Risk-Mitigating Technologies: the Case of Radiation Diagnostic Devices

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September 12, 2019

Abstract

We study the impact of consumers' risk perception on firm innovation. Our analysis exploits a major surge in the perceived risk of radiation diagnostic devices, following extensive media coverage of a set of over-radiation accidents involving CT scanners in late 2009. Difference-in-differences regressions using data on patents and FDA product clearances show that the increased perception of radiation risk spurred the development of new technologies that mitigated such risk and led to a greater number of new products. We provide qualitative evidence and describe patterns of equipment usage and upgrade that are consistent with this mechanism. Our analysis suggests that changes in risk perception can be an important driver of innovation and can shape the direction of technological progress.

Keywords: risk perception, innovation, medical devices, liability risk.

JEL Codes: O31, O32, O34, K13.

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1 Introduction

At least since Schmookler (1966), strategy, innovation, and economics scholars have emphasized the links between market demand, innovation incentives, and technological progress. The broad consensus is that market demand plays a crucial role in selecting from among the potential alternative paths opened up by scientific and technological progress (Dosi (1982); Kline and Rosenberg (1986); Di Stefano et al. (2012)).

Empirical research has shown that demand may steer technological progress through a variety of mechanisms. These include: market size (Acemoglu and Linn (2004)); heterogeneity in consumer needs (Adner and Levinthal (2001)); knowledge of local demand patterns (Fabrizio and Thomas (2012)); and feedback from customers and lead users (Von Hippel (1986); Chatterji and Fabrizio (2012)). Despite this extensive literature, shifts in demand driven by the perception of risk in using a product have, thus far, received little empirical and theoretical attention. Our paper fills this gap by examining firms' innovation responses to a significant change in perceived product safety and by characterizing the nature of the resulting innovations.

Health and safety concerns are of first-order importance in many aspects of our lives. With product liability accounting for the majority of civil personal injury cases in the U.S. (70 percent in 2016), such concerns are critically important to firms that produce these products. Moreover, prominent product failures tend to attract extensive media coverage and public attention—e.g., the fatal accident in 2018 involving Uber's autonomous vehicle and the Boeing 737 MAX crashes in Indonesia and Ethiopia in 2018 and 2019—and such attention can have profound impacts on the perceived safety level of the underlying technologies.

Changes in risk perception potentially differ from other demand-pull forces in a number of dimensions. First, consumers rarely have the full information about risk, and their learning process is typically subject to biases, such as the over-weighting of small-probability events and events that are highly publicized (Lichtenstein et al. (1978); Slovic et al. (1982)). Second, the impact of an increase in risk perception on product demand and, hence, innovation incentives is potentially ambiguous. On the one hand, the willingness to pay for safety will increase and drive up investments in safety features and safer machines (Viscusi (1993)). On the other hand, innovation incentives for products that are valuable in other dimensions but impose higher risk may decline. Third, changes in risk perception may exhibit externalities that potentially affect the entire product category. As a result, negative events may have far-reaching impact beyond firms that are directly involved (Jarrell and Peltzman, 1985), and their impact on innovation activities is also likely to be shaped by non-market forces such as regulation, the liability systems, and standard-setting organizations (Viscusi and Moore (1993); Barnett and King (2008); Berrone et al. (2013); Galasso and Luo (2017, 2018)). These features of risk perception may have important implications for the direction of technological progress, competitive advantage, and market structure.

We define innovations that reduce the probability of negative events and/or the severity of the consequences as risk-mitigating technologies (henceforth, RMTs). RMTs may take various forms, ranging from incremental to radical innovations (Henderson (1993)) and from process to product innovations (Cohen and Klepper (1996)). To examine the incentives to develop RMTs, our paper exploits a quasi-exogenous surge in risk perception that affected diagnostic medical devices emitting radiation. In October 2009, a medical center in Los Angeles disclosed that it had administered up to eight times the normal radiation dose to over 200 patients undergoing CT brain perfusion due to erroneous scanner settings caused by the hospital. We document a variety of evidence based on field interviews, industry accounts, congressional hearings, and surveys, suggesting that the extensive media coverage of this and other overdose accidents uncovered at the time increased patients' and medical providers' perceived risk of CT and other technologies using radiation.

We begin with an examination of the shock's impact on firm innovation in terms of both patenting and new product introductions. For patenting, we leverage the detailed patent classification system to define RMTs—that is, patent subclasses related to technologies aimed at protecting against radiation, controlling the level of radiation exposure, and detecting device malfunctions. Difference-in-differences analysis shows that after the shock, patenting in RMT subclasses (treatment group) experienced a large and statistically significant increase of over 100 percent relative to other non-RMT subclasses of radiation diagnostic devices (control group). We show that this surge was not driven by differential patenting trends in treated and control groups before the shock and that the finding is robust to different specifications and alternative ways to define treatment subclasses. Using non-RMT features of radiation diagnostic devices as the control group provides a direct test of the direction of technological change and can control for broad shocks affecting innovation incentives for radiation diagnostic devices. But the over-radiation shock may also affect patenting in such control subclasses negatively, leading to a potential over-estimation of the level of increase in RMT patenting. To this end, we further confirm that the increase in RMT patenting is also robust to using alternative control subclasses for which the shock's impact is likely to be more limited.

Our analysis of the FDA pre-market notifications shows that the over-radiation shock also led to an increase in new product introductions. In particular, the number of applications in radiation diagnostic devices increased significantly after the shock relative to control devices. Furthermore, using textual information extracted from the FDA application summary files, we confirm that the increase was driven by products for which radiation safety features are prominent.

We further complement our aggregate, quantitative analysis with an in-depth characterization of the nature of RMTs developed by CT producers after the shock. Specifically, we document two types of RMTs. The first type can be thought of as 'low-hanging fruit,' as the goal is to prevent over-radiation errors or

to manage dosage more efficiently without a substantial departure from existing technologies. Many of these new features, including alerts and notification systems, are implemented through a series of new standards set by the industry association. The second type of RMTs is qualitatively different because it requires a substantial departure from the method that has dominated the CT industry for the last 30 years. This alternative method involves the adoption of a long-shelved technique to reconstruct image data, which requires a significant sacrifice in speed and image quality but allows for levels of radiation dose reduction that are not achievable by simply 'tweaking' the existing technologies. This evidence is consistent with the idea that market demand can play a role in the selection and establishment of dominant designs (Utterback and Abernathy (1975)) or technological paradigms (Dosi (1982)).

A detailed firm-level analysis shows that innovation responses were industry-wide and came both from firms directly involved in the accidents and from firms that were not. We also find increased (net) entry by new players in the industry after the shock, together with an increase in the share of innovations by the largest incumbents. These patterns are consistent with the idea that changes in risk perceptions exhibit externalities and affect the entire product category, and that dominant players are well-positioned to take advantage of such market opportunities to incorporate new technologies into new products.

Having established the impact on innovation activities, we next provide evidence for our proposed mechanism: the over-radiation shock led to an increase in users' perceived risk of medical radiation, which, in turn, increased the willingness to pay for safety. Quantitatively, we document opposite effects at two different margins of demand. At the intensive margin (technology use), the number of services rendered for diagnostic procedures involving high radiation experienced a large and sharp drop after 2010. At the extensive margin (technology upgrade), however, hospitals' and clinics' propensity to replace or upgrade CT systems increased significantly after the shock relative to equipment emitting lower levels of radiation. The joint presence of a decline in usage and an increase in equipment upgrade, together with our results on innovation responses, is hard to reconcile with alternative mechanisms.

Taken together, our results show that risk perception can be an important driver of innovation and can shape the direction of technological progress. Safety-related shocks such as ours, by increasing demand for newer/safer products, may imply valuable market opportunities and create a new dimension along which firms can innovate, compete, and market their products. Large incumbents are likely to play an important role in the development and commercialization of risk-mitigating technologies, and the shock may perpetuate rather than diminish their market dominance.

2 Related literature

Our paper relates to studies on the relationship between tort liability risk and innovation. Despite much theoretical and policy attention (Huber (1989); Porter (1990); Daughety and Reinganum (1995); Hay and Spier (2005)), large-sample empirical evidence on this topic is relatively scarce. Examining a sample of large U.S. manufacturing firms in the 1980s, Viscusi and Moore (1993) find a positive relationship between product liability insurance costs and R&D expenditure, suggesting that, on average, product liability promotes rather than discourages innovation. Galasso and Luo (2017) also find a positive relationship between liability risk and innovation: on average, states passing tort reforms that decrease physicians' exposure to medical malpractice liability are associated with a significant decrease in medical-device patenting. Galasso and Luo (2018) exploit a major quasi-exogenous increase in liability risk faced by US polymer suppliers to medical implants. In contrast to the two prior studies, they show that suppliers responded by restricting input supplies, which resulted in a large and negative impact on downstream innovation in medical implants. This paper makes two contributions to the understanding of liability risk and innovation. First, while Viscusi and Moore (1993) and Galasso and Luo (2017) suggest that liabilities may incentivize the development of risk-mitigating technologies, neither paper directly measures this type of innovation. This paper characterizes and measures risk-mitigating technologies and provides direct evidence for a change in the direction of innovation. Second, it shows that even in the absence of changes in the liability rules, altered risk perception of a product may lead to changes in technological development and industry standards.

More broadly, our analysis relates to the vast economics and management literatures on the determinants and directions of technological change. Ahuja et al. (2008); Cohen (2010), and Di Stefano et al. (2012) provide comprehensive overviews of the academic debate on the sources of innovation. While Schmookler's seminal work on the primary role of market demand raised a number of important empirical and theoretical concerns, more-recent studies have made progress in addressing these issues and providing new evidence for the linkages between market demand and innovation (Acemoglu and Linn (2004); Finkelstein (2004)). While these studies mostly focus on market size and factor prices, the economics and strategy literatures on the environment have examined the innovation responses to climate change and natural disasters (Miao and Popp (2014); Popp (2019)), as well as to regulatory and normative pressures (Berrone et al. (2013)). We contribute to this line of research by examining the innovation responses to demand shifts driven by increases in the risk perception of product use.

Our paper also relates to the literature on product recalls, especially the stream of research that explores the effect on competitors who do not suffer direct costs but may experience reduced demand due to consumers' revised beliefs about the safety of the product category (Jarrell and Peltzman (1985); Borenstein

and Zimmerman (1988); Dranove and Olsen (1994); Freedman et al. (2012)).[1] We are aware of two papers on the impacts of product recalls on innovation: Ball et al. (2019) show that product recalls in medical devices have negative impacts on focal firms but positive effects on their rivals; Krieger et al. (2019), in the context of drugs withdrawn from the market, find the opposite—a positive effect on focal firms' R&D projects (mostly through acquisitions) but a negative effect on rival firms. Our paper is different from these two studies in terms of the nature of the shocks (consumer risk perception without disruptions to firms, as there are no product recalls); our focus on innovations that specifically address safety concerns; and the underlying mechanisms.

3 Theoretical considerations

Risk perceptions may have important impacts on consumer choices, especially when markets fail to provide full insurance against uncertainty (Arrow (1970)). In the context of product safety, one can think of the risk associated with the use of a product as the probability of a negative event and the severity of the consequences (e.g., minor or major injuries). Such negative events may occur to the user of the product directly or to a third party for whom the user bears the cost indirectly, such as through legal liabilities.

Often, consumers do not have precise risk information. Their choices of products and their intensity of use are based on the perception of risk. Risk perception evolves as new information is revealed over time—e.g. through personal experience, news reporting of accidents, and publication of new scientific studies. This new information can serve as either good news or bad news, leading to a downward or upward revision in risk perception. The magnitudes of these revisions depend on the precision of consumers' prior belief and the precision of the new information. Thus, a couple of fatal accidents may result in a large increase in the perceived risk associated with emerging technologies, such as driverless cars, but may have little influence on consumers' assessment of products for which rich statistical data are available.[2]

Learning about risk implies that informational shocks that increase the risk that consumers perceive about a product may generate shifts in market demand. In particular, consumers' willingness to pay for risk reduction will increase (Viscusi (1993)). If this increase in willingness to pay for safety is sufficiently large, demand changes may serve as a "pull" force for innovation and incentivize the development of RMTs (Schmookler (1966)). Conceptually, RMTs reduce the probability of negative events and/or the severity

[1] Focusing on sales and stock prices, this literature finds that the spillover effect is more likely to be present when consumers' prior of rival firms' product safety is less precise, which, in turn, depends on the stringency of government regulation, the development stage of an industry, and whether firms share common practices (Borenstein and Zimmerman (1988); Freedman et al. (2012)). The spillover effect is also more likely when regulation is more stringent as a result (Dranove and Olsen (1994)).

[2] The risk perception literature finds that individuals tend to over-assess the risks of low-probability events and under-assess that of high-probability events, and some of the over-assessed risks are those that are highly publicized (Lichtenstein et al. (1978); Slovic et al. (1982)). Viscusi (1985) shows that these patterns of risk assessment are consistent with a Bayesian learning process even with fully rational agents, unless they acquire full information about the riskiness of the product.

of the consequences. Seatbelts and airbags, for example, reduce the risk of fatal accidents in automobiles. Often, RMTs involve trade-offs between different characteristics of a product. For example, installing a speed limiter on a motorcycle reduces the likelihood of serious accidents but also reduces the pleasure that some consumers derive from high speed.

RMTs may take various forms, depending on the nature of the hazards, the magnitudes of the demand changes, and the technological possibilities. They can be incremental innovations that refine existing technologies or radical innovations that may establish new, dominant designs (Utterback and Abernathy (1975); Dosi (1982); Anderson and Tushman (1990)). Moreover, while many examples of RMTs are product innovations, process innovations—e.g., an assembly-line redesign that is more effective at identifying defects or the use of checklists during surgeries to reduce medical errors (Gawande (2009))—can also be RMTs.

While an increase in risk perception increases the willingness to pay for product safety, its impact on the overall demand for a product and, hence, on overall innovation incentives, is potentially ambiguous. In Appendix B, we make this point more formally with a model that links an increase in risk perception to innovation incentives. The framework builds on Galasso and Luo (2017) and considers products characterized by multi-dimensional heterogeneity. Specifically, products are characterized by a quality level (capturing non-safety aspects such as the speed and image quality of CT scans) and a risk level (capturing safety aspects such as the likelihood of an accidental overdose). There is a feasible set of quality-risk combinations, which captures the possible directions of development notionally allowed by science (Dosi (1982)).

In deciding which product to adopt, consumers may need to trade off safety with quality. An increase in risk perception reduces the demand for riskier products but increases the demand for safer ones. This demand shift, in turn, shapes R&D investments at both the marginal and infra-marginal levels.

Specifically, at the margin, as risk perception increases, some high-quality but riskier products that were profitable before the demand shift will no longer be developed. At the same time, some low-quality but safer products that were unprofitable before will become profitable after the demand shift and attract R&D investment. Among infra-marginal products—i.e., those attracting R&D investments both before and after the change in risk perception—there will also be an increase in the profitability of safer technologies but a decrease in the profitability of riskier ones. R&D investments will increase for the former and decrease for the latter. The combination of these opposite effects implies that, while safer technologies will experience an increase in R&D investments, the overall level of innovation may increase or decrease.

Though micro-founded to fit our empirical setting, two insights derived from the model can be quite general. First, under fairly general conditions, an increase in risk perception should induce a change in the direction of innovation investments, with safer products attracting more R&D investments relative to riskier

ones. Second, while potentially ambiguous, the overall effect on innovation is likely to be positive if the set of technological possibilities leading to safer products is sufficiently large. In other words, if the increase in risk perception takes place in a setting in which the safety of existing products differs substantially from the maximum safety level allowed by science, the increase in investments to develop safer products will dominate the decrease in innovation experienced by riskier products. Conversely, if the increase in risk perception takes place in a setting in which product safety is close to what is technologically feasible, the increased investments in safety will be dominated by the decreased investments in riskier products. This second result has broader implications for the role of demand-pull forces, suggesting that large shifts in economic, institutional and social factors may have no effect on, or even slow down, technological progress when scientific opportunities are limited.

4 Background

Computed tomography (CT) is a medical imaging method that combines multiple X-ray projections taken from different angles to produce detailed cross-sectional images of areas inside the body. Judged by primary care physicians as one of the most important innovations in medicine (Fuchs and Sox (2001)), more than 62 million CT scans were performed in 2006 in the U.S. (Brenner and Hall (2007)).

Key advantages of CT over standard X-rays and ultrasound are its superior image quality and the ability to see from different angles and planes. Contrasting magnetic resonance imaging (MRI) that delivers more-detailed images, especially of soft tissues and ligaments, CT takes seconds (instead of more than 30 minutes), is cheaper and more available, and can be used on patients with implants. A major disadvantage of CT, however, is the relatively high levels of (ionizing) radiation required. As Pelc (2014) puts it, "[A]n underlying principle of all X-ray imaging, and especially CT, is that we 'pay for' image quality with radiation dose." According to the FDA, the dose of a CT chest exam, for example, is about 350 times that of a chest X-ray.

4.1 Over-radiation accidents and extensive media coverage

On October 8 2009, the FDA warned hospitals across the countries that the Cedars-Sinai Medical Center in Los Angeles had mistakenly administered up to eight times the normal radiation to 206 patients undergoing CT brain perfusion. The error had been made a year prior to the disclosure, when the hospital had reconfigured a scanner to improve doctors' ability to see blood flow in the brain.[3]

These accidents were reported by multiple media outlets in the next few days, including the Los Angeles Times, the Associated Press, NPR, and NBC. On October 15th, Walt Bogdanich at the *New York Times*, by

[3] Alan Zarembo, "Cedars-Sinai radiation overdoses went unseen at several points," Los Angeles Times, October 14.

then a three-time Pulitzer Prize winner, reported these accidents together with a contemporaneous case in Northern California of a 2.5-year-old boy who was scanned for 68 minutes for a procedure normally taking a few minutes.[4] This was the start of a series of over 20 articles—titled 'The Radiation Boom'—on the medical radiation risk associated with imaging technologies and radiation therapies published by the *New York Times* in a span of two years.[5] Bogdanich was a 2011 Pulitzer Prize finalist for "his spotlighting of medical radiation errors that injure thousands of Americans, sparking national discussion and remedial steps."[6]

4.2 Change in risk perception

Anecdotal and survey evidence suggests that the over-radiation accidents and their extensive media coverage—which we collectively refer to as the 'over-radiation shock' hereafter—have increased the awareness levels of both patients and medical providers about medical radiation risk.

Prior to the shock, a highly-cited study based on a 2002 survey (Lee et al. (2004)) shows that 47 percent of radiologists and nine percent of emergency-room physicians believed that CT scans increase the lifetime risk of cancer; and roughly 75 percent of both groups significantly underestimated the radiation dose from a CT scan. After the shock, Boutis et al. (2014), based on a 2012 survey, show that almost all responding physicians are aware of the potential malignancy risk from a head CT, and only 25 percent underestimated the radiation dose. For patients, Zwank et al. (2014), using a 2010 survey, show that 25 percent of the patients believed that radiation from CT can increase the lifetime risk of cancer, significantly higher than the three percent reported in Lee et al. (2004). Both post-2010 studies refer to mass media coverage as a likely reason for the significant increase in patient and physician awareness.

Concerned about the public misunderstanding the nature of radiation at the dose of CT imaging and being overly fearful, the medical community stressed not to lose sight of the contributions of CT to more-effective surgeries, shorter hospital stays, and better diagnosis and treatment of cancer.[7] At the same time, it agreed that CT should be used only when appropriate (Thrall (2012)). According to Freiherr (2010), these events seem to have also led to a fundamental change in radiologists' mindset—"from requesting the highest

[4] Walt Bogdanich, "Radiation Overdoses Point up Dangers of CT Scans," *New York Times*, October 15, 2009.

[5] Radiation therapies are very different from CT imaging; they irradiate tumors with particle beams produced by linear accelerators and will result in much more severe consequences if mistakenly over-radiated. We exclude radiation therapies from both the treatment and the control groups in our analysis.

[6] Source: www.pulitzer.org/finalists/walt-bogdanich.

[7] In March 2010, a two-day national "CT Dose Summit" gathered radiologists, state and federal regulators, and CT scan equipment manufacturers. Dianna Cody and Cynthia McCollough, two of the conference organizers and medical physicists themselves, emphasized that the recent media attention might lead to "a fundamental misunderstanding of the nature of radiation." "Basic facts—a typical chest CT scan is comparable to the radiation exposure from radon gas annually emitted in the average home, for example—rarely make it into news articles. As a result, for too many people the mention of radiation connotes Chernobyl and the atom bomb," McCollough said. Source: https://medicalxpress.com/news/2010-05-medical-physicists-ct-scans-safe.html.

image quality to requesting 'good enough' images obtained with minimal radiation doses."

4.3 Subsequent events

Immediately after the disclosure of these accidents, the FDA initiated an investigation of the scanners involved. The manufacturer of the scanners involved in both sets of accidents was GE Healthcare.[8] The investigation, which concluded in October 2010, revealed more widespread overexposure: the agency became aware of about 385 patients from six different hospitals who were exposed to excess radiation; and the reported cases involved scanners manufactured by GE and Toshiba. The FDA concluded, however, that these companies had not violated FDA regulations; that is, these scanners, if used according to the manufacturers' specifications, would not result in overexposure. The FDA did, however, issue a letter to the Medical Imaging Technology Alliance (MITA), an industry association of equipment manufacturers, suggesting improvements that the industry could make to its equipment and user training.

Public concerns raised by these events also led to a congressional hearing held in February 2010 by the House of Representatives.[9] The testimonies by industry representatives emphasized innovations that the industry had already introduced—such as weight- and age-based protocols and automatic exposure control—that could help reduce the radiation dose; they were also collaborating with various stakeholders on measures to prevent future errors. Testimonies by medical professionals and researchers emphasized the importance of CT imaging and made suggestions for improving current education and accreditation programs for machine operators. During the hearing, participants discussed legislation co-sponsored by 134 members from both political parties. This legislation would require federal or state certification for personnel performing medical imaging exams or radiation therapies, but the bill was never enacted.

5 Data and methods

We investigate the impacts of the over-radiation shock on a number of outcome variables, ranging from innovation by firms, to equipment upgrade by hospitals and clinics, and to the ordering of exams by physicians. This section describes the two datasets used to examine the impacts on innovation: (i) patent applications filed at (and eventually granted by) the US Patents and Trademarks Office (USPTO); and (ii) pre-market notifications submitted to and approved by the Food and Drug Administration (FDA).

5.1 Patent applications

The USPTO assigns patents to one or more technology classes following the Cooperative Patent Classification (CPC) scheme. Our baseline analysis focuses on the 140 subclasses in group A61B6, "Apparatus for

[8] An analysis of the cumulative abnormal returns suggests a negative stock market reaction to the over-radiation news for GE but not for the other leading CT scan producers.

[9] The *New York Times* articles were mentioned eight times in the brief opening statement by Hon. Frank Pallone.

radiation diagnosis," which captures radiation diagnostic devices, including standard X-rays and CT.

Based on the class descriptions provided by the USPTO, we identify eight patent subclasses (234 patents) related to reducing radiation risk. We refer to them as RMT subclasses and allocate them to the treatment group. Two examples are A61B6/542 "Control of devices for radiation diagnosis involving control of exposure" and A61B6/107 "Protection against radiation, e.g. shielding." The complete list of treated subclasses is provided in the data appendix. In Section 6.1, we show that our results are robust to a different (keyword-based) method of defining treated subclasses. We use the remaining 132 subclasses (4,328 patents related to non-RMT features of radiation diagnostic devices) as the control group in our baseline analysis.

We assign patents to treatment versus control groups based on their primary CPC subclasses. Our baseline patent sample spans 2005-2015, as data after 2015 are sparse due to long grant delays; and we date patents using their application rather than grant year. There are 2.96 patent applications per year per subclass (Table 1, first panel), and about six percent of the observations (subclass-year) belong to RMT subclasses.

5.2 FDA premarket notifications

CT scanners and other X-ray diagnostic devices are classified as class-II "moderate to high risk" devices, for which a manufacturer intending to market in the U.S. must submit premarket notification (510k) to the FDA. The strength of the FDA data lies in the fact that they are about new product introductions and capture innovations that are not necessarily patentable. The challenge, however, is that each product may embody various features, making it difficult to separately capture RMT versus the other features of a product, as we can do with patents. In Section 6.2, we exploit the texts of the applications to help confirm that changes we detect are likely to be driven by products for which RMTs are prominent features.

The FDA classifies each product with a specific product code that identifies the generic category of the product. We define a product code as treated if it relates to radiology diagnostic devices that emit ionizing radiation.[10] There are 19 treated product codes (1,242 applications); examples include computed tomography (CT) X-ray system, emission computed tomography system (PET/CT), mammographic X-ray system, and diagnostic X-ray high voltage generator. The control group includes product codes on non-radiation diagnostic devices and all class-II devices in non-radiology medical specialties, such as orthopedics and general and plastic surgery. In total, there are 1,458 control product codes and 33,371 applications.

The panel dataset spans 2005-2017; we use the application year, not the FDA's decision year, and because approval time of class-II devices is typically a few months, we can extend the analysis up to 2017. On average, there are 1.8 pre-market notifications per year in a product code (Table 1, second panel).

[10] We identify whether a device is diagnostic based on the regulation numbers associated with a product code. Information on whether a device emits ionizing radiation is provided by the FDA Radiation-Emitting Electronic Product Codes Database.

5.3 Econometric model

Our empirical strategy relies on a standard difference-in-differences estimation:

$$Y_{c,t} = \alpha + \beta Treated_c \times After2010_t + \delta_t + f_c + \varepsilon_{c,t}, \quad (1)$$

where the dependent variable, $Y_{c,t}$, captures innovation activities in technology area c—which is defined as a subclass for the patent analysis and a product code for the FDA data—and year t. As defined above, for patents, the treatment group, $Treated_c$, includes RMT features of radiation diagnostic devices, whereas for the FDA data, it includes diagnostic devices in radiology emitting ionizing radiation. The dummy $After2010_t$ equals 1 for every year after (and including) 2010; and δ_t and f_c are year and technology-area fixed effects. The coefficient β of the interaction term $Treated_c \times After2010_t$ is the difference-in-differences estimator. We cluster the standard errors at the technology area level for all regressions.

The accidental nature of the over-radiation incidents and the rich documentation at the time provide quite convincing evidence for the exogeneity of our shock. We provide additional evidence in support of our choice of treatment timing. In the Appendix, panel (a) of Figure A1 plots the timing of news articles referring to CT scan and X-ray radiation risk, retrieved from the Factiva (Dow Jones) database. The figure shows that following the first wave of reporting in October 2009, media coverage of radiation and dosage of imaging devices spiked in 2010. Panel (b) of the same figure shows that, relative to control devices, the average number of months that the FDA took to approve an application increased substantially for radiation diagnostic devices starting from the fourth quarter of 2009. This is consistent with the idea that the regulator scrutinized these devices more after the shock. Lastly, panel (c) plots the Google search trend for the term "CT scan radiation," which also suggests that public interest became more intense after late 2009.

6 Innovation responses to the over-radiation shock

6.1 Patent applications

Figure 1 compares the average number of patent applications between RMT and non-RMT subclasses in radiation diagnostic devices. It provides a first look at our main result: patenting in control subclasses was stable throughout the period, whereas patenting in RMT subclasses was stable before 2009, dropped slightly in 2009 and 2010, and increased substantially after 2010.

Table 2 presents the difference-in-differences estimates specified in equation (1). Column 1 shows that after 2010, patenting in RMT subclasses experienced an average increase of 1.78 patents per year relative to control subclasses (p-value is 0.029). Assuming the same difference between the two groups before and

after 2010, the hypothetical average number of patents for RMT subclasses would have been 1.63 per year after 2010. This implies that the increase in RMT patenting after 2010 was about 110 percent. Column 2 produces a similar estimate, dropping subclasses with zero patents during the entire sample period. Column 3, following Moser and Voena (2012), shows that our baseline result is robust in an unbalanced panel that includes only observations for which we observe at least one patent in this subclass in previous years.

Because the over-radiation shock involves CT scanners, we expect the surge in RMT patenting to be driven mostly by CT technology. We define CT patents as those referring to subclass A61B6/032, "Transmission computed tomography [CT] ," as either primary or secondary classification. The DID coefficient of this much smaller sample is reported in column 4 of Table 2. The estimate is economically large (corresponding to an increase of about 300 percent), with a p-value of 0.07. This result supports our interpretation that the increase in RMT patenting is related to the over-radiation shock.[11] Appendix Table A1 shows that our results are robust to a number of different specifications, including models addressing the skewed and count nature of our dependent variable, such as Poisson and negative binomial.[12]

A potential concern is that RMT subclasses have been identified based on our interpretation of the subclass description. As an alternative approach, we identify RMT subclasses using a keyword method. We first construct a dictionary of keywords related to dose and radiation control (e.g., "dose control," "reducing radiation," and "X-ray exposure;" see the full list of keywords in Appendix C). We then classify a patent as an RMT patent if its title contains at least one of the keywords. We compute the fraction of RMT patents in each subclass based on all patents in radiation diagnostic devices applied between 1975 and 2015, and we define the treatment group as subclasses for which this fraction is above a certain threshold. Appendix Table A2 confirms our baseline result, using various threshold definitions.[13]

6.1.1 Pre-treatment trend and time-specific treatment effects

Figure 2 plots the year-specific differences between the treatment and control groups, β_t, and their 95-percent confidence intervals based on the following specification (2009 is the baseline year):

$$Patents_{c,t} = \alpha + \sum_t \beta_t RMT_c \times Year_t + \delta_t + f_c + \varepsilon_{c,t}. \quad (2)$$

[11] The difference-in-differences coefficient in a fixed effects Poisson model is 1.368 and significant at the 0.01 level.

[12] Recall that we allocate patents to treatment and control groups based on their primary subclasses. We confirm our baseline result also using a patent's secondary classification. In 2005-09, nine percent of the patents in A61B6 listed an RMT subclass as a secondary classification (but not as the primary classification), whereas 19 percent did so between 2010 and 2015. Appendix Table A3 reports a series of patent-level regressions confirming this increase. Furthermore, the unique number of primary subclasses for which an RMT subclass was listed as a secondary classification by at least one patent increased from 52 to 93, suggesting that risk mitigation had become a more prevalent feature across different types of radiation diagnostic devices.

[13] Unreported results also confirm that these results are not driven by any single most-frequently used keywords.

Before the over-radiation shock, the estimated differences between treatment and control subclasses are not statistically different from those in 2009; the year-specific difference-in-differences coefficients after 2010 are positive and increasingly larger, and they become statistically significant in 2013.

6.1.2 Alternative control groups

The control group in our baseline analysis provides two main advantages. First, contrasting RMT with non-RMT features of radiation diagnostic devices is the most direct way to test the hypothesis that risk perception affects innovation incentives and shapes the direction of technological progress. Second, an analysis within radiation diagnostic devices allows us to control for broad, unobservable shocks that may affect all features of radiation diagnostic devices. Accounting for such confounding factors would be more difficult with a control group that is technologically more distant. Specifically, with a more distant control group, a relative increase in RMT patenting may not capture a change in the direction of innovation because patenting on non-RMT features of radiation diagnostic devices might have increased even more.

Our baseline control group, however, may be subject to spillover effects for a number of reasons. First, because the market is highly concentrated, many firms are active in both treatment and control groups.[14] If these firms are subject to budget constraint, they may move resources away from non-RMT to RMT technologies, leading to an over-estimation of the level of increase in RMT patenting. Second, the heightened fear about radiation may chill innovation in radiation diagnostic devices overall, also leading to a large drop in non-RMT patenting. Empirically, these spillovers imply that the control group may also be affected by the shock and affect the interpretation of the difference-in-differences coefficients in our baseline analysis.

In this section, we show that our main finding is robust to using alternative controls for which spillover concerns discussed above are limited. Specifically, we use two alternative control groups. The first (column 1 of Table 3) includes non-radiation diagnostic devices such as MRI and ultrasound (CPC groups 'A61B5' and 'A61B8'). This control group is less likely to experience a substitution effect if firms allocate budgets and personnel relatively independently across technology groups. Note that demand-side spillover may still be at play if the shock induces hospitals and clinics to increase the use of non-radiation diagnostic tools.[15] Such contamination is less concerning, however, as it should increase innovation in these substitute products and make our difference-in-differences coefficient more conservative. To further mitigate potential supply-

[14] 87 percent of RMT patents and 68.36 percent of non-RMT patents in radiation diagnostic devices are by 37 unique assignees that patent in both groups.

[15] This is consistent with our theoretical model, in which an increase in risk perception generates an increase in the profitability of all products safer than the current standard (both safer radiation diagnostic devices and substitute non-radiation devices). To see this empirically, we run a series of difference-in-differences regressions and find a ten-percent increase in patents and FDA applications for MRI and ultrasound, though the estimates are significant only for patents. These results are consistent with a demand increase for substitute non-radiation diagnostic tools. At the same time, the relatively smaller magnitude relative to the innovation response in radiation diagnostic devices suggests that it was more profitable to improve the safety of radiation technologies than to develop substitute non-radiation devices.

side and demand-side spillovers, we employ the second alternative control group (column 3 in Table 3) consisting of medical implants such as replacement joints and pacemakers (CPC subsection 'A61F'). These devices are not substitutes for radiation diagnostic devices and are technologically very different.

To further isolate any spillover effects due to firms patenting in both treatment and control groups, we also use more-restrictive specifications that exclude patents by these common patentees from the analysis. When using non-radiation diagnostic devices as the control group, because the percentage of RMT patents by common patentees is still very high at 80 percent, we exclude patents by common patentees from only the control group (column 2 in Table 3).[16] When using medical implants as the control group, in addition to excluding patents by the common patentees from the control group (column 4), we go a step further and exclude such patents from both the control and the treatment groups (column 5). The last specification is still very stringent, as 56 percent of the RMT patents are excluded due to common patentees.[17]

The results across all columns in Table 3 confirm a relative increase in RMT patenting after the shock; the estimates are statistically significant at least at the ten-percent level. Assuming the same average difference between the treatment and control groups before and after 2010, the difference-in-differences coefficients of the first four columns represent an increase of between 56 and 87 percent. Even for the last column, in which we exclude more than half of the RMT patents, the increase is still 36 percent (p-value is 0.073).

6.2 FDA pre-market notifications

In this section, we present difference-in-differences estimates on new product introductions using the FDA data. The dependent variable in column 1 of Table 4 is the number of 510k applications in a product code-year. Recall that our treatment group includes the 19 product codes of radiation diagnostic devices, and the control group includes non-radiation diagnostic devices in radiology and all class-II devices outside radiology. The result shows that after 2010, the number of applications in treated product codes increased by 1.25 per year relative to the control group (p-value is 0.07). This increase represents a 30-percent difference, assuming the same difference between the treatment and control groups before and after 2010.

In columns 2 and 3, we use the same control group as in column 1 but focus on two specific sub-samples of the treatment group: column 2 excludes devices emitting high levels of radiation from the treatment group, whereas column 3 excludes devices emitting low levels of radiation.[18] Though not statistically different from each other, the difference-in-differences coefficient in column 3 is substantially greater in magnitude

[16] 14.08 percent of the control patents are by common patentees.

[17] Even with medical implants as the control group, the percentage of RMT patents by common patentees is still quite high because of the sheer size of the large conglomerates that patent in the treatment group, so that they are likely to have some patents in other medical areas, no matter how remote. Only 0.49 percent of the control patents are by common patentees.

[18] To distinguish between devices with high or low radiation levels, we follow the FDA 2010 White Paper that lists computed tomography (CT), fluoroscopy, and nuclear medicine imaging exams (such as a positron emission tomography (PET) scan) as imaging procedures with relatively high radiation levels, versus other radiation-emitting procedures such as standard X-rays.

and more statistically significant than that in column 2, consistent with the idea that the increase documented in column 1 is driven mainly by devices more affected by the over-radiation shock.

To provide additional evidence that the increase in applications in the treatment group is, indeed, linked to the over-radiation shock, we further identify applications that emphasize radiation safety features. In particular, for each application in the treatment group, we search for the keyword 'dose' in the "Summary of Safety and Effectiveness." Example phrases including this keyword are 'dose check,' 'dose efficiency,' and 'dose reduction.' Overall, 18 percent of the 1,242 applications include this keyword. The regression in column 4 counts only applications in a treated product code that did not mention 'dose' in their summary files, and column 5 counts only applications that did; and the dependent variable of the control group is the same as in previous columns. The coefficient in column 4 is small and statistically insignificant, whereas that in column 5 is large and significant at the 0.05 level. This contrast further corroborates the idea that the increase in radiation diagnostic devices is associated with a stronger emphasis on dose and radiation control.

Column 6, building on column 5, further excludes from the control group non-radiation diagnostic devices (substitutes for our treated devices) that may have experienced potential demand-side spillover effect. The estimate confirms the result in column 5. Based on the sample in column 6, Appendix Figure A2 examines the timing of the effect of the 2010 shock. There is no evidence of pre-trends: the coefficients before 2010 are small and statistically insignificant. The relative number of treatment group applications that include safety features began to increase after 2010, with an increasing magnitude over time.[19]

Overall, the FDA data show an increase in the number of new products after 2010 for radiation diagnostic devices and that this increase was driven by applications explicitly referring to radiation control. It is worth noting that, because there is typically a delay between invention and commercialization, the relative fast response in product introduction (as illustrated in Figure A2) suggests that the response in the short run was likely to have been based on non-patentable technologies (therefore, not captured by the patent data) or on patentable technologies that were readily available prior to 2010. In the next section, we provide a detailed description of RMTs in the case of CT scanners that is consistent with this interpretation.

6.3 Characterizing RMTs: the case of CT scanners

Based on field interviews, industry and clinical publications, and textual analysis of FDA applications, we uncover two types of RMTs that were developed after the shock.

[19] Appendix Table A4 confirms the robustness of our findings to a number of alternative specifications, including alternative econometric models—using the logarithm of (one plus) the number of applications as the dependent variable or a Poisson model.

6.3.1 Progress along the existing, dominant technological path

The first type of RMTs appeared to tackle 'low-hanging fruit,' in the sense that the goal of the improvement was to prevent radiation overdose or to manage dosage more efficiently. These innovations, though important, did not require substantial R&D investment or departure from existing technologies. Examples include dose display; alert and notification systems for dose exceeding pre-assigned thresholds; standardized dose recording softwares; and redesigned use protocols for certain procedures (Mahesh (2016)). These safety-check features are consistent with the FDA's recommendations after its investigation of the over-radiation accidents and were implemented through a series of new standards set by the industry association.[20,21]

6.3.2 Change in the technological path

The second type of RMTs involved a substantial departure from the existing technological path (Utterback and Abernathy (1975); Dosi (1982); Anderson and Tushman (1990)). The technology allows for a reduction in radiation dose of up to 90 percent, which is not achievable by simply 'tweaking' the existing technologies.

Specifically, the change involves shifting away from the dominant method of image reconstruction to an alternative (long-shelved) method. For over 30 years, the dominant method had been filtered back projection (FBP), which projects X-ray data 'linearly' into image data (Ramirez-Giraldo et al. (2018)). Although FBP is fast and robust, the image resolution is strongly dependent on the dosage used; in other words, "we 'pay for' image quality with radiation dose" (Pelc (2014)).

An alternative approach, called 'iterative reconstruction (IR),' starts with an initial guess of an object and iteratively improves on the initial estimate through a dynamic optimization process (Mayo-Smith et al. (2014)). This 'non-linear' methodology breaks the strong dependence of noise on radiation dose and, therefore, allows for substantial reductions in radiation dose (Pelc (2014)). IR was first introduced when CT was invented in the 1970s, but it was shelved due to its high computational intensity: IR took about 45 minutes to reconstruct a single slice, while FBP could process slices in 30 seconds.[22] Our interviews with industry practitioners, along with industry white papers and clinical publications, suggest that CT manufacturers invested in and marketed IR algorithms heavily after the over-radiation shock.

It is important to note that IR algorithms involve a substantial reduction in other quality aspects, at least initially. These include a slower speed even with today's computing power; low image quality for

[20]The FDA's recommendations in its 2010 letter to MITA, the industry association, include providing particular information and training on high-risk procedures; clarification and recommendations of parameter settings; pop-up notification at threshold to alert the operator of high radiation dose; and user-accessible organization of dose-related information. Source: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm232551.htm.

[21]MITA published the CT Dose Check standard in October 2010. The 2013 XR-28 standard explicitly responded to the FDA's recommendations. Both standards became a part of a later MITA Smart Dose standard (XR-29, 2013).

[22]Dave Fornell, "Iterative Reconstruction 101," Imaging Technology News, July 23, 2013.

certain clinical applications; an 'over-smoothed' and 'artificial' appearance that makes the images difficult to interpret and require retraining of radiologists (Ramirez-Giraldo et al. (2018)). According to one estimate, radiologists needed about 90 days to adjust to the new image texture.[23]

6.3.3 Textual analysis of the FDA application summary files

To provide quantitative evidence for the two types of safety features described above, we conduct a textual analysis using the 294 FDA applications filed between 2005 and 2017 in product code JAK, "Computed tomography X-ray system." For each application, we examine all phrases in the application summary file that include the term 'dose,' and we determine, based on keywords used together with 'dose,' whether the product (i) achieves a substantial dose reduction relative to previous products; and/or (ii) provides safety checks or tools to manage radiation dose more efficiently.

Appendix Figure A3 shows that both types of safety features were rarely mentioned in the application summary files before 2010, whereas they were increasingly more likely to appear afterwards. Between 2014 and 2017, for example, 37.5 percent of all applications mentioned dose check or efficiency, and 25 percent mentioned dose reduction. The lower percentage of dose-reduction mention is consistent with the idea that such features require more substantial investment than do features related to dose efficiency or dose check.

The same figure also illustrates an increasing adoption of the IR method after 2010. Overall, 52 percent of all CT systems adopted after 2010 included an IR option, and 20 percent of the software packages were specifically related to this method. Moreover, all 118 applications after 2010 without an IR option failed to mention 'dose reduction,' whereas 38 out of 66 applications that included an IR option did mention the term, consistent with our understanding that substantial dose reduction is achievable only with the IR method.

6.4 Firm-level analysis and impacts on market structure

In this section, we provide a firm-level analysis that confirms the technology-area level analysis and provides insights into how safety-related shocks affect the competitive dynamics and market structure. We distinguish among the top-five firms—the two largest are GE and Siemens, followed by Toshiba, Philips, and then Hitachi—and smaller players, including smaller firms, research entities, and individuals.[24]

We report three sets of results. First, columns 1-3 of Table 5 report firm-level patent regressions. The unit of analysis is firm-patent subclass-year, and the regressions include year, firm, and subclass fixed effects. The control group, non-RMT subclasses of radiation diagnostic devices, is the same as in our baseline

[23] "Iterative Reconstruction in CT: What Does It Do? How Can I Use It?" by William P. Shuman, November 2010, Image Wisely, American College of Radiology.

[24] The top five firms comprised the CT group of the industry association MITA at the time of the shock; and they had the highest numbers of patents in radiation diagnostic devices during the pre-sample period 1995-2005. According to the IBISWorld Procurement Report, these five firms had the largest market shares in 2014: GE and Siemens each had 20-25 percent shares of the U.S. market; Toshiba 15-20 percent; Philips 10-15 percent; and Hitachi less than five percent.

analysis. Column 1, using all firms, confirms the significant increase in RMT patenting after the shock.[25] Columns 2 and 3 examine the top-five firms and smaller players separately: the increase for the largest five firms represents a 280-percent difference, while that for smaller players represents a 110-percent increase. In Appendix Table A5 (panel a), we run the same regression for each of the top five firms individually. The difference-in-differences coefficients are all positive and economically large: they are significant for the largest firms; for Toshiba and Philips, the estimates are less precise (p-values are 0.101 and 0.148).

Columns 4-6 of Table 5 provide an analogous analysis of FDA applications in which the unit of analysis is firm-product code-year. Column 4 confirms a significant increase for the number of FDA applications in radiation diagnostic devices, relative to control devices outside radiology. Column 5 shows that the increase is large and significant for the five largest firms, representing a 60-percent difference; the change is economically smaller for smaller players, though still at 31 percent, and less significant (p-value is 0.144). Individual regressions for the top-five firms (Appendix Table A5, panel b) show a similar pattern across the largest four firms, though the estimates are noisy.

Second, Appendix Figure A4 examines firms' responses in terms of the two types of RMTs that we identified for CT scanners: large and small players appear similar in their responses through incremental features such as safety checks and dose-efficiency management, but responses by large firms were faster and more intense for more-complex technologies that can reduce dose– in particular, the development and implementation of IR algorithms. A further breakdown in Appendix Figure A5 shows that the two largest firms—GE and Siemens—were the fastest in incorporating IR in 2010, Toshiba and Philips responded in 2011, and Hitachi, the smallest of the top-five, in 2015.

Third, the above firm-level panel analysis uses firms already in the market before the shock. Appendix Table A6 provides some (weak) evidence for more entry in radiation diagnostic devices after the shock, relative to control product markets. The number of new entrants increases by about 35 percent (p-value = 0.210), and the unique number of firms active in the market also increases (by 26 percent, p-value = 0.051), indicating an increase in net entry.

To summarize, the results in this section illustrate the following two patterns: (i) innovation responses in RMTs appear to be industry-wide, and the positive response is observed both for firms that were directly involved in these accidents (GE, in particular, and Toshiba) and for firms that were not (e.g., Siemens and Philips); and (ii) together with a greater net entry by new players in the industry, the shares (of innovations, at least) for the largest incumbents seem to have increased. Though not definitive, these results are consistent with the idea that CT producers, overall, might have benefited from the market opportunities created by the increased demand for newer/safer technologies, at least in the medium run. Moreover, the over-radiation

[25] Including firm-specific linear year trends produces a very similar coefficient, 0.148, and standard error, 0.068.

shock appears to have perpetuated the market dominance of large incumbents, rather than diminishing it. This conjecture is supported by the 2014 IBISWorld Procurement Report, which shows that the market shares of the largest players in the U.S. increased between 2011 and 2013.

A number of factors may explain these patterns. First, as discussed previously, information shock on product safety is likely to exhibit externalities and to affect the entire product category—in particular, the demand of mainstream customers served by large incumbents. Thus, conditions often characterized in theories such as disruptive innovation—that is, the innovation is initially not valued by mainstream customers—are not satisfied in our context (Christensen and Bower (1996)). Second, the types of RMTs described in Section 6.3 do not fit a situation in which incumbent firms are less competent to respond in terms of organizational capabilities or resources (Henderson and Clark (1990)). In contrast, large incumbents in our setting are well-positioned, in terms of R&D resources and marketing and distribution capabilities, to develop and incorporate these RMTs into their products.

Lastly, it is worth pointing out that our results differ from most of the product-recall literature that tends to find negative effects on the focal firms. This may be partly because the news reporting was clear from the beginning that the accidents were due to technician errors, and because the FDA investigation quickly concluded that the focal companies had not violated any regulations. Thus, different from Ball et al. (2019), operational or financial disruption for the focal firms was limited in our setting.

7 Demand effects of an increase in risk perception

The above analysis shows that the over-radiation shock led to a significant increase in innovation activities in terms of both RMT patenting and new products. In this section, we provide direct evidence for our proposed mechanism—i.e., higher risk perception increases the willingness to pay for safety—by unbundling the shock's impact on demand.

As in most medical settings, the demand side of diagnostic devices involves multiple players. The key decision makers regarding the use of diagnostic technologies—i.e., the intensive margin of demand—are physicians who prescribe exams. They (at least partially) internalize the radiation risk because they care about their patients and want to avoid the liability costs associated with overuse and accidents. The key decision makers of equipment upgrade—i.e., the extensive margin of demand—are managers of hospitals and clinics, who may demand safer machines to reduce the liability costs of errors and to account for the preferences of their physicians and radiologists.

Survey and anecdotal evidence presented in Section 4 shows a significant increase in risk perception by all of these parties after the shock. In the following, we show a large decline in the number of high-radiation imaging exams; at the same time, hospitals and clinics exhibit a greater propensity to upgrade equipment

that emits high levels of radiation. These opposite effects at the intensive and extensive margins, together with our findings on innovation, are hard to reconcile with alternative explanations.

7.1 Equipment use

The Medicare Part B National Summary data provide the total number of imaging services rendered to Medicare beneficiaries (people older than 65) in a procedure-year. Procedures are defined by 'current procedural terminology' (CPT) codes, which specify the technology, organ, and techniques (e.g., CT chest without contrast). To construct a balanced panel, we keep codes present throughout 2005-2017. This leaves 340 codes in seven diagnostic technologies (e.g., CT and MRI), corresponding to 76 percent of the total number of services rendered in this time period. The final dataset includes 4,420 year-procedure observations.

Columns 1-2 in Table 6 present the difference-in-differences coefficients for the logarithm of the number of services provided, controlling for CPT and year fixed effects. Column 1 compares high-radiation procedures (including CT, PET/CT, and fluoroscopy) to low-radiation X-rays; and column 2 uses non-radiation procedures—MRI and ultrasound—as the control group. The results show that, relative to control procedures, the number of high-radiation procedures dropped significantly after 2010 (by about 20 percent). (Unreported) regressions confirm these results using only control procedures that match treated, high-radiation procedures in terms of pre-trends. Appendix Figure A6 plots the year-specific effect of the over-radiation shock on high-radiation procedures relative to matched control procedures of MRI and ultrasound. The figure shows little pre-trend, a slight drop in 2010 and 2011 (p-value=0.115), and a large and significant decline starting in 2012 that had yet to recover as of 2017.

Five of the six hospitals involved in the FDA investigation were located in California and one in Alabama. Appendix Table A7 reports triple-differences regression results using state-level Medicare data.[26] The results show that the relative decline in high-radiation procedures was significantly more pronounced in the two states with hospitals directly involved in the FDA investigation, providing further support for the link to the over-radiation shock. The results also show a general decline in high-radiation procedures even in other states. This is not surprising given the negative externality of product-safety information, the mass media attention, and the subsequent national-level conversation about radiation safety.

We also cross-validate the above result with an alternative dataset provided by the Organization for Economic Co-operation and Development (OECD).[27] Appendix Figure A7 (panel a) shows that in the U.S., relative to MRIs' increasing trend throughout our sample period, CT broke the increasing trend in 2012

[26]Columns 3 and 4 in Appendix Table A7 include control variables for state liability laws (cap on non-economic damages and joint and several liability rule) and political preferences (a dummy indicating Republican-controlled government and legislature). All the regressions also include all the double-interaction terms.

[27]The downside of the OECD data is that they are extrapolated from surveys covering only about 200 sites. On the positive side, the data include services for patients of all ages, unlike the Medicare data, which cover only the elderly.

and declined afterwards. Relative to the peak in 2011, the average number of CT exams between 2012 and 2017 represents a ten-percent reduction, a likely underestimation because it does not take into account the hypothetical continuation of the increasing trend in the absence of the over-radiation shock.[28]

Overall, results in this section show a relative decline in high-radiation procedures after the shock. The slower growth of CT use has also been documented by the medical literature, which also suggests that fear of radiation was an important factor (Lee and Levy (2012)). Of course, the decline in high-radiation procedures could have been driven by drops in Medicare payments. We examine this alternative explanation in a series of (unreported) difference-in-differences regressions and find no evidence for differential drops in the payment for high-radiation procedures after 2010, relative to control procedures.[29]

7.2 Equipment upgrade

The key data source for equipment upgrade is the X-ray assembler dataset provided by the FDA. Manufacturers of X-ray systems are required to file reports upon installation of a certifiable system or component(s). A key limitation of this dataset is that it contains only X-ray equipment and lacks non-radiation equipment such as MRI or ultrasound. Thus, we compare the propensity to upgrade CT equipment to that of chest X-ray and dental X-ray equipment, based on the fact that radiation exposure from CT is substantially greater than that from standard X-rays and is in line with our finding that the use of low-radiation X-ray devices was less affected by the shock. We identify reports that are likely to capture the installation of new CT systems or substantial upgrades of existing CT systems as reports for which the intended use of the components is "CT whole body scanner" and for which the installation involves at least three major components (X-ray control, high voltage generator and tube housing). With a similar approach, we identify records that are likely to capture replacement or substantial upgrades of control devices: non-fluoroscopic chest X-ray and dental X-ray systems. The final sample is based on 6,161 CT assembly reports and 4,389 chest X-ray and 2,246 dental X-ray assembly reports for 2008-18 (data before 2008 are not systematically available).

We generate a balanced panel in which the unit of observation is a site-equipment type-year.[30] Column 3 of Table 6 contrasts the number of assembly reports on CT systems versus chest X-ray systems, controlling for year and site$\times$equipment type fixed effects. The result shows that, within a site, the propensity to replace or upgrade a CT system after 2010 exceeds that for a chest X-ray system; and the magnitude of the coefficient is equivalent to a 25-percent difference. Column 4 shows a similar result contrasting CT systems

[28] Appendix Figure A7 (panel b) shows no decline in CT relative to MRI exams in other OECD countries after 2010, which is different from the general decline in the U.S. This may have been driven by a multiplicity of factors, including differences in the intensity and scope of media coverage and regulatory scrutiny; different levels of CT use before the shock; and heterogeneity in the medical and liability systems.

[29] Relative to MRI and ultrasound, payments for high-radiation procedures actually increased by nine dollars after 2010, though the difference is not statistically significant.

[30] Sites (hospitals or clinics) are defined as unique combinations of firm name, city and state in which the equipment is installed.

with dental X-ray systems.

Similar to the equipment use analysis, Appendix Table A8 reports triple-differences results exploiting the location information of these sites. The results also show a general increase in the propensity to upgrade CT systems after 2010 for hospitals (or hospitals located in states) not directly involved, but the magnitude is significantly larger for the six hospitals under investigation (or hospitals located in California and Alabama, the two states in which the six focal hospitals are located).

In principle, the higher propensity to upgrade CT scanners could have been a result of lower prices charged by CT producers. Historical CT prices turn out to be very difficult to obtain. The only information we were able to find is from the 2014 IBIS Procurement Report, which estimates that the benchmark price of CT scanners had been, instead, rising monotonically between 2005 and 2014.[31]

7.3 Qualitative evidence

The above results are consistent with our hypothesis that the over-radiation shock substantially increased users' willingness to pay for safer machines. In this section, we provide qualitative evidence that links such demand changes to the development of the RMTs we described in Section 6.3.

First, our interviews with two industry insiders familiar with these events made it quite clear that CT producers ultimately responded to market demand. One interviewee pointed out that CT producers had always been conscious of radiation dose and had been innovating to address these concerns. However, before the shock, the most important request from physicians and radiologists was to 'see more stuff,' while dose control had been a secondary consideration.[32] Only after the accidents did the demand for safety-related features became a first-order consideration.[33] As discussed in Section 6.3, to adopt these new technologies hospitals faced non-trivial costs for adjusting their operational routines and retraining radiologists, and it took the producers several improved versions to address drawbacks in image quality and speed of the IR technology. A substantial demand shift (and, hence, the willingness for the users to incur such adoption costs) seemed necessary for CT producers to develop these technologies profitably.

Second, there is also direct evidence of users' requests for safer machines. The CEO of Cedars-Sinai Medical Center—where the adverse events took place—submitted a written document to the FDA immediately after the disclosure of the accidents. The document listed suggestions for changes to CT machines, such as dose display, alerts, and password protection that can prevent radiation overdose, which are exactly

[31] "IBISWorld Procurement Report: 30105050 CT Scanners," by Keiko Cadby, July 2014, IBIS World.

[32] As summarized in Pelc (2014), "historically, the main drivers for technological improvements have been the physicians' demand for improved image quality, speed, and new clinical applications."

[33] This is clear from various historical sources that we identified. The following quote is just one such example: "Radiation dose will be an enormous topic over the next five years," stated David Waldman, chair of the imaging sciences department at University of Rochester Medical Center, in an interview with Diagnostic Imaging in December 2010.

in line with the 'low-hanging fruit' type of RMTs later developed by producers.

Finally, there is also evidence that RMTs are mentioned in marketing messages by hospitals to mitigate their patients' fear. For example, the Ridgeview Imaging Center in Minnesota, a testing site of Siemens' machine equipped with the IR option, displayed this technology on its website as "providing patients with the lowest-possible radiation dose;" and David Gross, the center's chief of radiology, told Diagnostic Imaging that "our referring docs know that we have done as much as we can to reduce the radiation given to the patient" and that "this is a real selling point."[34] CT producers also explicitly highlighted the dose-reduction aspect of IR technologies in addressing their customers—physicians and hospitals. For example, the front page of GE's product brochure for Veo—the second generation of its IR algorithm—prints the following in large font: "The breakthrough that is rewriting the rule of CT imaging." On the next page, it says that the new technology allows "enhanced image quality at a radiation dose never before thought possible."

7.4 Alternative mechanisms

This section discusses three alternative mechanisms for our findings.

Regulatory pressure It is possible that the development of the RMTs was driven mainly by regulatory pressure. The evidence reported in the previous section suggests that regulatory prescriptions were mostly internalizing requests from users. Moreover, in Section 6.3.1, we discussed how the FDA's recommendations and the new standards developed by the industry association involved only the 'low-hanging fruit" type of RMTs. Thus, while regulatory pressure may have facilitated the diffusion of safety-check features of CT scanners, it cannot quite explain the second type of RMTs—IR technologies—which go far beyond regulatory prescriptions.

Changing guidelines for medical practice Medical societies and associations may also have changed their guidelines in response to the over-radiation shock and, hence, shaped demand. An analysis of the recommendations by medical associations show that they focused mainly on the organizational aspects of radiation facilities, such as the development of routines for systematic protocol reviews, techniques to identify and correct errors, and qualification requirements for CT technicians (Hendee and Herman (2011)). The few recommendations to vendors focused only on safety-check features (not IR), in line with demands from patients and medical providers.

Increased risk perception by CT producers The over-radiation shock may have changed risk percep-

[34] "Iterative reconstruction cuts CT dose without harming image quality," by Greg Freiherr, December 14, 2010, Diagnostic Imaging. Similarly, Leslee Shaw, the co-director of the Emory Clinical Cardiovascular Research Institute, stated in an interview: "There is a lot of concern today about the overuse of CT and overexposure of patients to radiation. So, having as a marketing piece that you are very concerned about patient-centered imaging and safety, and that you are using new technology to decrease dose—that is something you can make a great business case for. Or, to tell people that you are updating your technology to look precisely for improved patient care." Source: https://www.dicardiology.com/article/what-consider-when-buying-new-ct-scanner.

tion among CT producers, which, in turn, could have spurred the development of these RMTs. As discussed above, our interviews suggest that CT producers had always been conscious of potential risks of radiation, as dose information is clearly measured and should have been known to CT producers and other specialists (Lee et al. (2004) show that radiologists, who are specialists, were more aware of such risk than patients and even physicians prior to the shock). Our reading of the scientific literature suggests that the evidence moved only slightly in favor of an association between CT scans and cancer risk over our sample period, with epidemiological cohort studies published after 2012 and subject to criticisms (Harbron (2016)). Thus, new scientific results are unlikely to explain the swift reactions of the industry in incorporating RMTs.[35]

8 Conclusion

In this paper, we examine the impact of changes in risk perception on innovation, taking advantage of the disclosure and the extensive reporting of a set of unexpected CT scan over-radiation accidents in late 2009. Our results show significantly increased patenting of features of radiation diagnostic devices that mitigate radiation risk, relative to other features—on the order of 110 percent. Using FDA data, we find a significant increase in the number of new applications for radiation diagnostic devices, driven by products for which radiation control features are prominent. For the underlying mechanisms, we provide survey, interview, and other qualitative evidence suggesting that risk perception by users (physicians, radiologists, hospital administrators, and patients) changed substantially after the over-radiation shock. Quantitatively, we find that the shock led to (i) fewer high-radiation diagnostic procedures performed; and (ii) a greater propensity to upgrade CT scanners. These opposite effects on device use and equipment upgrade are consistent with the idea that changes in risk perception played an important role in driving firms' innovation investments.

Ultimately, our paper suggests that changes in risk perception can be an important driver of innovation and can shape the direction of technological progress. Increased risk perception, in principle, has ambiguous effects on the demand for a product. In settings such as ours—in which there are sufficiently large technological possibilities to develop safer technologies—the positive effect of a higher willingness to pay for safety may dominate the chilling effect that risk has on innovation. Finally, large players may play an important role in the development and, even more so, in the commercialization of risk-mitigating technologies, and this has important implications for the dynamics of competitive advantage and market structure.

[35] Of course, it could be that CT producers' perception of their liability risk increased after the shock. However, liability risk is tightly linked to industry standards and regulatory requirements, which prescribed only safety-check features and not more substantial dose-reduction technologies as IR.

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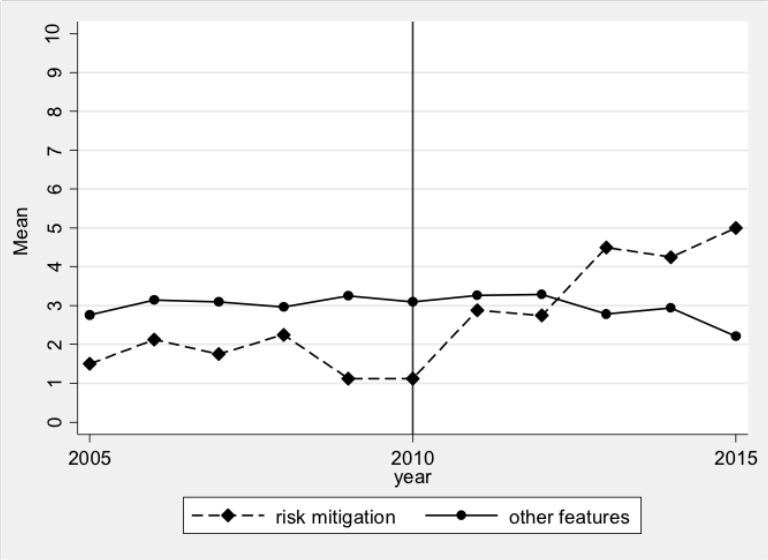
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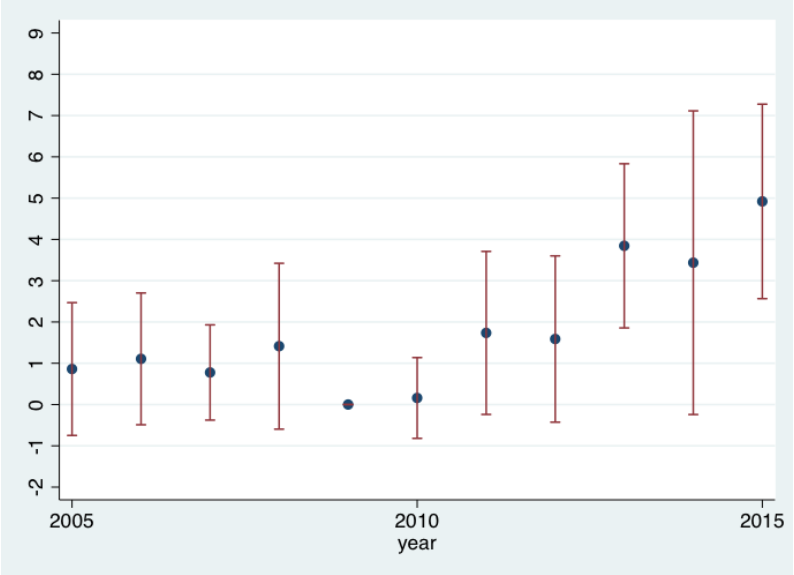
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Figure 1: Patenting in RMT subclasses vs. other subclasses in radiation diagnostic devices



Note: raw data. Average number of patents in risk-mitigating technology subclasses versus other subclasses in radiation diagnostic devices (i.e., CPC group A61B6).

Figure 2: Dynamic effects of the over-radiation shock on patenting



Note: year-specific DID coefficients estimated from equation (2). The treatment group includes RMT subclasses, and the control group includes other subclasses in radiation diagnostic devices (i.e., CPC group A61B6).

Table 1: Summary statistics

(a) Patent applications

	Obs.	Mean	Std. Dev.	Min	Max
Patents	1540	2.962	6.185	0	97
Year	1540	2010	3.163	2005	2015
RMT subclass	1540	0.057	0.232	0	1

(b) FDA applications

	Obs.	Mean	Std. Dev.	Min	Max
Applications	19,201	1.803	5.331	0	110
Year	19,201	2011	3.742	2005	2017
Ionizing diagnostic devices	19,201	0.013	0.113	0	1

Note: Patents = the number of patent applications in a subclass-year. RMT subclass = 1 for subclasses reducing the risk of over-radiation, controlling the level of patient exposure, and detecting faults or malfunctions. Applications = number of class II 510k applications in a product code-year. Ionizing diagnostic devices = 1 for product codes related to diagnostic devices in radiology that emit ionizing radiation.

Table 2: Effects of the over-radiation shock: patent analysis

Dependent variable	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)
RMT × After 2010	1.783**	1.785**	2.650**	0.828*
	(0.809)	(0.814)	(1.166)	(0.456)
Year effects	Y	Y	Y	Y
Subclass effects	Y	Y	Y	Y
Note	Baseline	Drop if all zeros	Start at first patent	Only CT patents
Observations	1540	1507	1001	1298

Note: OLS regressions. Patents = the number of patent applications in a subclass-year. RMT = 1 for patent subclasses involving risk-mitigating technologies. Column 2 drops subclasses with zero patents during the entire sample period; column 3 uses an unbalanced panel that includes only observations for which we observe at least one patent in this particular subclass in previous years; and column 4 uses only CT patents (that is, those referring to subclass A61B6/032 as either primary or secondary classification). Standard errors (in parentheses) are clustered at the subclass level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 3: Alternative control groups for the patent analysis

Dependent variable	Patents	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)	(5)
RMT × After 2010	1.522**	1.648**	1.229*	1.423**	0.360*
	(0.719)	(0.717)	(0.720)	(0.719)	(0.201)
Year effects	Y	Y	Y	Y	Y
Subclass effects	Y	Y	Y	Y	Y
Control group	A61B5 & A61B8	A61B5 & A61B8	A61F	A61F	A61F
Drop common patentees	NO	from control	NO	from control	from treatment and control
Observations	8756	8756	8767	8767	8767

Note: OLS regressions. Patents = the number of patent applications in a subclass-year. The control group used in columns 1-2 includes diagnostic medical devices that do not use radiation or ultrasound (CPC group A61B5) and diagnostic devices that use ultrasound (CPC group A61B8). The control group used in columns 3-5 includes medical implant patents (CPC subsection A61F). Common patentees are assignees that patent in both treatment and control groups. Standard errors (in parentheses) are clustered at the subclass level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 4: Effects of the over-radiation shock: FDA application analysis

Dependent variable	Apps	Apps	Apps	Apps (w/o dose)	Apps (w/ dose)	Apps (w/ dose)
	(1)	(2)	(3)	(4)	(5)	(6)
Ionizing diagnostic	1.247*	0.868	1.897*	0.231	1.088**	1.102**
devices × After 2010	(0.690)	(0.873)	(1.076)	(0.580)	(0.442)	(0.441)
Year FE	Y	Y	Y	Y	Y	Y
Product code FE	Y	Y	Y	Y	Y	Y
Treatment group	All radiation diagnostic	Low radiation diagnostic	High radiation diagnostic	All radiation diagnostic	All radiation diagnostic	All radiation diagnostic
Control group	Non-radiation diagnostic and non-radiology	Non-radiation diagnostic and non-radiology	Non-radiation diagnostic and non-radiology	Non-radiation diagnostic and non-radiology	Non-radiation diagnostic and non-radiology	Non-radiology
Observations	19201	19110	19045	19201	19201	18876

Note: OLS regressions. Apps = the number of FDA applications in a product code-year. In column 4, the dependent variable for the treatment group (i.e., radiation diagnostic devices in radiology) counts only applications not containing the word 'dose' in the summary files, whereas in columns 5 and 6, the dependent variable for the treatment group counts only applications containing the word 'dose' in the summary files. Ionizing diagnostic devices = 1 for product codes of diagnostic devices in radiology that emit ionizing radiation. Standard errors (in parentheses) are clustered at the product code level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 5: Firm-level analysis

	Patent applications			FDA applications		
	All Patents	Top-5 Patents	Non top-5 Patents	All Apps	Top-5 Apps	Non top-5 Apps
	(1)	(2)	(3)	(4)	(5)	(6)
RMT × After 2010	0.152**	0.217*	0.146*			
	(0.062)	(0.127)	(0.076)			
Ionizing diagnostic devices × After 2010				0.079**	0.329**	0.052
				(0.032)	(0.141)	(0.035)
Year FE	Y	Y	Y	Y	Y	Y
Subclass (or product code) FE	Y	Y	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y	Y	Y
Observations	17567	4389	13178	152399	2652	149747

Note: OLS regressions. Patents = the number of patent applications in a firm×patent subclass×year. The control group used in columns 1-3 includes non-RMT subclasses of radiation diagnostic devices (the same as our baseline analysis in Table 2). Apps = the number of FDA applications in a firm×product code×year. Control devices in columns 4-6 are class-II devices outside radiology (the same as column 6 in Table 4). Standard errors (in parentheses) are clustered at the subclass (or product code) level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 6: Demand effects of the over-radiation shock

	Equipment use		Equipment upgrade	
Dependent Variable	log(Services)	log(Services)	Assembly reports	Assembly reports
	(1)	(2)	(3)	(4)
High-radiation procedures × After 2010	-0.214**	-0.189*		
	(0.096)	(0.100)		
CT Scanners × After 2010			0.004***	0.003***
			(0.001)	(0.001)
Year effects	Y	Y	Y	Y
Procedure (or site-equipment type) effects	Y	Y	Y	Y
Control group	Low radiation X-ray	MRI & ultrasound	Chest X-ray	Dental X-ray
Observations	3042	2054	715330	715330

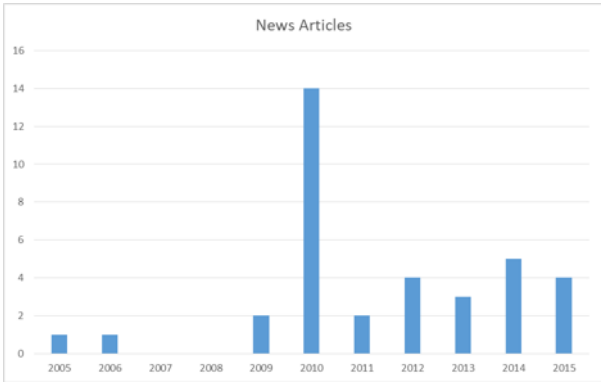
Note: OLS regressions. Services = number of Medicare services reported for the procedure (i.e., a CPT code) in a given year. High-radiation procedures include CT, PET/CT, and fluoroscopy. Control procedures in column 1 are standard X-ray procedures with low radiation; and control procedures in column 2 are non-radiation procedures (that is, MRI and ultrasound). Assembly reports = the number of assembly reports related to a specific equipment type in a site-year. Control equipment type in column 3 is low-radiation chest X-ray systems, and that in column 4 is low-radiation dental X-ray systems. Standard errors (in parentheses) are clustered at the procedure (or site-equipment type) level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Online Appendices (not for publication)

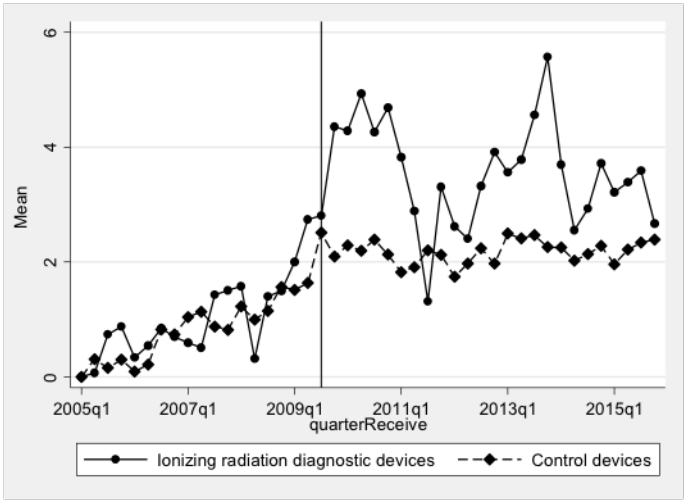
A. Appendix Tables and Figures

Figure A1: Timing of the over-radiation shock

(a) Media mentions of CT scan and X-ray radiation



(b) FDA approval time (months)



(c) Google Trends of keyword "CT Scan Radiation"

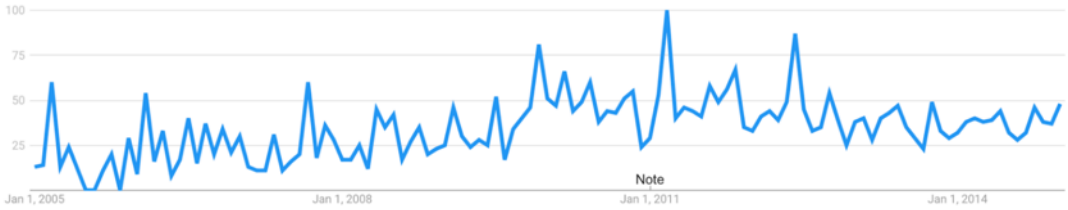
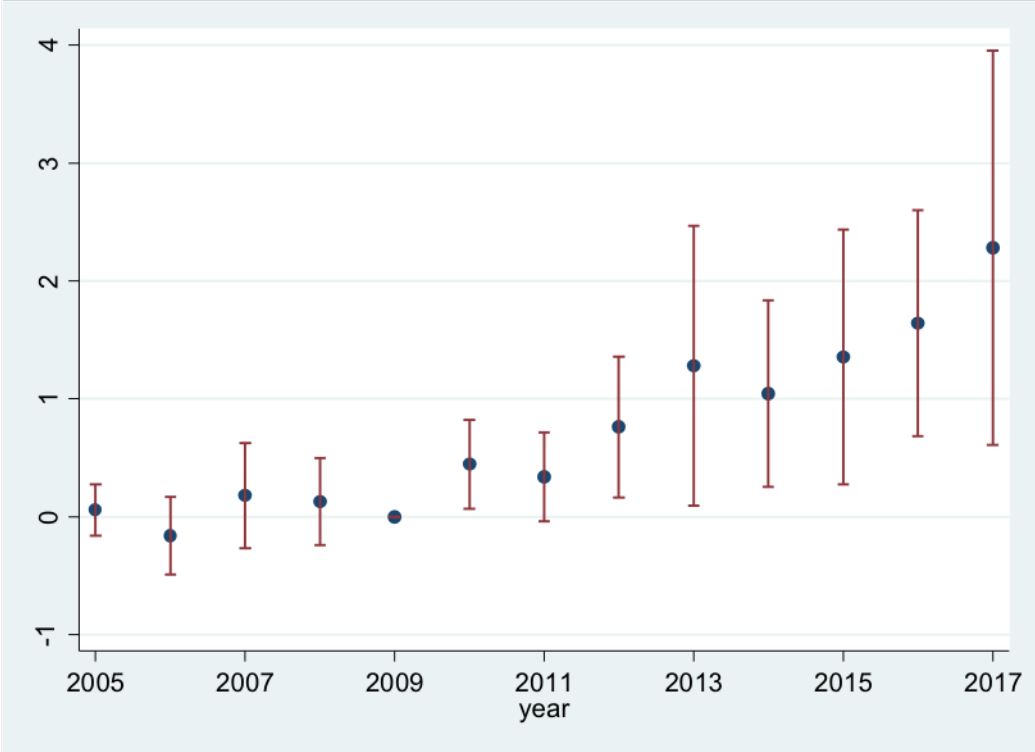


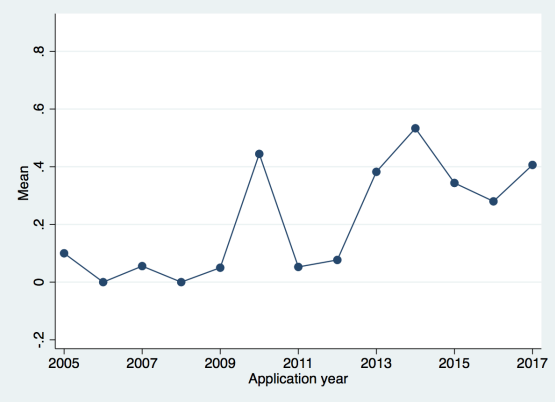
Figure A2: Dynamic effects of the over-radiation shock on FDA pre-market notifications



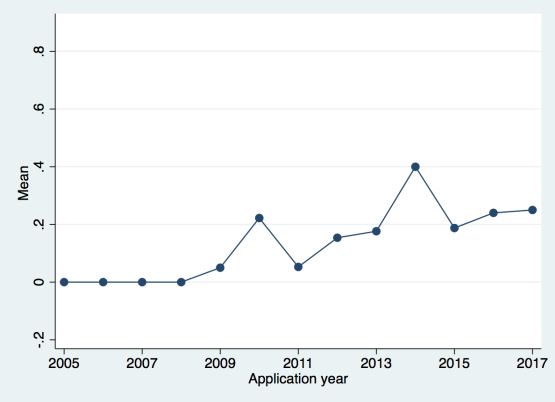
Note: year-specific DID coefficients estimated from a specification analogous to equation (2). The sample is the same as in column 6 in Table 4, where the treatment group includes all product codes of diagnostic devices in radiology that emit ionizing radiation, and the control group includes all product codes of class-II devices in non-radiology medical specialities. The dependent variable for the treatment group counts only applications containing the word 'dose' in the summary files. The model includes year and product code fixed effects.

Figure A3: Risk-mitigating technologies in CT Scanners

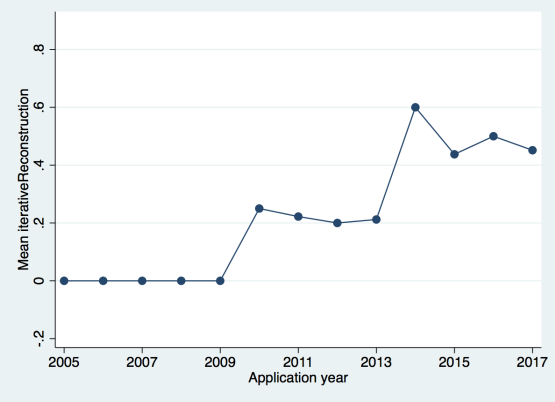
(a) Dose check and dose efficiency



(b) Dose Reduction



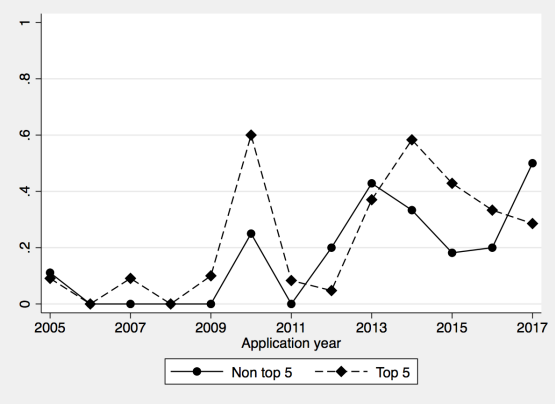
(c) Iterative Reconstruction



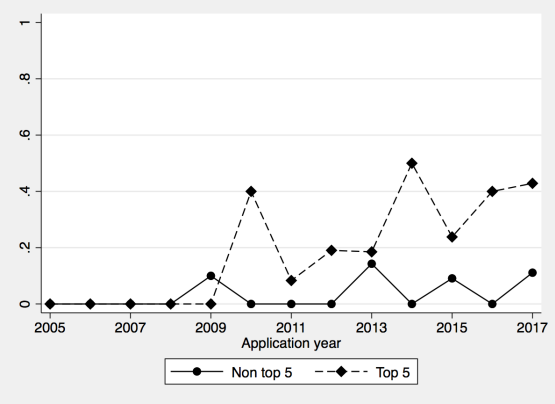
Note: percentages of applications in a given year, including a certain type of safety-related features in the summary files. The data are based on 294 510k applications in the product code JAK (CT scanners).

Figure A4: Risk-mitigating technologies in CT Scanners: top five firms versus smaller firms

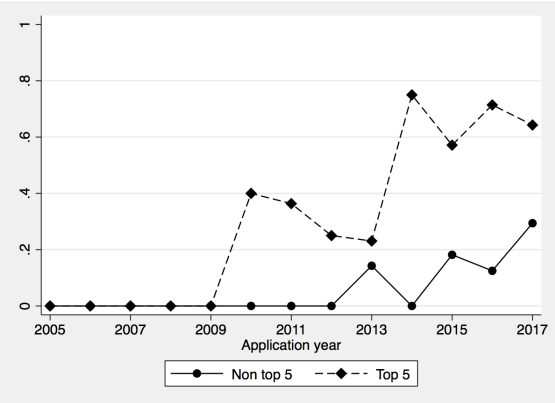
(a) Dose check and dose efficiency



(b) Dose Reduction



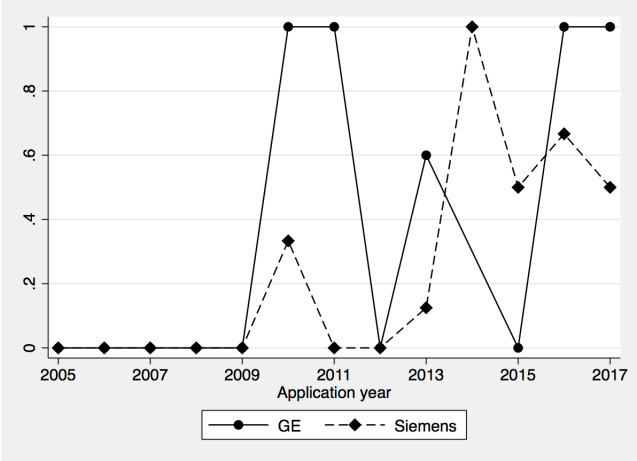
(c) Iterative Reconstruction



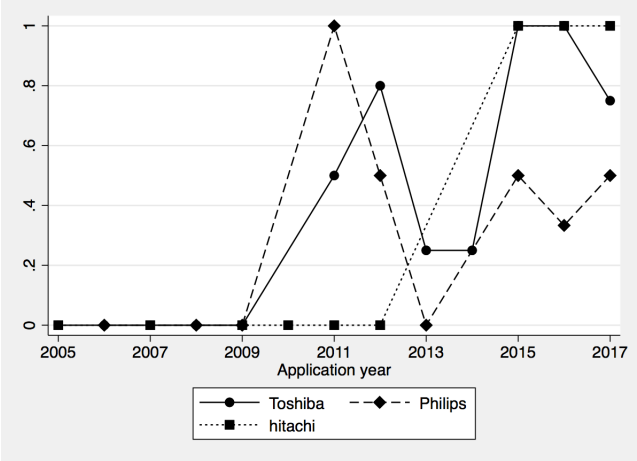
Note: percentages of applications in a given year, including a certain type of safety-related features in the summary files. The data are based on 294 510k applications in the product code JAK (CT scanners). Top-5 firms are GE, Siemens, Toshiba, Philips, and Hitachi.

Figure A5: Iterative reconstruction in CT Scanners: each of the top five firms

(a) Iterative Reconstruction (GE and Siemens)

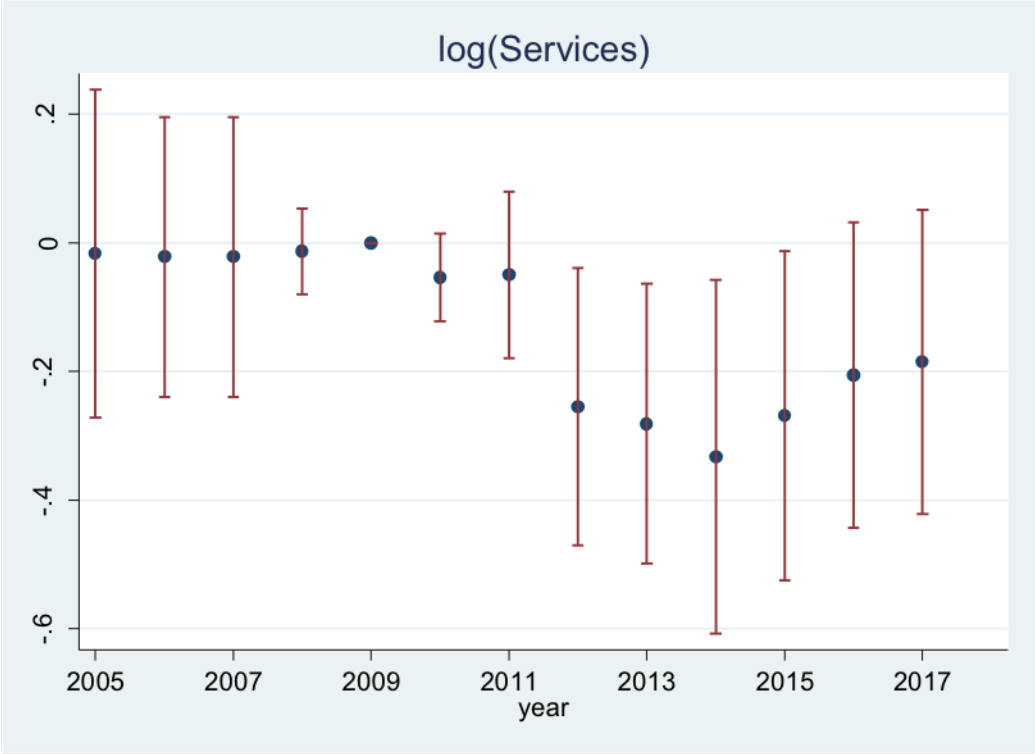


(b) Iterative Reconstruction (Toshiba, Philips, and Hitachi)



Note: percentages of applications in a given year, including IR algorithm. The data are based on 510k applications in the product code JAK (CT scanners).

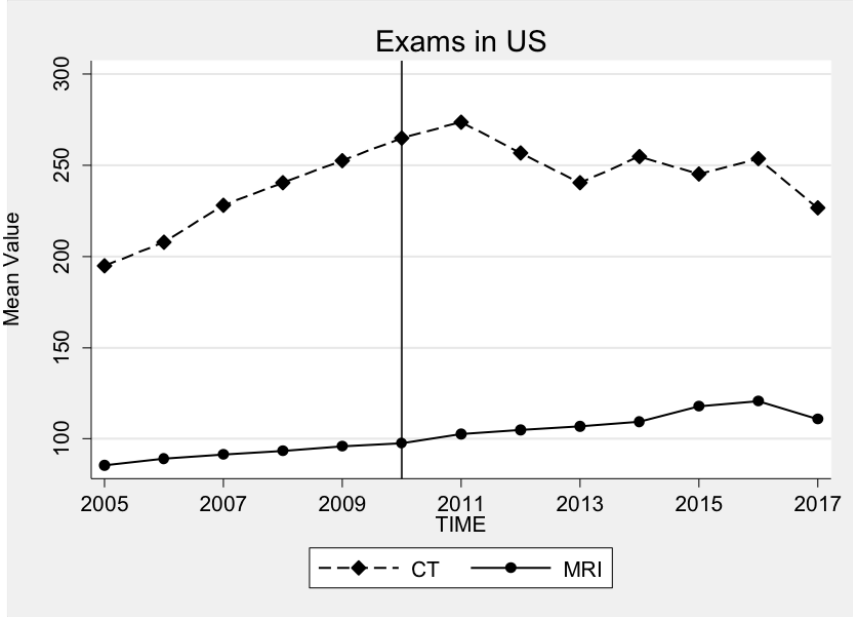
Figure A6: Year-specific effects on the number of CT services relative to MRI and ultrasound



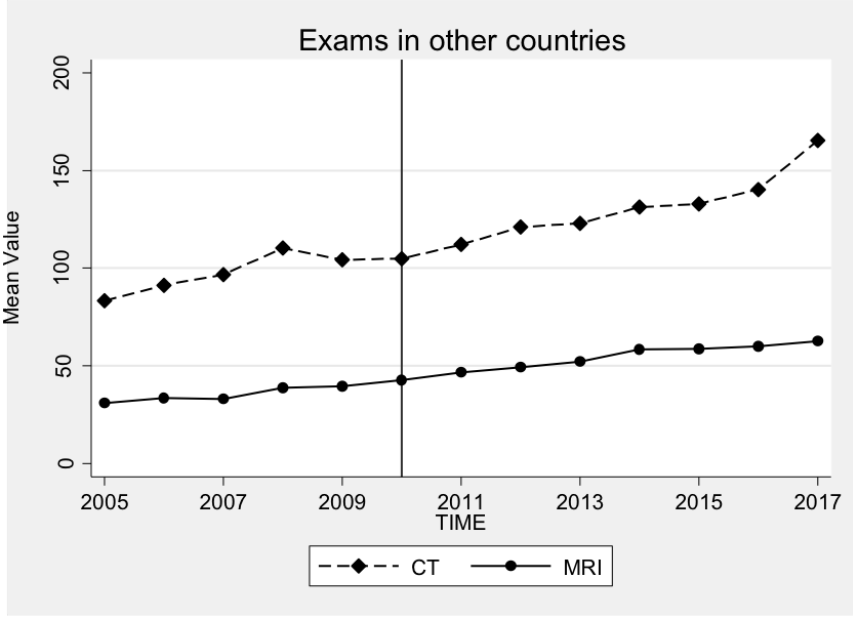
Note: The treatment group includes Current Procedural Terminology (CPT) codes for high-radiation procedures, including CT, PET/CT, and fluoroscopy; and the control group includes CPT codes for MRI and ultrasound that match to the treated CPT codes in terms of pre-trends. The dependent variable of the difference-in-differences regression is log(number of services), and the regression controls for CPT and year fixed effects.

Figure A7: Estimated numbers of CT and MRI exams per million people (OECD data)

(a) United States



(b) Other coutries



Note: https://data.oecd.org/healtheqt/computed-tomography-ct-scanners.htm. The data in the U.S. are based on IMV benchmark reports that extrapolate data to the national level based on a survey of over 200 sites.

Table A1: Patenting response to the over-radiation shock: robustness

Dependent variable	log(Patents+1)	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)	(5)
RMT × After 2010	0.219*	0.476**	0.708***	4.607**	1.783**
	(0.118)	(0.205)	(0.248)	(2.104)	(0.817)
Year effects	Y	Y	Y	Y	Y
Subclass effects	Y	Y	Y	Y	Y
Model	OLS	Negative binomial	Poisson	Weighted OLS	Bootstrap
Observations	1540	1507	1507	1540	1540

Note: Patents = the number of patent applications in a subclass-year. Column 4 weights each observation by the (square root of) total patenting in the subclass during the pre-sample period of 1995-2004. Standard errors (in parentheses) are clustered at the subclass level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A2: Keyword approach to identifying RMT patent subclasses

Dependent variable	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)
RMT × After 2010	1.509**	1.688**	1.614**	1.845***
	(0.714)	(0.743)	(0.699)	(0.681)
Year effects	Y	Y	Y	Y
Subclass effects	Y	Y	Y	Y
RMT-patent fraction threshold for defining treatment group	Top 5%	Top 5% and drop mixed classes	Top 10%	Top 15%
Observations	1540	1320	1540	1540

Note: OLS regressions. Patents = the number of patent applications in a subclass-year. RMT = 1 for patent subclasses involving risk-mitigating technologies. Column 2 defines the treatment group in the same way as column 1, but drops subclasses from the control group if more than two percent of their patents are RMT patents. Standard errors (in parentheses) are clustered at the subclass level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A3: Effects of the over-radiation shock using secondary patent classification

Dependent variable	At least one RMT secondary subclass (1)	At least one RMT secondary subclass (2)	At least one RMT secondary subclass (3)
Year 2005	-0.014	-0.008	0.021
	(0.020)	(0.021)	(0.034)
Year 2006	-0.007	0.003	-0.001
	(0.020)	(0.020)	(0.031)
Year 2007	-0.018	-0.004	0.015
	(0.020)	(0.020)	(0.030)
Year 2008	-0.021	-0.017	-0.028
	(0.020)	(0.020)	(0.030)
Year 2010	0.031	0.040*	0.044
	(0.023)	(0.023)	(0.033)
Year 2011	0.058**	0.063***	0.063*
	(0.023)	(0.024)	(0.036)
Year 2012	0.085***	0.094***	0.097***
	(0.024)	(0.024)	(0.037)
Year 2013	0.090***	0.111***	0.100**
	(0.027)	(0.027)	(0.040)
Year 2014	0.120***	0.143***	0.126***
	(0.027)	(0.027)	(0.043)
Year 2015	0.059*	0.075**	0.033
	(0.033)	(0.032)	(0.050)
Number of secondary subclasses	0.016***	0.017***	0.020***
	(0.002)	(0.002)	(0.003)
Number of claims	-0.001	0.001	0.001
	(0.001)	(0.001)	(0.001)
Primary subclass effects	N	Y	Y
Assignee effects	N	N	Y
Observations	4,131	4,131	4,131

Note: Patent-level linear probability regressions. Sample includes all patents in radiation diagnostic medical devices (A61B6) for which the primary subclass is not RMT. Dependent variable = 1 if patent lists at least one RMT subclass as secondary subclass. Robust standard errors (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A4: FDA Pre-market notifications: robustness

Dependent variable	Apps (with dose)	Apps (with dose)	log[Apps (with dose)+1]	Apps (with dose)
	(1)	(2)	(3)	(4)
Ionizing diagnostic	0.829**	1.373**	0.145**	1.774***
device×After 2010	(0.368)	(0.536)	(0.072)	(0.370)
Year FE	Y	Y	Y	Y
Product code FE	Y	Y	Y	Y
Control group	Non-radiology	Non-radiology	Non-radiology	Non-radiology
Note	Only years 2005-15	Drop codes with no applications	Log DV	Poisson
Observations	15972	18824	18876	18824

Note: OLS regressions. Apps (with dose) = the number of FDA applications in a product code-year, counting only radiation diagnostic device applications (the treatment group) containing the word 'dose' in the summary files. Ionizing radiology device = 1 for product codes related to radiology devices emitting radiation. Standard errors (in parentheses) clustered at the product code level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A5: Firm-level analysis: each of the top five firms

(a) Patent analysis

Firm	GE	Siemens	Toshiba	Philips	Hitachi
Dependent variable	Patents	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)	(5)
RMT × After 2010	0.198*	0.397**	0.166	0.104	0.066
	(0.118)	(0.179)	(0.100)	(0.071)	(0.062)
Year FE	Y	Y	Y	Y	Y
Subclass FE	Y	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y	Y
Observations	1122	1155	803	913	396

(b) FDA analysis

Firm	GE	Siemens	Toshiba	Philips	Hitachi
Dependent variable	Apps	Apps	Apps	Apps	Apps
	(1)	(2)	(3)	(4)	(5)
Ionizing diagnostic devices	0.203	0.467	0.587	0.449	0.156
× After 2010	(0.199)	(0.297)	(0.342)	(0.345)	(0.107)
Year FE	Y	Y	Y	Y	Y
Product code FE	Y	Y	Y	Y	Y
Firm FE	Y	Y	Y	Y	Y
Observations	637	1209	91	546	169

Note: OLS regressions. In panel (a), patents = the number of patent applications in a firm×patent subclass×year. The control group includes non-RMT subclasses of radiation diagnostic devices (the same as our baseline analysis in Table 2). In panel (b), apps = the number of FDA applications in a firm×product code×year. Control devices are class-II devices outside radiology (the same as column 6 in Table 4). Standard errors (in parentheses) are clustered at the subclass (or the product code) level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A6: Entry and unique number of firms active in the market (FDA data)

	Number of entrants	Unique number of firms
	(1)	(2)
Ionizing diagnostic devices	0.236	0.801*
× After 2010	(0.188)	(0.409)
Year FE	Y	Y
Product code FE	Y	Y
Observations	18876	18876

Note: OLS regressions. Dependent variable in column 1 is the number of new firms entering a product code-year. A firm's entry year is defined as the first year in which the firm shows up in a given product code based on the entire 510 k application data (starting from the 1970's). Dependent variable in column 2 is the number of unique FDA applicants in a given product code-year. Standard errors (in parentheses) clustered at the product code level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A7: Equipment usage in Medicare data: state-level analysis

Dependent Variable	log(Services)	log(Services)	log(Services)	log(Services)
	(1)	(2)	(3)	(4)
High-radiation procedures ×	-0.262***	-0.275***	-0.271***	-0.270***
After 2010	(0.016)	(0.018)	(0.017)	(0.018)
High-radiation procedures ×	-0.126**	-0.108*	-0.113**	-0.108**
After 2010 × FDA States	(0.050)	(0.063)	(0.065)	(0.051)
Year effects	Y	Y	Y	Y
State-procedure effects	Y	Y	Y	Y
Sate controls	N	N	Y	Y
Control group	Low radiation	MRI and ultrasound	Low radiation	MRI and ultrasound
Observations	51568	42196	48862	40062

Note: OLS regressions. Services = number of Medicare services reported for the procedure in a given year. High-radiation procedures are CT, PET/CT, and fluoroscopy. Control procedures in columns 1 and 3 are standard X-ray procedures with low radiation; and control procedures in columns 2 and 4 include non-radiation procedures (that is, MRI and ultrasound). FDA States are California and Alabama, in which the six hospitals involved in the FDA's investigation are located. State controls include dummies for cap on non-economic damages, joint and several liability rule, and a dummy indicating Republican-controlled government and legislature. Standard errors (in parentheses) clustered at the procedure-state level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table A8: Equipment upgrade: location-specific analysis

Dependent variable	Assembly reports	Assembly reports	Assembly reports	Assembly reports
	(1)	(2)	(3)	(4)
CT Scanners X After 2010	0.003***	0.002**	0.005***	0.004***
	(0.001)	(0.001)	(0.001)	(0.001)
CT Scanners X After 2010	0.206***		0.233***	
X FDA Hospital	(0.034)		(0.039)	
CT Scanners X After 2010		0.006***		0.005**
X FDA State		(0.002)		(0.002)
Year effects	Y	Y	Y	Y
Site-equipment type effects	Y	Y	Y	Y
Location controls	N	N	Y	Y
Observations	715330	715330	526700	526700

Note: OLS regressions. Assembly reports = the number of assembly reports related to a specific equipment type in the site-year. The control group includes low-radiation dental X-ray systems. FDA hospitals are six hospitals involved in FDA investigation. FDA States are California and Alabama, in which the six hospitals are located. Location controls include dummies for state-level tort liability systems, including cap on non-economic damages and joint and several liability rule; a dummy indicating Republican-controlled government and legislature; and unemployment rate at the county level. Standard errors clustered at the site (clinic or hospital) level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

B. Theoretical model

In this appendix, we develop a simple theoretical model to explore the effects of an increase in consumer risk perception on innovation incentives. The framework builds on Galasso and Luo (2017) and considers products that are characterized by multi-dimensional heterogeneity (Weyl and Tirole (2012)). Risk perception affects technological progress through its impact on technology adoption, which, in turn, shapes upstream R&D investments.

B.1 Basic framework

There are a representative (consumer) hospital and an innovator. A radiation diagnostic device, i, is characterized by two parameters: b_i and r_i, where b_i captures the quality of the image, speed and other non-safety related features of the product, and r_i captures the safety aspect of the product (e.g., the required dose level if properly configured and the probability of overdose accidents). Note that a lower value of r_i indicates a safer product. Overdose accidents may happen due to the malfunctioning of the machine or operator errors. In the following, we use 'over-radiation' to broadly refer both to overdose accidents (if the dose amount is above the correctly-specified amount) and to other medical risks potentially arising from products that generally use high dose levels (even with the right specifications).

The expected cost of over-radiation for the hospital is H. One way to micro-found H is $H = pC + L$, where p is the perceived probability that radiation will lead to cancer; C is the monetary and non-monetary costs of cancer to the patient (which is, at least partially, internalized by the hospital and its physicians because they care about their patients' well-being); and L captures the likelihood and expected costs (monetary and non-monetary) associated with malpractice disputes in an overdose event.

We model an increase in risk perception resulting from the over-radiation shock that we study in the paper as an *increase* in H, which captures the combined effect on the perceived risk of cancer for the patient, p, and the likelihood and expected costs of malpractice litigation faced by the hospital, L.

The hospital's utility, when it adopts product i is

$$U_i = b_i - r_i H. \tag{A1}$$

The innovator has an idea for a new radiation device, which we denote as N. The hospital can buy a standard product, O, at a price that we normalize to zero. We assume that there is a feasible set of quality-

risk combinations, $b_i \in [0,1]$ and $r_i \in [0,1]$. This captures the possible directions of development notionally allowed by science, as in Dosi (1982). We model the idea-generation process following Scotchmer (1999) and assume that b_N and r_N are independent draws from the uniform distribution over the interval $[0,1]$.

We assume that b_O and r_O are exogenously given and that $U_O > 0$ and $U_O < 1 - H$. These assumptions rule out extreme outcomes and ensure that there are no regions in which the old technology is dominated or dominant for all values of r_N.

An idea can be developed into a new product through an R&D process. Successful development takes place with probability $p(x) = x$ if the innovator incurs a research cost $C(x) = x^2/2$. As in Aghion et al. (2016), we refer to x as the "innovation intensity," which captures the likelihood of successfully developing a new product.

The timing of the game is as follows. The innovator draws the idea, observes b_N and r_N and decides whether and how much to invest in R&D to develop the new product. If the new product is developed, the innovator makes a take-it-or-leave-it offer to the hospital, which then decides whether to adopt N or O. If N is not developed, the hospital adopts O.

B.2 The over-radiation shock and technology adoption

If new product N is developed, the innovator makes a take-it-or-leave-it offer to the hospital for a transfer, t. The hospital decides whether to accept the offer, which yields a payoff to $U_N - t$, or to adopt the old standard product, which yields U_O. This implies that the payoff of the innovator will be either $U_N - U_O$ or zero, depending on whether the new product offers the hospital higher utility than the old technology does.[36]

For a fixed level of (perceived) expected costs of over-radiation, H, the hospital trades off the safety dimension of a product with other quality dimensions. Riskier products ($r_N > r_O$) are adopted as long as their quality ($b_N - b_O$) is large enough. Conversely, safer products are adopted only if their quality is not too low. The following proposition identifies the threshold in r_N, below which the new product will be adopted.

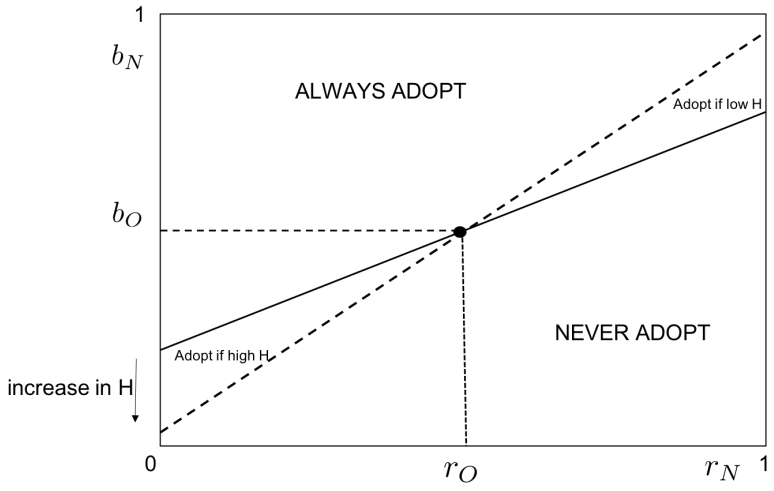
Proposition 1. *The hospital will adopt the new product when r_N is below the following threshold:*

$$r_N^* = r_O + \frac{b_N - b_O}{H}. \tag{A2}$$

Proof. Adoption of N occurs when $U_N \geq U_O$, which can be rewritten as $r_N \leq r_N^*$. □

[36] Our results are robust to replacing the take-it-or-leave it offer with a Nash bargaining protocol in which the surplus is split between the innovator and the hospital.

Figure A8: The effect the over-radiation shock on hospital's adoption decision



The over-radiation shock increases H and shifts the adoption threshold. The effect on adoption depends on the characteristics of the new product. First, there is an decrease in the adoption of high-quality but riskier products. Second, in contrast, there is an increase in the adoption of low-quality but safer products. Finally, there is no effect on the adoption of high-quality/low-risk or low-quality/high-risk products. These results are summarized in the figure below.

The overall effect of an increase in H on adoption is, therefore, ambiguous. The following proposition shows that when the old product is sufficiently risky, the increased incentive to adopt safer products dominates the chilling effect generated by the higher perception of radiation risk. As a result, the increase in risk perception would result in an overall increase in the propensity to adopt new products. That is,

Proposition 2. *An increase in H generates an overall increase in the propensity to adopt new products if and only if the old product is sufficiently risky (i.e., $r_O > 1/2$).*

Proof. The area above the adoption threshold in the (b_N, r_N) space is equal to

$$\begin{aligned} AD &= \int_0^1 (1 - b_O + H(r_O - x))dx \\ &= 1 - b_O + H(r_O - \frac{1}{2}), \end{aligned}$$

with derivative $\dfrac{dAD}{dH} = r_O - \frac{1}{2}$ which is positive if $r_O > 1/2$. □

B.3 The over-radiation shock and innovation incentives

So far, our analysis has focused on the effect of an increase in H on the hospital's adoption decision. Its impact on innovation incentives, however, combines the effect on adoption with the effect on the incentives to invest in R&D, which depend not only on whether the product will be adopted, but also on the expected profitability of the product if it is adopted. Note that for products that will be adopted, the expected profitability from a successful innovation is $U_N - U_O$. The innovator invests in R&D, x, to the point at which the marginal cost of R&D equals its marginal benefits (recall that x captures the likelihood of successfully developing a new product).

Similar to its impact on adoption, an increase in H may have a positive or a negative effect on innovation incentives, depending on the characteristics of the new products. For marginal products, because risk perception affects the hospital's adoption decision, some products become profitable after the change in risk perception, while others are no longer profitable. The former experience an increase in the innovation intensity, while the latter experience a drop. For infra-marginal products—that is, products that will be adopted both before and after—the over-radiation shock also affects their profits, which, in turn, affect R&D incentives. Recall that the profit from a successful innovation is equal to $b_N - b_O - H(r_O - r_N)$. An increase in H, therefore, increases innovation intensity for safer products (those with $r_N < r_O$) and decreases innovation intensity for less-safe products (those with $r_N > r_O$). The following proposition shows this result more formally.

Proposition 3. *An increase in H increases the research intensity for products that are safer than the current standard (i.e., $r_N < r_O$).*

Proof. The optimal innovation intensity for an innovator with idea (b_N, r_N) solves

$$\max_x x\left(b_N - b_O - H(r_N - r_O)\right) - \frac{x^2}{2},$$

which is equal to $x^*(b_N, r_N) = b_N - b_O - H(r_N - r_O)$, which is positive as long as $b_N \geq b_O + H(r_N - r_O)$. For a fixed r_N, we have that when $0 \leq r_N \leq \dfrac{1 - b_O}{H} + r_O$, the expected investment is

$$\begin{aligned} x^*(r_N) &= \int_{b_O + H(r_N - r_O)}^{1} (y - b_O - H(r_N - r_O))dy \\ &= \frac{1}{2}\left(b_O + Hr_N - Hr_O - 1\right)^2. \end{aligned}$$

The proposition follows from

$$\frac{dx^*(r_N)}{dH} = (r_O - r_N)\,(1 - b_O - H(r_N - r_O)),$$

which is positive when $r_O \geq r_N$. In the case in which $r_N > \dfrac{1-b_O}{H} + r_O$, we have the corner solution $x^*(r_N) = 0$, so the change in H has no effect. □

The relative magnitudes of the opposing effects on innovation incentives would depend on how the quality of the new product compares to that of the old (standard) product, as the relative importance of safety consideration is different.

In the following proposition, we show that when $r_O > 1/2$, the positive effect dominates regardless of the quality of the new product, and, hence, the overall net effect of an increase in H is positive. Recall that in this simple model, we assume that the possible risk-quality combinations are uniformly distributed in the unit square of $[0,1] \times [0,1]$. Intuitively, $r_O > 1/2$ implies that the safety level of the standard products is sufficiently different from the maximum safety level technologically allowed (i.e., $r = 0$). Thus, there are a large number of safer products that are technologically possible and can be developed. In such situations, an increase in H will result in a net increase in innovation incentives.

When the standard product is already sufficiently safe relative to the technological frontier (that is, if $r_O < 1/2$), we show that the negative effect of an increase in H on innovation intensity dominates for products of high quality, rendering the overall effect ambiguous.

Proposition 4. *The impact of an increase in H on innovation intensity is positive when the old technology is sufficiently risky* $(r_O > 1/2)$ *and ambiguous otherwise (i.e., when* $r_O \leq 1/2$*).*

Proof. The optimal innovation intensity for an innovator with idea (b_N, r_N) solves

$$\max_x x\,(b_N - b_O - H(r_N - r_O)) - \frac{x^2}{2},$$

which is equal to $x^* = U_N - U_O$. Consider an innovator with an idea with expected quality b_N. She will invest in R&D as long as

$$b_N - b_O - H(r_N - r_O) \geq 0,$$

or

$$r_N \leq \frac{b_N - b_O}{H} + r_O \equiv \bar{r}.$$

The innovation intensity for firms at b_N is

$$\int_0^{\bar{r}} b_N - b_O - H(x - r_O)dx = \frac{H\bar{r}^2}{2}. \tag{A3}$$

Considering the corner solutions when $\bar{r}$ is outside the unit interval in (3), we obtain the expected innovation intensity for a fixed level of

$$b_N : i(b_N, H) = \begin{cases} 0 & \text{if } b_N < b_0 - Hr_0 \\ \frac{H}{2}\left(\frac{b_N - b_O}{H} + r_O\right)^2 & \text{if } b_0 - Hr_0 \leq b_N < H + b_0 - Hr_0 \\ b_N - b_O + H(r_O - \frac{1}{2}) & \text{if } b_N \geq H + b_0 - Hr_0. \end{cases}$$

We exploit the above formula to study the impact of an increase in H on innovation, as well as the heterogeneity in the impact across technologies with different levels of expected effectiveness. To compute the total expected innovation investment, we integrate $i(b_N, H)$ for each value of b_N. The total effect comprises three parts. The first part is

$$\int_0^{b_O - Hr_0} 0 db_N = 0.$$

The second part is

$$\int_{b_O - Hr_O}^{H + b_O - Hr_O} \frac{H}{2}\left(\frac{b_N - b_O}{H} + r_O\right)^2 db_N = \frac{1}{6}H^2,$$

The third part of the innovation intensity is

$$\begin{aligned} & \int_{H + b_O - Hr_O}^{1} \left(b_N - b_O + H(r_O - \frac{1}{2})\right) db_N \\ = \; & \frac{1}{2}H^2 r_O^2 - \frac{1}{2}H^2 r_O - Hb_O r_O + \frac{1}{2}Hb_O + Hr_O - \frac{1}{2}H + \frac{1}{2}b_O^2 - b_O + \frac{1}{2}. \end{aligned}$$

This implies that the expected innovation intensity as a function of (b_O, r_O) is equal to

$$I(H, b_O, r_O) = \frac{1}{2}H^2 r_O^2 - \frac{1}{2}H^2 r_O + \frac{1}{6}H^2 - Hb_O r_O + \frac{1}{2}Hb_O + Hr_O - \frac{1}{2}H + \frac{1}{2}b_O^2 - b_O + \frac{1}{2},$$

The following derivative captures that the impact of an increase in radiation risk is:

$$\frac{\partial I}{\partial H} = \frac{1}{3}H + \frac{1}{2}b_O + r_O - Hr_O - b_O r_O + Hr_O^2 - \frac{1}{2}.$$

When $r_O = 0.5$, we have that $\partial I/\partial H = H/12 > 0$. Moreover, $\dfrac{\partial^2 I}{\partial H \partial r_O} = 1 - H - b_O + 2Hr_O$, which is increasing in r_O for every value of b_O if $r_O \geq 1/2$. We now look at the effect across various levels of b_N. When $b_N < b_O - Hr_O$, we have that $\dfrac{\partial i}{\partial H} = 0$ and $\dfrac{\partial^2 i}{\partial H \partial b_N} = 0$. When $b_O - Hr_O \leq b_N \leq H + b_O - Hr_O$, we have that

$$\frac{\partial i}{\partial H} = \frac{r_O^2}{2} - \frac{(b_N - b_O)^2}{2H^2} \geq 0.$$

The positive inequality follows because $b_O - Hr_O < b_N$ implies $b_O - b_N < Hr_O$, which, in turn, implies that $(b_N - b_O)^2 < (Hr_O)^2$. Moreover, $\dfrac{\partial^2 i}{\partial b_N \partial H} = -\dfrac{b_N - b_O}{H^2}$ which is increasing when $b_N - b_O < 0$ and decreasing when $b_N - b_O > 0$. Thus, the derivative is maximized at $b_N = b_O$. Finally, when $b_N \geq H + b_O - Hr_O$, we have that $\dfrac{\partial i}{\partial H} = (r_O - \frac{1}{2})$ and $\dfrac{\partial^2 i}{\partial H \partial b_N} = 0$. Notice that the maximum value that $\dfrac{\partial i}{\partial H}$ can take is $\dfrac{r_O^2}{2}$ because $\dfrac{r_O^2}{2} > r_O - \frac{1}{2}$ for any $r_O \leq 1$. □

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C. Data appendix

C.1 Risk-mitigating technology subclasses

The following lists the subclasses that we manually classify as Risk-mitigating Technology subclasses:

A61B 6/10 "Application or adaptation of safety means"

A61B 6/107 "Protection against radiation—e.g. shielding (techniques for handling radiation not otherwise provided for G21K)"

A61B 6/54 "Control of devices for radiation diagnosis"

A61B 6/542 "involving control of exposure"

A61B 6/544 "dependent on patient size"

A61B 6/545 "involving automatic set-up of acquisition parameters"

A61B 6/58 "Testing, adjusting or calibrating devices for radiation diagnosis"

A61B 6/586 "Detection of faults or malfunction of the device".

Theses subclasses were chosen by exploiting a two-stage process. First, reading the description of the subclasses from the USPTO website, we identified subclasses A61B6/107, A61B6/542, A61B6/544, A61B6/545 and A61B6/586 as subclasses including risk-mitigating technologies. Second, for each of these subclasses, we also included its related higher-level 'parent' subclasses. We did so 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.

C.2 Keyword analysis

The keywords in the dictionary are: "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."