# Risk-Mitigating Technologies: the Case of Radiation Diagnostic Devices*

Alberto Galasso† Hong Luo‡

March 9, 2020

**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. Using data on radiation diagnostic device patents and FDA product clearances, we find 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. Using CT scanners as a case study, we provide an in-depth characterization of two different types of risk-mitigating technologies that firms developed after the shock. Firm-level analysis shows that while firms were similarly responsive in their patenting activities, large incumbents were significantly more responsive than smaller firms in terms of new product introductions; and, in the case of CT scanners, large incumbents were also significantly more responsive in terms of the more-radical type of risk-mitigating technologies. We also provide qualitative evidence and describe patterns of equipment usage and upgrade that are consistent with increased risk perception and, consequently, a greater willingness to pay for safety. Overall, our findings suggest that changes in risk perception can be an important driver of innovation, can shape the direction of technological progress, and can impact market structure.

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

**JEL Codes:** O31, O32, O34, K13.

*We thank Ashish Arora, Andrea Fosfuri, Chris Snyder, Neil Thompson, and seminar and conference participants at Bocconi Assembly for Innovation and Cooperation, DRUID, Harvard Business School, NBER Law and Economics Meeting, and University of Toronto for their valuable feedback. Tejas Ramdas provided excellent research assistance. We are grateful for financial support from the Social Sciences and Humanities Research Council of Canada.

†University of Toronto, CEPR, and NBER; email: Alberto.Galasso@Rotman.Utoronto.Ca.

‡Harvard Business School; email: hluo@hbs.edu.

# 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 (Mowery and Rosenberg, 1979; Dosi, 1982; Cohen, 2010). Empirical research has examined a variety of mechanisms such as market size (Acemoglu and Linn, 2004); heterogeneity in consumer needs (Sutton, 1998; Adner and Levinthal, 2001); and feedback from customers and lead users (Von Hippel, 1986; Chatterji and Fabrizio, 2012). Despite this extensive literature, demand driven by the perception of risk from using a product has, 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 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), safety concerns are critically important to firms commercializing new products. Moreover, prominent accidents 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—which can have profound impacts on the perceived risk associated with the underlying technologies.

An increase in the perceived risk of a product may affect its demand and, in turn, influence the rate and direction of technological progress. On the one hand, the willingness to pay for safety will increase (Viscusi, 1993), and this may induce firms to develop risk-mitigating technologies (henceforth, RMTs)—that is, innovations that reduce the probability of negative events and/or the severity of the consequences. On the other hand, higher risk perception may suppress the demand for the focal product category and, consequently, chill R&D investments. Thus, while an increase in risk perception may direct innovation toward RMTs relative to other quality dimensions, the impact on the level of investments in RMT and the focal product category is potentially ambiguous. Three features of the economic and technological environment may lead to an aggregate positive effect. First, substitution away from the focal product category to alternative product categories needs to be limited. Second, there must be sufficient technological opportunities for safer products that are also economically viable. Third, regulatory, legal, or political uncertainty needs to be sufficiently contained.

Our empirical analysis examines the impact of a quasi-exogenous surge in risk perception for 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 provide a variety of qualitative evidence suggesting that the extensive media coverage of this accident increased patients' and medical providers' perceived risk of CT and other technologies using radiation.

Empirical results based on different innovation measures show that the surge in risk perception shifted firm innovation toward RMTs. We exploit the detailed patent classification system to identify RMTs—that is, patent subclasses related to technologies aimed at protecting against radiation, controlling the level of radiation exposure, and detecting device malfunctions. We find that after the shock, patenting in RMT subclasses experienced a large and statistically significant increase of 1.78 patents per year (about 110 percent) relative to non-RMT subclasses of radiation diagnostic devices. An examination of the FDA pre-market notifications shows that the number of applications (that is, new product introductions) in radiation diagnostic devices also increased by about 30 percent after the shock, relative to other medical devices that do not use radiation. 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 were prominent.

We further complement the aggregate, quantitative analysis that we discuss above with an in-depth case study of CT scanners. Specifically, we document two types of RMTs developed by CT producers after the shock. The first type can be thought of as incremental, as the goal is to prevent over-radiation errors or to manage dosage more efficiently without a substantial departure from existing technologies. The second type of RMTs is qualitatively different because it requires a substantial departure from a method that has dominated the CT industry for the last 30 years. This technology built on a long-shelved technique to reconstruct image data, which requires a significant sacrifice of speed and image quality but allows for a reduction in radiation dose that is 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).

We conduct a detailed firm-level analysis to examine the differential responses by large incumbents versus smaller firms. The results on all types of radiation diagnostic devices show that while firms were similarly responsive in their patenting activities, large incumbents were significantly more responsive than smaller firms in terms of new product introductions. In the case of CT scanners, we find that the industry overall has adopted incremental safety-check or dose-efficiency features, but large incumbents are significantly more likely and quicker to develop and commercialize the more-radical type of RMTs that substantially reduce dose. Finally, we also find that the shock increased (net) entry by new players in the industry, while, at the same time, enlarging the share of innovations by large incumbents. These patterns, collectively, are consistent with the idea that safety-related shocks, by increasing demand for safer products, may

generate valuable market opportunities; and dominant players may have an advantage in exploiting them. We discuss a number of factors that could explain this large-incumbent advantage, including the ability to spread high fixed costs via high market shares (Cohen and Klepper, 1996) and complementary assets such as the existing relationships with hospitals and physicians and their brand names (Teece, 1986; Tripsas, 1997).

Finally, we 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. We show that the number of diagnostic procedures involving high radiation experienced a large and sharp drop after 2010. At the same time, hospitals' propensity to 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 inventive activities and shape the direction of technological progress. Safety-related shocks, by increasing demand for safer products, may generate valuable market opportunities and create a new dimension along which firms can innovate, compete, and commercialize their products. Large incumbents are likely to play an important role in the development and commercialization of RMTs, and risk-perception shocks may perpetuate rather than diminish their market dominance.

## 2 Related literature

Our analysis contributes to the vast economics and management literatures on the determinants of the rate and direction of technological progress. Mowery and Rosenberg (1979), Cohen (2010), and Di Stefano et al. (2012) provide comprehensive reviews of the debate on the sources of innovation—in particular, on the 'demand-pull' and 'technology-push' perspectives. While Schmookler's seminal work on the primary role of market demand raised a number of theoretical and empirical concerns, more-recent studies have made progress in addressing some of these issues—in particular, by empirically disentangling demand and supply forces (Acemoglu and Linn, 2004; Finkelstein, 2004). While these studies focus on market size, studies on the environment have examined the innovation responses to natural disasters (Miao and Popp, 2014) and to regulatory and normative pressures (Berrone et al., 2013). Our paper contributes to this line of research by examining the innovation responses to demand shifts driven by increases in risk perception of product use.

Furthermore, our paper builds on studies that develop taxonomies of technological innovation and link them to the relative (dis)advantages of large and small firms (Anderson and Tushman, 1990; Henderson and Clark, 1990; Scherer and Ross, 1990; Henderson, 1993; Christensen and Bower, 1996; Cohen and

Klepper, 1996; Tripsas, 1997). As Cohen (2010) summarizes, the literature argues that large incumbents may have an advantage for costly and risky R&D projects because of capital market imperfections and scale economies in R&D; when firms can spread the fixed costs of innovation over a large volume of sales; and when complementary assets and capabilities are important. In contrast, smaller firms may have an advantage for innovation that requires significant changes to the firm's organizational capabilities and architectural knowledge or to consumer composition and behaviors. We contribute to this literature by documenting and conceptualizing RMTs, and by theoretically discussing and empirically examining the differences between large incumbents and small firms in RMT development and commercialization.

Our paper also relates to the literature on product recalls, especially the stream that explores spillover effects on competitors (Jarrell and Peltzman, 1985; Dranove and Olsen, 1994; Freedman et al., 2012). We are aware of two papers on the impacts of product recalls on innovation: Ball et al. (2019) show a negative impact on focal firms but a positive effect on their rivals for medical devices; and Krieger et al. (2019) find the opposite for drug withdrawals—a positive effect on focal firms' number of projects but a negative effect on rival firms. Our paper is different from these two studies in terms of: (i) the nature of the shocks (consumer risk perception with no disruptions to firms, as there are no product recalls); (ii) our focus on innovations that specifically address safety concerns; and (iii) the underlying mechanisms.

Finally, our paper contributes to our understanding of the link between tort liability and innovation. Despite much theoretical and policy attention (Huber, 1989; Porter, 1990; Daughety and Reinganum, 1995), large-sample empirical evidence remains scarce (Viscusi and Moore, 1993; Galasso and Luo, 2017, 2018). Contrasting the dominant policy view of a chilling effect, Viscusi and Moore (1993) and Galasso and Luo (2017) show that, on average, higher liability risk induces higher R&D spending and more patenting. They conjecture that this is likely due to the incentivizing effect on safer products, but neither paper directly measures this type of innovation. That is what we do in this paper.

# 3 Theoretical considerations

This section discusses the nature of RMTs and the mechanism through which an increase in risk perception may affect the direction of technological progress and innovation incentives. We also discuss how the effects may differ between large incumbents and smaller firms. We conclude the section by discussing some boundary conditions for the proposed effects.

## 3.1 Risk-mitigating technologies

Conceptually, we define RMTs as innovations that reduce the probability of negative events and/or the severity of their consequences. Windshield wipers, for example, reduce the likelihood of accidents in au-

tomobiles, while seat belts and airbags mitigate the severity of accidents. RMTs may take various forms, depending on the nature of the hazards, the demand, and the technological possibilities. They can be incremental innovations that refine existing technologies or radical innovations that potentially establish new, dominant designs (Utterback and Abernathy, 1975; Dosi, 1982). Moreover, RMTs may involve redesigns of both products and processes—e.g., assembly-line modifications that are more effective at identifying safety defects or the use of checklists during surgeries to reduce medical errors (Gawande, 2009).

RMTs differ from innovations involving other quality dimensions in two ways. First, RMTs create value not only by increasing consumers' willingness to pay (as products are safer) but also by reducing firms' product liability costs. In other words, RMTs inherently possess features of both product innovations and cost-reducing innovations. Second, the value created by RMTs is strongly influenced by non-market forces—such as safety regulations, product liability systems, media attention, and consumer activism—and by the efficiency of the insurance markets.

### 3.2 Risk perception as a demand-pull force and the role of firm size

Consumers rarely have full information about risk. 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 through, for example, personal experience, news reporting of accidents, and publication of new scientific studies. This new information can serve as either good 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.[1]

This learning process implies that shocks that increase the risk that consumers perceive about a product may increase consumers' willingness to pay for safety (Viscusi, 1993). Such an increase may serve as a "demand-pull" force that incentivizes the development of RMTs and affects the *direction* of technological progress (Schmookler, 1966).

Typically, products are characterized by multiple dimensions. For simplicity, consider two dimensions: the quality level (which captures non-safety aspects of a product, such as the speed and image quality of CT scans) and the risk level (e.g., the likelihood of an over-radiation event).[2] In deciding which product to purchase, consumers trade off safety and quality. An increase in risk perception reduces the demand for

[1] 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).

[2] One can formalize the statements in this paragraph in a simple mathematical model, see Galasso and Luo (2019).

riskier products but increases the demand for safer ones. This demand shift, in turn, shapes firms' R&D decisions among the possible directions notionally allowed by science (Dosi, 1982). 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 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. Thus, the combination of these effects imply that safer technologies will experience an increase in R&D investments relative to riskier ones.

Apart from directional changes, one may expect the magnitude of the demand shift to shape the types of RMTs developed. In particular, small shifts in risk perception may be sufficient for firms to implement minor changes to their products. But sufficiently large shifts may be required to incentivize more substantial technological advances, especially those that are more costly for firms to develop and/or for users to adopt.

There are a number of reasons to expect large incumbents to play an important role in the development and commercialization of RMTs, especially for innovations that require large investments. First, safety-related shocks may exhibit externalities that can impact the entire product category (Jarrell and Peltzman, 1985). This implies that the resulting increase in demand for safety may not be localized to a particular segment, and that firms can appropriate returns from RMT investments across a wide range of products and customers. Thus, large firms may have an advantage because their high output levels lead to greater R&D cost spreading (Cohen and Klepper, 1996; Sutton, 1998). Second, large firms may also benefit from owning complementary assets and capabilities (Teece, 1986; Tripsas, 1997). In medical fields, in particular, new technologies often require extensive clinical studies, which may benefit larger firms because of their existing relationships with hospitals, clinics, and physicians. Third, large firms have a stronger incentive to protect their brand and reputation, which, in turn, commands greater trust from consumers (Schmalensee, 1982). This is especially relevant when there is uncertainty about product safety. Lastly, the fact that changes in risk perception may affect the entire product category implies that conditions underlying theories such as disruptive innovation (Christensen and Bower, 1996)—that is, the innovation is initially not valued by mainstream customers served by large incumbents—are less likely to be satisfied for RMTs.

The presence of these size advantages does not imply that smaller firms will not be active in the development of RMTs. Smaller firms may have an advantage when RMTs require radical changes in firms' organizational capabilities or architectural knowledge (Henderson and Clark, 1990) or involve competency-destroying discontinuities and drastically different knowledge and skills (Tushman and Anderson, 1986).

Furthermore, in the presence of a well-functioning market for technology, smaller firms may be active in the innovation stage and commercialize RMTs by licensing them to more-established firms (Arora et al., 2001; Gans et al., 2002; Arora and Gambardella, 2010; Conti et al., 2019).

### 3.3 Boundary conditions

While a higher risk perception is likely to increase the share of RMT innovation relative to other quality dimensions, whether the level of RMT investments will, indeed, increase is potentially ambiguous. The discussion in the previous section suggests that innovation responses may depend on the market structure at the time of the shock. In the following, we discuss a number of factors that may limit the positive effect of a higher risk perception on RMT innovation. We will also briefly explain why these conditions are unlikely to bind in our empirical setting (which we will describe in detail in later sections).

**Attractiveness of substitute product categories.** An increase in risk perception will not only shift demand towards safer products within a product category, but also towards safer substitutes. For example, the 2011 Fukushima nuclear meltdown may not only increase the demand for safer nuclear reactor designs, but may also shift demand towards alternative, non-nuclear energy sources such as natural gas or solar. This implies that the degree of substitutability across technology categories affects the incentives to develop safer products for the focal category. In particular, in the presence of highly substitutable product categories, the focal category may experience a large drop in demand, which, in turn, suppresses RMT innovation. In the case of CT scanners, the substitutability provided by alternative non-radiation technologies is far from perfect, as CT dominates alternative technologies in terms of image quality, speed, or costs. Moreover, for some medical applications, there are no alternatives to a CT scan.

**Economic and scientific feasibilities.** Large shifts in risk perception may have little effect on technological progress when technological opportunities are limited (Rosenberg, 1974; Klevorick et al., 1995). Technological possibilities that are scientifically as well as economically viable need to be present for RMT innovation to flourish. Moreover, the nature of risk reduction also matters. Innovation incentives may be dampened in settings in which the effectiveness of RMTs is hard to measure, demonstrate, or understand. As we discuss in Section 6.3.2, in the case of CT, firms faced a number of scientifically feasible possibilities that were also not prohibitively costly to develop. Furthermore, the effectiveness of RMTs in reducing radiation risk could be easily understood and objectively measured.

**Regulatory, legal, or political uncertainty.** Regulatory, legal, or political uncertainty may also suppress innovation incentives. Firms may even be concerned about the possibility that the entire product category will be banned. For example, the FDA banned the cosmetic use of silicone breast implants in 1992 (for 14 years) due to health concerns of leaking silicone, despite the lack of substantive scientific evidence (Angell,

1996). In Japan, after the Fukushima accidents, supporting nuclear technologies became an untenable political proposition. As we explain in the next section, in our setting, regulatory and liability uncertainty was curtailed by a timely and clear response by the FDA and the courts.

# 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. As opposed to magnetic resonance imaging (MRI), which delivers more-detailed images but can take 30 minutes or more, CT takes seconds, is substantially 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.

In days following the FDA warning, these accidents were reported by multiple media outlets, including the *Los Angeles Times*, the Associated Press, NPR, and NBC. On October 15, Walt Bogdanich at the *New York Times*, by 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. This was the start of a *New York Times* series of more than 20 articles—titled 'The Radiation Boom'—over two years on the medical radiation risk associated with imaging technologies and radiation therapies.[3] 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."

[3]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 patients are mistakenly over-radiated. We exclude radiation therapies from both the treatment and the control groups in our analysis.

### 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) showed 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, showed that almost all responding physicians were 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, showed that 25 percent of the patients surveyed 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 that the public misunderstood the nature of radiation at the dose required for CT imaging and were overly fearful, the medical community stressed that people should not lose sight of the contributions of CT to more-effective surgeries, shorter hospital stays, and better diagnosis and treatment of cancer. At the same time, medical professionals 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 image quality to requesting 'good enough' images obtained with minimal radiation doses."

### 4.3 Subsequent events

The FDA initiated an investigation immediately after the disclosure of these accidents. The manufacturer of the scanners involved in both sets of accidents was GE Healthcare. The investigation revealed more widespread overexposure: the agency became aware of about 385 patients from six different hospitals (located in California and Alabama) who were exposed to excess radiation; and the reported cases involved scanners manufactured by GE and Toshiba. The FDA concluded in October 2010, 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.[4] 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 in user training.

[4]GE Healthcare was named the defendants in two class action lawsuits filed in late 2009. The Alabama court granted GE's motion to dismiss in March 2010, only four months after the filing of the lawsuit.

Public concerns raised by these events also led to a congressional hearing by the House of Representatives in February 2010. The testimonies by industry representatives emphasized innovations that the industry had already introduced—such as weight- and age-based protocols—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.

# 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), which capture patentable technologies close to their invention stage; and (ii) pre-market notifications submitted to and approved by the Food and Drug Administration (FDA) that measure new product introductions as well as innovations that are not patentable.

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

[5]The complete list of treated subclasses is provided in the online appendix. In the appendix, we also show that our results are robust to a different (keyword-based) method of defining treated 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 RMTs 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 confirm that the changes we detect are driven by products for which RMTs are prominent features.

The FDA classifies each product with a specific product code that identifies its generic category. We define a product code as treated if it relates to radiology diagnostic devices that emit ionizing radiation.[6] 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 of 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. 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).

## 5.3 Econometric model

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

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

where $Y_{c,t}$ 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. The accidental nature of the over-radiation incidents and the rich documentation at the time provide support for the exogeneity of the shock. We discuss additional evidence in support of our choice of treatment timing in the online appendix. $\delta_t$ and $f_c$ are year and technology-area fixed effects.

[6] 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.

The coefficient $\beta$ 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.

# 6 Innovation responses to the over-radiation shock

## 6.1 Patent applications

Panel (a) in 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.

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 2 of Table 2 . The estimate is economically large (corresponding to an increase of about 300 percent), with a p-value of 0.07, supporting our interpretation that the increase in RMT patenting is related to the over-radiation shock.[7] The online appendix 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.

Panel (b) of Figure 1 plots the year-specific differences between the treatment and control groups, $\beta_t$, and their 95-percent confidence intervals based on the following specification (2009 is the baseline year):

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

Before the over-radiation shock, the estimated differences between treatment and control subclasses are not statistically different from those in 2009, which helps to rule out anticipation concerns. The year-specific difference-in-differences coefficients after 2010 are positive and increasingly larger, and they become statistically significant in 2013. A number of factors may explain the increasing pattern. Developing new, patentable technologies requires time. Moreover, historical sources suggest that the shock caused a perma-

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

nent, rather than transitory, increase in people's awareness of radiation risk.[8]

By contrasting RMT with non-RMT features of radiation diagnostic devices, our baseline analysis directly tests the hypothesis that changes in risk perception may shape the direction of technological progress. As discussed in Section 3.3, whether the level of RMT investments will increase is potentially ambiguous. It is possible that the heightened fear about radiation chills innovation in radiation diagnostic devices overall and leads to a large drop in non-RMT patenting. Thus, an increase in the share of RMT patenting relative to non-RMT features does not necessarily imply an increase in the level of RMT patenting. Furthermore, because the market is highly concentrated, many firms are active in both the treatment and control groups.[9] If these firms are subject to budget constraints, they may move resources away from non-RMT to RMT technologies, also leading to an over-estimation of the level of increase in RMT patenting.

In columns 3 and 4 of Table 2 we show that the level of RMT patenting also increases when we use alternative controls for which the concerns discussed above are limited. Specifically, we use two alternative control groups. The first (column 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 budget-reallocation effect if firms allocate budgets and personnel relatively independently across technology groups. Note that a demand-side substitution effect may still be at play if the shock induces hospitals and clinics to increase the use of non-radiation diagnostic tools.[10] Such a substitution effect 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-side and demand-side spillovers, we employ the second alternative control group (column 4) 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.[11]

## 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 3 is the number of 510k applications in a product

[8] For example, David Waldman, chair of the Imaging Sciences department at University of Rochester Medical Center, stated in an interview with *Diagnostic Imaging* in December 2010: "Radiation dose will be an enormous topic over the next five years."

[9] About 87 percent of RMT patents and 68 percent of non-RMT patents in radiation diagnostic devices are by 37 unique assignees that patent in both groups.

[10] This is consistent with our discussion of boundary conditions in Section 3.3. To examine the issue 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 relative to medical implants (the second alternative control group used in this section), 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.

[11] In the online appendix, by excluding patents by these common patentees from the analysis, we further isolate spillover effects due to firms patenting in both treatment and control groups.

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.[12] Though not statistically different from each other, the difference-in-differences coefficient in column 3 is substantially greater in magnitude 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 does not mention 'dose' in their summary files, while column 5 counts only applications that do; 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 a potential demand-side spillover effect. The estimate confirms the result in column 5.[13]

Overall, the FDA data show that the number of radiation diagnostic devices increased after 2010 and that this increase was driven by applications explicitly referring to safety features. (Unreported) time-specific regression results show that the increase in applications including safety features started immediately after the shock. Given the typical delay between invention and commercialization, the relative fast response in product introduction suggests that the short-run response was likely to have been based on non-patentable technologies (therefore, not captured by the patent data) or on patentable technologies that were readily

[12] 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.

[13] We show in the online appendix that our findings are robust to a number of alternative specifications.

available prior to 2010. In the next section, we provide a detailed description of RMTs in the case of CT scanners, which is consistent with both interpretations.

## 6.3 Characterizing RMTs: the case of CT scanners

Based on industry and clinical publications, and textual analysis of FDA applications, we uncover two types of RMTs that were developed by CT producers after the shock.[14]

### 6.3.1 Progress along the existing, dominant technological path

The first type of RMTs are incremental, 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. Note that, as the industry representatives testified during the congressional hearing, CT producers had already been innovating along the safety dimension even before the shock. These include improvements in cover shields, components of radiation sources, radiation receptors, and various types of methods to utilize radiation dose more effectively and to control radiation exposure. Apart from continual improvement along these lines, the industry pushed for additional safety-check features after the over-radiation shock. These 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.[15]

### 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). Specifically, the change involved shifting away from the dominant method of image reconstruction to an alternative (long-shelved) method. This alternative method allowed for a reduction in radiation dose of up to 90 percent, which is not achievable by 'tweaking' the existing method.

For 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 fast and robust, the image resolution is strongly dependent on the dosage, which underlies why "we 'pay for' image quality with radiation dose"

[14]Focusing on a single product type—in particular, the one that was most directly involved in the over-radiation accidents—allows us to dig deeper into the scientific and industry literatures and to provide a more comprehensive and more precise analysis.

[15]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. 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).

(Pelc, 2014). The 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 dose reductions (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.[16] Our conversations with information from 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 involved 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 certain clinical applications; and 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.[17]

A common feature of both types of RMTs is that their impact on risk reduction can be easily demonstrated and understood (e.g., the required dose level is precisely measured). Moreover, the development costs for these RMTs were not prohibitive. Even for the second, more-radical type (i.e., IR-based image reconstruction), the basic computational principle was well understood by the time of the shock, as it involved a shelved technology, and the new feature could be integrated into a complex CT system in a modular fashion. This allowed large firms to introduce an early version of the new technology soon after the shock, even though it took an additional few years for them to improve speed and image quality to a satisfactory level.

#### 6.3.3 Quantification of both types of RMTs

To provide quantitative evidence for the two types of RMTs described above, we conduct the following analysis using the summary files of the 294 FDA applications filed between 2005 and 2017 in product code JAK, "Computed tomography X-ray system."[18]

First, for each application, we examine all phrases 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 (defined as 'dose reduction' keywords); and/or (ii) provides safety checks or tools to manage radiation dose more efficiently (defined as 'dose check/efficiency' keywords). The data

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

[17] "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.

[18] As discussed previously, the FDA applications data have the advantage of capturing features that are not patentable or based on older inventions whose patents were filed before our sample period.

show 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 2010 and 2017, 30.1 percent of all applications mentioned 'dose check/efficiency' keywords, and 20.3 percent mentioned 'dose reduction' keywords. The lower percentage of applications referring to dose reduction is consistent with the idea that these features require more substantial investment than those related to incremental changes.

Second, we identify application files that describe products that embed IR algorithms—that is, their summary file contains the phrase "iterative reconstruction" or other trade names that companies use for such algorithms. Adoption of the IR method began in 2010 and steadily increased afterwards. In particular, none of the applications before 2010 included any reference to the IR method, while 35.8 percent of the applications after 2010 did. Moreover, after 2010, all 118 applications without IR failed to mention dose-reduction keywords, whereas 38 out of 66 applications with IR did refer to dose reduction, consistent with our understanding that substantial dose reduction is achievable only with the IR method.

# 7 Large incumbents, smaller firms, and market structure

In this section, we examine how innovation responses to the shock differ by firm size and the likely impact on market structure. In particular, we distinguish between the top five firms and smaller players. Among the top five, GE and Siemens were consistently the two largest in terms of their shares of the product market during our sample period. Toshiba was the third, then Philips, followed by Hitachi.[19]

Table 4 reports firm-level regressions of patent and FDA analysis of all types of radiation diagnostic devices. The unit of analysis in columns 1-3 is firm-patent subclass-year, and the regressions include year, firm, and subclass fixed effects. Column 1, using all firms, confirms the significant increase in RMT patenting relative to non-RMT patenting in radiation diagnostic devices after the shock. Columns 2 and 3 examine the top five firms and smaller players (including smaller firms, universities and research institutions, and individuals) separately: the results show an increase (marginally significant) in patenting for both the largest five firms and smaller players. The increase, however, is not statistically different across firm size. The unit of analysis in columns 4-6 is firm-product code-year. Column 4 confirms a significant increase in the number of FDA applications (that is, new products) for radiation diagnostic devices, relative to control devices outside radiology. Column 5 shows that the increase is large and significant for the top five firms, while the change for smaller firms is economically small and not statistically significant at the conventional level (p-value is 0.144); and the difference across firm size is statistically significant.

[19]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 a 20-25 percent share of the U.S. market; Toshiba, 15-20 percent; Philips, 10-15 percent; and Hitachi, less than five percent.

The above results show that, while innovation responses in RMTs appear to be industry-wide in terms of patenting, large incumbents are significantly more responsive than smaller firms in terms of new product introductions. Because these different innovation measures potentially reflect different types of firm capabilities, the significantly greater response by large incumbents in new product introductions may be explained by their superior capabilities for developing innovation outputs that are not patentable (and, hence, are not captured by patent data) and, potentially more importantly, by their advantages in commercialization, such as manufacturing, sales, and distribution capabilities.

A closer look at the case of CT scanners also reveals interesting differences by firm size for different types of RMTs. Figure 2 plots the percentages of applications in CT technologies that refer to the two types of RMTs that we documented in Section 6.3. The figure shows that, after the shock, the top five firms and smaller players did not differ in their propensity to include incremental dose-check and/or dose-efficiency features, but the top five firms were much faster and more intense in their incorporation of more-complex technologies that reduce dose. In particular, after 2010, 31 percent of the applications by the top five firms and 29 percent by smaller firms mentioned 'dose check/efficiency' keywords (p-value is 0.75). However, 28 percent of the applications by the top five firms mentioned 'dose reduction' keywords, compared to only 6.1 percent by smaller firms (p-value $< 0.01$). Similarly, the fraction of applications by the top five firms with IR technology—the underlying technology for dose reduction—was 46.3, while that for smaller firms was 14.7 (p-value $< 0.01$; this comparison is not presented in Figure 2).

The above results show that, while CT scanner producers overall have adopted incremental RMTs, large incumbents have been significantly more likely and quicker to develop and commercialize the more-radical type of RMTs. An examination of patents related to IR technologies does *not* show a statistically significant difference in the increase in the number of patent applications across firm size.[20] Because of the small number of patents in this sample, this analysis should be taken with caution. Nonetheless, it suggests that the differential responses in the more-radical type of RMTs (illustrated in Figure 2b) were also driven by the superior development and commercialization capabilities of large incumbents, rather than the differences in their inventing capabilities. In light of our discussion in Section 3.2 and our understanding of the institutional details, two sets of reasons may explain this advantage.

First, the development and commercialization of the IR technologies appear to require substantial investments. As explained previously, IR technologies entail substantial tradeoffs between dose reduction

[20] We identify 33 patent applications related to IR technology filed between 2005 and 2015 at the USPTO, with 15 granted before 2018. An analysis of these applications shows that after the over-radiation shock, the number of IR patent applications per year doubled (from 2 to 4.2, and p-value is 0.22). 70 percent of the 33 applications were by top five firms, and the rest by smaller firms, research institutions, and individuals. This proportion is statistically similar before and after the shock; in particular, it was 69 percent before the shock and 73 percent after the shock.

and other quality dimensions such as image quality and speed. The industry, and each of the largest firms, launched two to three generations of these products in order to address these concerns—such improvements require substantial and sustained resources. There is also evidence suggesting that firms engaged in significant sales and marketing campaigns to launch these products. For example, the front page of GE's product brochure for Veo—the second generation of its IR algorithm—displays the following in large font: "The breakthrough that is rewriting the rule of CT imaging," and adds that this technology helps physicians to achieve "the enhanced image quality at a radiation dose never before thought possible." Fixed costs explain a large proportion of these R&D and commercialization investments. Thus, firms with greater market shares were likely to be in a better position to develop and commercialize technologies that require more-substantial investments, as they are better able to spread the fixed costs. A further breakdown within the top five firms also shows a monotonic relationship between firm size and the speed and intensity of the introduction of IR technology, which is consistent with the idea of a size advantage through fixed-cost spreading.[21]

Second, the adoption of IR technologies also requires substantial retraining of radiologists and other adjustments on the hospital side. Non-trivial adoption costs, combined with quality uncertainty of the new technology, also tend to benefit large firms. First, users are more likely to trust larger firms with more-established reputation for product quality and customer service, as well as with greater resources, especially when a continual improvement of product quality is critical. Second, larger firms may also have had an advantage in providing concrete evidence of the technology's performance via a greater number of clinical studies or studies by more-credible researchers and clinicians. This advantage could have arisen from their existing installed base, greater resources to sponsor clinical studies, and their relationships with hospitals and physicians. Lastly, because CT imaging is such a critical research tool, researchers started to mention the IR technology embedded in a specific firm's CT equipment in a variety of clinical studies. This resulted in more references to larger firms' products in scientific publications, which might have provided indirect marketing to the research-oriented medical community. Data based on scientific publications provide quantitive evidence for (i) the significant uncertainty over the performance of IR technology, especially regarding its ability to reduce dose while maintaining high image quality; and (ii) a positive relationship between the number of clinical studies that mention IR technology embedded in a specific firm's CT scanners (as a general research tool) and its market share.[22]

[21] The two largest firms (GE and Siemens) were the fastest to incorporate the IR method, doing so in 2010, whereas Toshiba and Philips responded in 2011, and Hitachi in 2015.

[22] Searching, in Google Scholars, for "iterative reconstruction" and "CT" and "dose" in titles alone yields about 200 articles published between 2010 and 2015. These are mostly clinical studies that evaluate the various metrics of this new technology, and this large number is consistent with our understanding that there was significant uncertainty over how well this new technology performed. Relaxing the search terms to the entire articles yields over 2K results published in 2010 and 2011 alone. The majority of these search results are articles that use imaging—and, in particular, the IR techniques embodied in the CT scanners—to conduct various types of clinical studies. Adding an additional search term of a specific firm's name yields a positive relationship between

Apart from the differential responses by firm size in the product markets, there is also evidence for more entry after the shock in radiation diagnostic devices (not just CT scanners).[23] Though not definitive, the results suggest that the radiation diagnostic industry overall might have benefited from the market opportunities created by the increased demand for safer technologies, at least in the medium run. Large incumbents, especially, appeared to have been better positioned to take advantage of such a demand shift.[24]

# 8 Demand effects of an increase in risk perception

We have shown 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, by unbundling the shock's impact on demand, we provide direct evidence for our proposed mechanism—i.e., higher risk perception increases the willingness to pay for safety.

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 showed 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 and, at the same time, a greater propensity of hospitals and clinics to upgrade equipment that emits high levels of radiation. These opposite effects at the intensive and extensive margins are hard to reconcile with alternative explanations.

## 8.1 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

firm size and the number of search results. In particular, the largest two firms (Siemens and GE Healthcare) are associated with 766 and 423 articles, the middle two (Toshiba and Philips) with 212 and 455 articles, and the smallest of the top five firms (Hitachi), is associated with 114 articles. The positive relationship suggests a potentially powerful certification effect that larger firms might have benefitted from as hospitals and clinics needed to consider which firm's products to adopt.

[23] Regression results using the FDA data (online appendix) show that, relative to control product markets, the unique number of firms active in the product market for all types of radiation diagnostic devices increased (by 26 percent, p-value = 0.05).

[24] Despite a greater net entry, the share of innovations by the largest incumbents seems to have increased. The FDA data show that the share of new applications by the top five firms in radiation diagnostic devices in general increased by about seven percentage points after the shock, compared to before. The increasing dominance of the largest firms is further supported by the 2014 IBISWorld Procurement Report on the CT scanner market only, which shows that in the U.S., the shares of machines sold by the largest CT producers increased between 2011 and 2013.

contrast). To construct a balanced panel, we keep the 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 5 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. The online appendix provides further details and additional supporting evidence for the relative decline in high-radiation procedures.

We also cross-validate the above result with an alternative dataset provided by the Organization for Economic Co-operation and Development (OECD).[25] The OECD data show that in the U.S., relative to MRIs' increasing trend throughout our sample period, CT broke the increasing trend in 2012 and declined afterwards. Relative to its peak in 2011, the average number of CT exams between 2012 and 2017 represents a ten-percent reduction.

Overall, the 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 suggests fear of radiation as an important factor (Lee and Levy, 2012). Of course, the decline in high-radiation procedures could have been driven by a drop 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.

## 8.2 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 omits 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

[25] 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.

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.[26] Column 3 of Table 5 contrasts the number of assembly reports on CT systems versus chest X-ray systems, controlling for year and site×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 by a magnitude of 25 percent. Column 4 shows a similar result contrasting CT systems with dental X-ray systems. The online appendix provides additional supporting evidence for this finding.

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 was from the 2014 IBIS Procurement Report, which estimates that the benchmark price of CT scanners had been, instead, rising monotonically between 2005 and 2014.

### 8.3 Qualitative evidence of demand shifts

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, conversations with two industry insiders familiar with these events made it quite clear that CT producers ultimately responded to market demand. One executive 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.[27] Only after the accidents did the demand for safety-related features became a first-order consideration. As discussed previously, in adopting these technologies, hospitals faced non-trivial costs for adjusting their operational routines and retraining radiologists. A substantial demand shift seemed necessary for CT producers to develop these technologies profitably.

Second, there is 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

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

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

the disclosure of the accidents. The document listed suggestions for changes to CT machines, such as dose display, alerts, and password protection that could prevent radiation overdose, which are exactly in line with some of the incremental types of RMTs later developed by producers.

Finally, there is also evidence that RMTs are mentioned in hospitals' marketing messages to mitigate their patients' fear. For example, the Ridgeview Imaging Center in Minnesota, a testing site of Siemens' machine equipped with the IR option, described this technology on its website as "providing patients with the lowest-possible radiation dose." As discussed previously, CT producers also explicitly highlighted the dose-reduction aspect of IR technologies in addressing their customers—physicians and hospitals.

### 8.4 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 safety-check features of CT scanners. Thus, while regulatory pressure may have facilitated the diffusion of these safety checks, 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 perception among CT producers, which, in turn, could have spurred the development of these RMTs. As discussed above, industry sources suggest that CT producers had always been conscious of the 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 were more aware of such risk than patients and even physicians were prior to the shock). It is possible that CT producers' perception of their liability risk may have increased after the shock. However, liability risk is tightly linked to industry standards and regulatory requirements, which prescribed only safety-check features and not substantial dose-reduction technologies.

# 9 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 an increase in the patenting of features of radiation diagnostic devices that mitigate radiation risk—on the order of 110 percent—relative to other features. 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. Using CT scanners as a case study, we provide an in-depth characterization of two different types of risk-mitigating technologies that firms developed after the shock. Firm-level analysis shows that while firms were similarly responsive in their patenting activities, large incumbents were significantly more responsive than smaller firms in terms of new product introductions; and, in the case of CT scanners, in terms of the more-radical type of risk-mitigating technologies. We also provide qualitative and quantitative evidence that supports our proposed mechanism—that is, the over-radiation shock has changed users' risk perception, thereby increasing their willingness to pay for safety.

Ultimately, our paper suggests that changes in risk perception can be an important driver of innovation and 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 sufficient and economically viable technological possibilities to develop safer technologies; substitutability provided by alternative product categories is far from perfect; and regulatory and legal uncertainty is relatively contained—the positive effect of a higher willingness to pay for safety may dominate the chilling effect that higher risk has on innovation. Finally, large firms may play an important role in the development and commercialization of RMTs, and this has important implications for the dynamics of competitive advantage and market structure.

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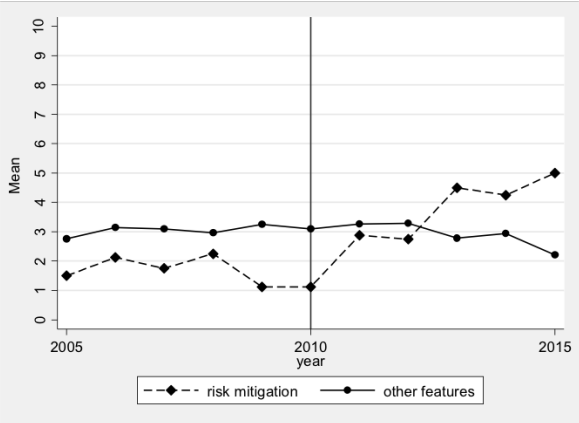
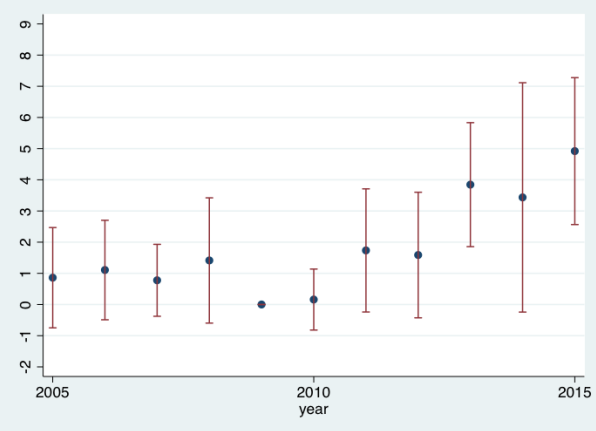
Figure 1: Dynamic effects of the over-radiation shock on patenting

(a) Raw data



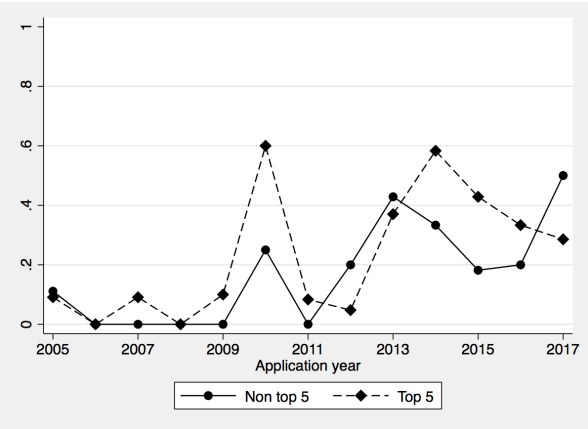

(b) DID coefficients



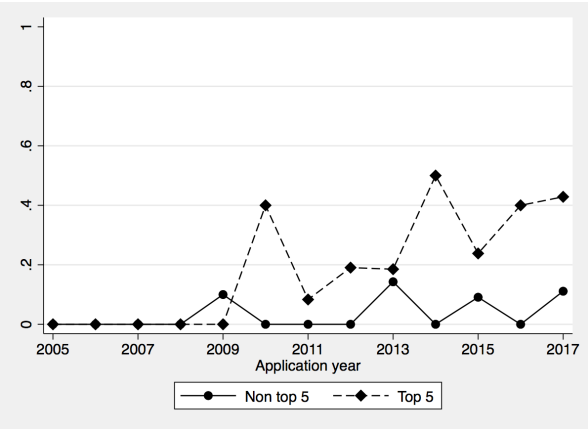

*Note*: Panel (a) is based on raw data and plots the average number of patents in RMT subclasses versus other subclasses in radiation diagnostic devices (i.e., CPC group A61B6). Panel (b) plots year-specific DID coefficients estimated from equation (2).

Figure 2: Risk-mitigating technologies in CT Scanners: top five firms versus smaller firms

(a) Dose check/efficiency keywords




(b) Dose reduction keywords




*Note*: percentages of applications in a given year that include 'dose check/efficiency' keywords or 'dose reduction' keywords in the summary files. Dose check/efficiency keywords indicate the incremental-type of RMTs, while dose-reduction keywords indicate radical-type of RMTs. 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.

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 (1) | Patents (2) | Patents (3) | Patents (4) |
|---|---|---|---|---|
| RMT × After 2010 | 1.783** | 0.828* | 1.522** | 1.229* |
| | (0.809) | (0.456) | (0.719) | (0.720) |
| Year effects | Y | Y | Y | Y |
| Subclass effects | Y | Y | Y | Y |
| Treatment group | RMTs in in A61B6 | RMTs in CT | RMTs in in A61B6 | RMTs in in A61B6 |
| Control group | non-RMTs in A61B6 | non-RMTs in CT | A61B5 & A61B8 | A61F |
| Observations | 1540 | 1507 | 8756 | 8767 |

*Note*: OLS regressions. Patents = the number of patent applications in a subclass-year. RMT = 1 for patent subclasses involving risk-mitigating technologies in radiation diagnostic devices (A61B6). The treatment group in column 1 are RMT subclasses in radiation diagnostic device (A61B6), and the control group are non-RMT subclasses in A61B6. Column 2 uses a subset of the patents used in column 1; it includes only CT patents (that is, those referring to subclass A61B6/032 as either primary or secondary classification). The treatment group in columns 3 and 4 is the same as column 1, but the control group in column 3 includes diagnostic medical devices that do not use radiation or ultrasound (CPC group A61B5) and diagnostic devices that use ultrasound (CPC group A61B8), and the control group used in column 4 includes medical implant patents (CPC subsection A61F). Standard errors (in parentheses) are clustered at the subclass level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 3: 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 devices × After 2010 | 1.247* | 0.868 | 1.897* | 0.231 | 1.088** | 1.102** |
| | (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 4: Innovation responses by firm size

| | 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 3). Standard errors (in parentheses) are clustered at the subclass (or product code) level. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 5: 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 for (not for publication)

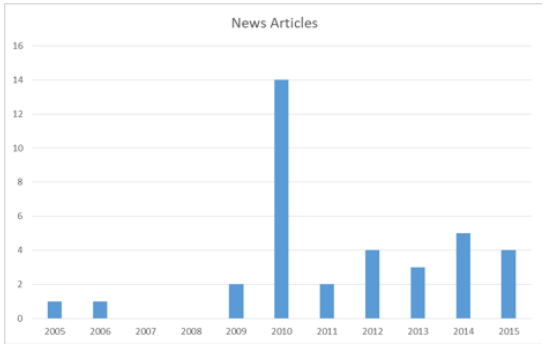
# A. Additional Empirical Analysis

## A.1 Timing of the shock

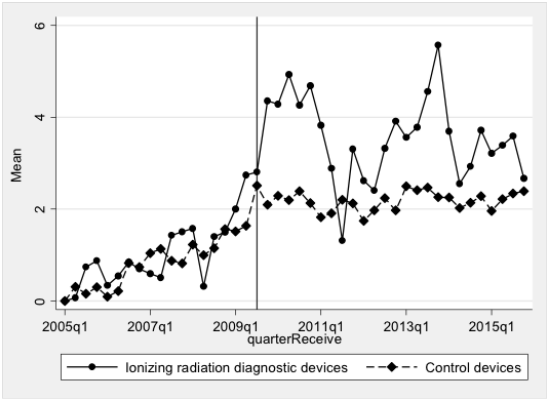
Figure A1 provides additional evidence for the choice of our treatment timing—that is, years including and after 2010. Panel (a) plots the timing of news articles referring to CT scan and X-ray radiation risk, retrieved from the Factiva (Dow Jones) database. The figure shows that following the first 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 in 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.

Figure A1: Timing of the over-radiation shock

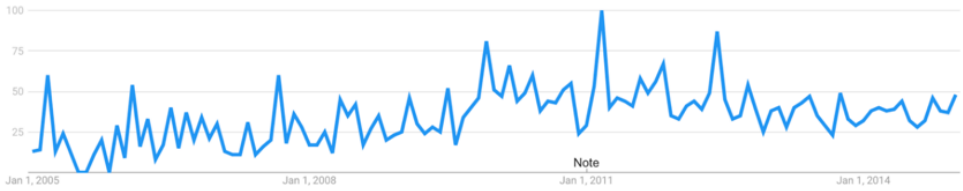
(a) Media mentions of CT scan and X-ray radiation




(b) FDA approval time (months)




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




## A.2 Robustness of the patent analysis

Table A1 shows that our baseline results presented in Table 2 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.

In columns 3 and 4 of Table 2, we use alternative control groups outside radiation diagnostic devices to mitigate potential spillover effects. This exercise shows that the level of RMT patenting also increases. To further isolate any spillover effects due to firms patenting in both treatment and control groups, we exploit

Table A1: Effects of the over-radiation shock: patent analysis (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*: Additional robustness checks for the patent analysis. 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. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

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 1 in Table A2).[28] When using medical implants as the control group, in addition to excluding patents by the common patentees from the control group (column 2), we go a step further and exclude such patents from both the control and the treatment groups (column 3). The last specification is still very stringent, as 56 percent of the RMT patents are excluded due to common patentees.[29] The results across all columns in Table A2 confirm a relative increase in RMT patenting after the shock; the estimates are statistically significant at least at the ten-percent level.

A potential concern about our baseline analysis 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 B.2). 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. Table A3 confirms our baseline result using various threshold definitions. Unreported results also confirm that these results are not driven by any single most frequently used keyword.

Finally, 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. 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.

[28] About 14 percent of the control patents are by common patentees.

[29] 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.

Table A2: Alternative control groups for the patent analysis

| Dependent variable | Patents (1) | Patents (2) | Patents (3) |
|---|---|---|---|
| RMT × After 2010 | 1.648** | 1.423** | 0.360* |
| | (0.717) | (0.719) | (0.201) |
| Year effects | Y | Y | Y |
| Subclass effects | Y | Y | Y |
| Control group | A61B5 & A61B8 | A61F | A61F |
| Drop common patentees | from control | from control | from treatment and control |
| Observations | 8767 | 8767 | 8767 |

*Note*: OLS regressions. Patents = the number of patent applications in a subclass-year. The control group used in columns 1 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 2-3 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 A4 reports a series of patent-level regressions estimating the following linear probability model:

$$SecondaryRMT_{itcj} = Year_t + \beta NSecond_{itcj} + \gamma NClaims_{itcj} + \kappa_c + f_j + \varepsilon_{itcj},$$

where $SecondaryRMT_{itcj}$ is a dummy that equals one when patent $i$, with application year $t$, primary subclass $c$ and owned by firm $j$ lists at least one risk-mitigating subclass for secondary classification. The dummies $Year_t$ are the coefficients of interest—they capture the application- year effects with 2009 as the baseline. The sample is cross-sectional and includes all the patents in A61B6 with a non-RMT primary subclass. The regressions control for the number of secondary subclasses of a patent, $NSecond_{itcj}$, which is important because the propensity to have an RMT subclass as the secondary classification mechanically increases with the number of secondary subclasses. The regressions also include the number of claims in the patent, $NClaims_{itcj}$; primary subclasses effects, $\kappa_c$; and patent owner (assignee) effects, $f_j$.

Column 1 of Table A4 estimates the above specification without including primary subclass or assignee fixed effects; column 2 includes primary subclass fixed effects; and column 3 includes both primary subclass and assignee fixed effects. Across all specifications, the application-year coefficients before 2010 are small, both positive and negative, and statistically insignificant. After 2010, the application-year coefficients are all positive, and the magnitude increases substantially over time (except for the last year, 2015). These results confirm our baseline result that patents filed after the over-radiation shock were substantially more likely to include risk-mitigating features in the invention.[30] Overall, these results provide further support for the idea that RMTs became a more prominent goal of research activities after the over-radiation shock.

[30] As a robustness test, we replicated the regression in column 3 in a smaller sample of patents with at least one reference to the class A61B6/032 "Transmission computed tomography [CT]."The estimates (unreported) are qualitatively and quantitatively similar to those obtained for the full sample.

Table A3: Keyword approach to identifying RMT patent subclasses

| Dependent variable | Patents (1) | Patents (2) | Patents (3) | Patents (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. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

## A.3 Robustness of the FDA application analysis

Table A5 provides robustness of the FDA application analysis. These include: (i) using the 2005-15 sample period, which is equivalent to that used in our patent analysis; (ii) dropping product codes with no applications during our sample period; and (iii) alternative econometric models—using the logarithm of (one plus) the number of applications as the dependent variable or a Poisson model.

## A.4 Effect of the over-radiation shock on market entry

Table A6 uses the FDA application data and examines the effect of the over-radiation shock on entry. 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 510k application data (starting from the 1970s). Exits are much harder to study because we do not have a long enough post-period to define exit reliably. For example, some firms may take a few years in between to launch a different product; thus, not observing the firm in a given product code until the end of our sample period does not really mean that this firm has exited. For this reason, we analyze, instead, the number of unique firms active in a given product code in a year. A reduction in this measure is suggestive of net exit from the product code. Again, to be conservative, both regressions cluster the standard errors at the product-code level. Otherwise, both coefficients are highly significant.

Column 1 of the following table presents the regression results for which the unit of analysis is 'product code X year,' and the dependent variable is the number of new firms entering a market in a given year. Even though the coefficient is not statistically significant at the conventional level (p-value = 0.210), the magnitude is economically large, at 35 percent, assuming the same difference between treatment and control groups before and after the shock. Column 2 shows that the number of unique firms in radiation diagnostic devices also increases significantly (p-value is 0.051). The economic magnitude is 26.3 percent, again assuming the same difference between treatment and control groups before and after the shock. These results suggest that after the shock, relative to control product markets, there is an increase in the net entry by new players in radiation diagnostic devices.

Table A4: 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 A5: Effects of the over-radiation shock: FDA application analysis (robustness)

| Dependent variable | Apps (with dose) (1) | Apps (with dose) (2) | log[Apps (with dose)+1] (3) | Apps (with dose) (4) |
|---|---|---|---|---|
| Ionizing diagnostic device×After 2010 | 0.829** (0.368) | 1.373** (0.536) | 0.145** (0.072) | 1.774*** (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*: Additional robustness checks for the FDA application analysis. 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 A6: Entry and unique number of firms active in the market (FDA data)

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

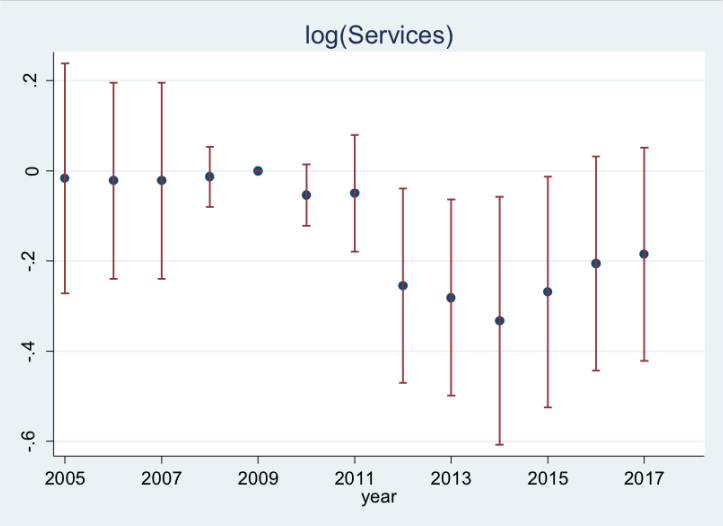
*Note*: OLS regressions. Dependent variable in column 1 is the number of new firms entering a product code-year. A firm's entry year is defined as the first year in which the firm shows up in a given product code based on the entire 510 k application data (starting from the 1970's). Dependent variable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

## A.5 Additional results on equipment use

Appendix Figure A2 plots the year-specific effect of the overdose shock on high-radiation procedures relative to matched control procedures of MRI and ultrasound. The results show little pre-trend, a slight drop in 2010 and 2011 (p-value is 0.115), and a large decline starting in 2012 that had yet to recover as of 2017.

We cross-validate the results using Medicare data reported in the paper with an alternative dataset provided by the Organization for Economic Co-operation and Development (OECD). Figure A3 (panel a) shows that in the U.S., relative to MRIs' increasing trend throughout our sample period, CT broke the increasing trend in 2012 and declined afterwards. Relative to the peak in 2011, the average number of CT exams be-

Figure A2: 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.

tween 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. Figure A3 (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.

Finally, recall that five of the six hospitals involved in the FDA investigation were located in California, and one was in Alabama. Table A7 reports triple-differences regression results using state-level Medicare data.[31] 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.

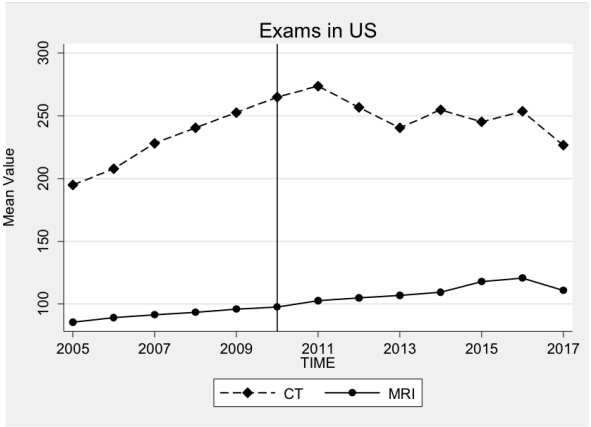
## A.6 Additional results on equipment upgrade

Similar to the equipment use analysis, 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 among 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).

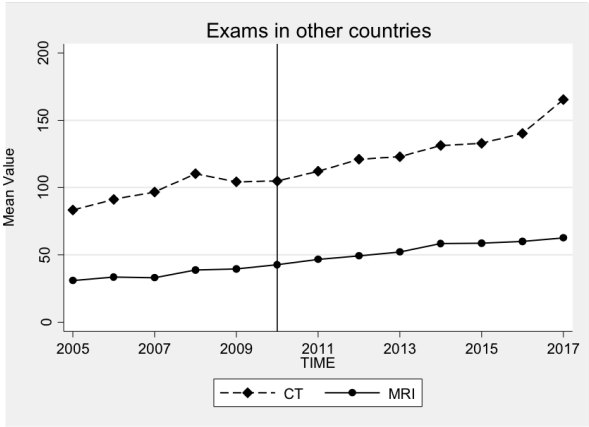
[31] Columns 3 and 4 in Table A7 include control variables for state liability laws (cap on non-economic damages and joint and several liability rule) and political preferences (a dummy indicating Republican-controlled government and legislature). All of the regressions also include all the double-interaction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

Figure A3: 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 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*: triple-differences regression results using state-level Medicare data. 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. All the regressions also include all the double-interaction terms. State controls are state tort systems (such as dummies for cap on non-economic damages and 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 (1) | Assembly reports (2) | Assembly reports (3) | Assembly reports (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) |
| | Dental | Dental | Dental | Dental |
| 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*: Similar to the equipment use analysis, this table reports triple-differences results exploiting the location information of these sites. 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 the six hospitals involved in the 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 the 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. Data appendix

## B.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.

## B.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."