Online Appendices: Risk-Mitigating Technologies—the Case of Radiation Diagnostic Devices

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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.

A.2 Robustness of the patent analysis

Table A1 shows that our baseline results presented in Table **??** 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 more-restrictive specifications that exclude patents by these common patentees from the analysis. When

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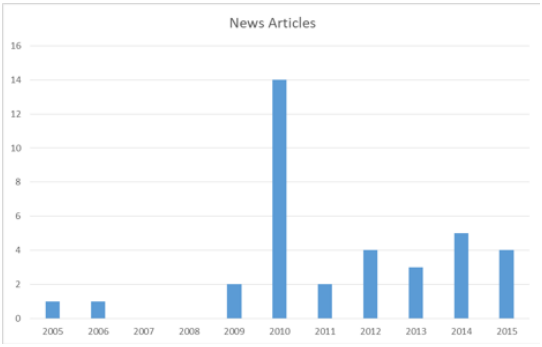
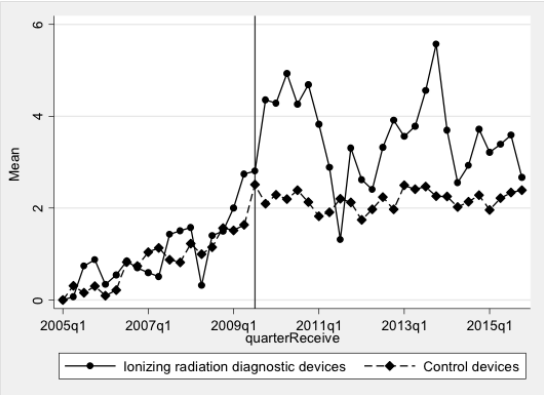
Figure A1: Timing of the over-radiation shock

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



(b) FDA approval time (months)



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

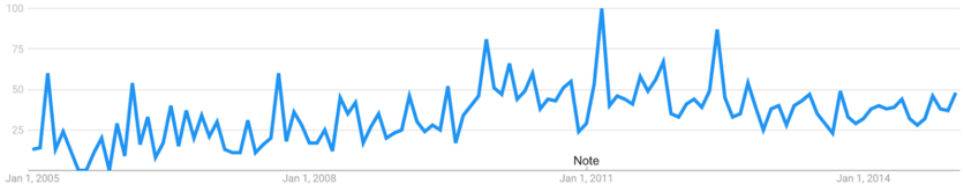


Table A1: Effects of the over-radiation shock: patent analysis (robustness)

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. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

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).[1] 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.[2] 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.

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. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

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

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

[2] 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.

results also confirm that these results are not driven by any single most frequently used keyword.

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. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

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.

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, κ_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.[3] Overall, these results provide further support for the idea that RMTs became a more prominent goal of research activities after the over-radiation shock.

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

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

Note: 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. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

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

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

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

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.

Figure A2: Year-specific effects on the number of CT services relative to MRI and ultrasound

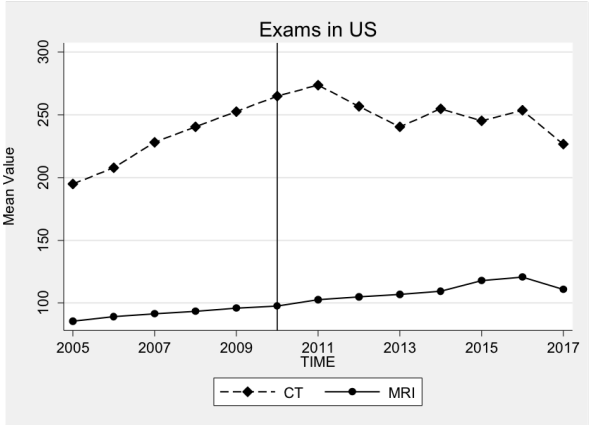
Note: The treatment group includes Current Procedural Terminology (CPT) codes for high-radiation procedures, including CT, PET/CT, and fluoroscopy; and the control group includes CPT codes for MRI and ultrasound that match to the treated CPT codes in terms of pre-trends. The dependent variable of the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

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 between 2012 and 2017 represents a ten-percent reduction, a likely underestimation because it does not take into account the hypothetical continuation of the increasing trend in the absence of the over-radiation shock. 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.

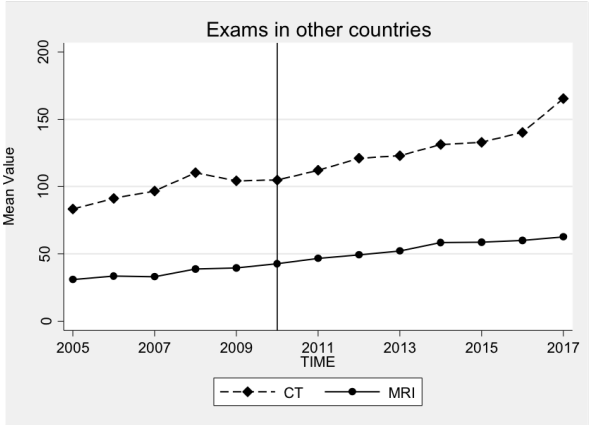
Finally, recall that five of the six hospitals involved in the FDA investigation were located in California, and one was in Alabama. Table A7 reports triple-differences regression results using state-level Medicare

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.

data.[4] 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).

[4]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.

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."