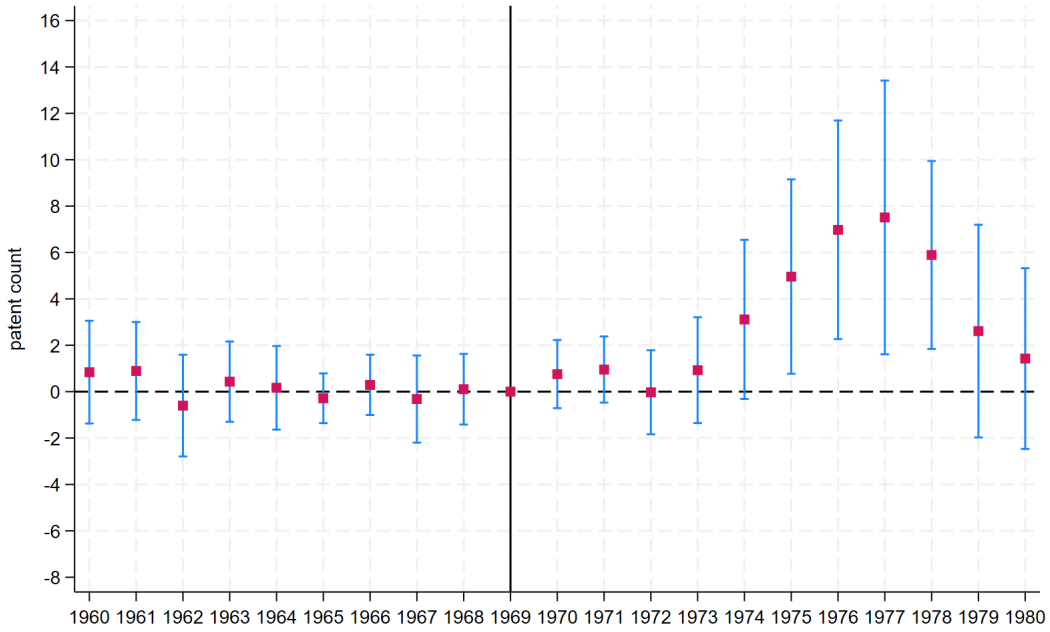


Figure A-5: Event Study Estimates (Raw Count, with Medical Implants as the Control Group)

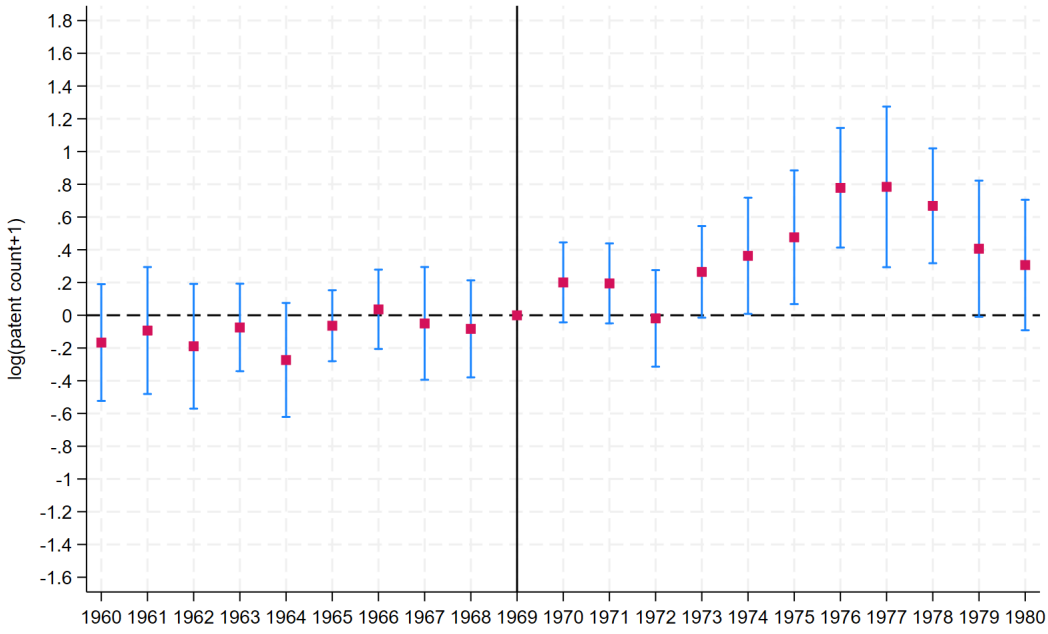


Figure A-6: Event Study Estimates (with Drugs as the Control Group)

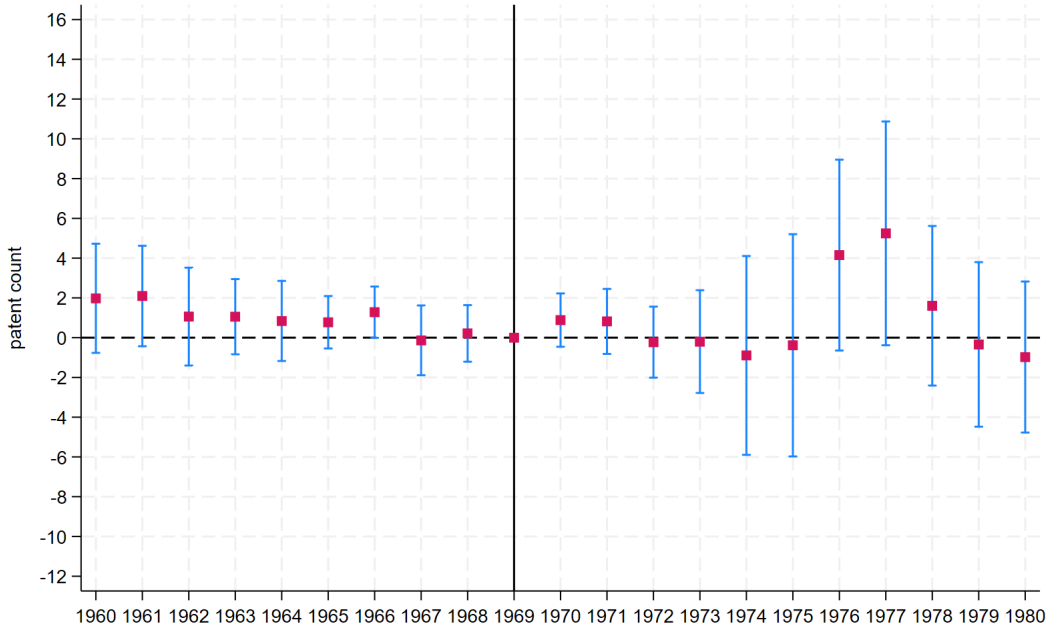


Figure A-7: Event Study Estimates (with Drugs as the Control Group (Raw Count))