

## Risk Perception, Tort Liability, and Emerging Technologies

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### Abstract

Artificial intelligence, the Internet of Things, and robotic technologies bear great promise for improving our lives through safer products and new medical technologies. Driverless cars reduce accidents caused by human errors. Robot-assisted surgeries require minimal incisions and allow for faster recoveries. Smart products connected to the internet enable producers to communicate safety hazards to users and possibly fix the problems in real-time. At the same time, these novel technologies may also impose new risks of harm: connectivity may render the systems vulnerable to cyberattacks, the self-learning and opaque nature of machine-learning algorithms may make problems difficult to predict or diagnose, and the complexity of system integration and value chain could make a product's functioning more reliant on that of others. In the context of this paper, lawmakers in various countries are grappling with the questions of whether and to what extent the current legal framework on safety and liability can adequately protect consumers. This paper will discuss several lessons based on the relationships among risk perception, tort liability, and innovation.

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### **Background to the Study**

In February 2020, the European Commission released its “Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and Robotics,” which provides a comprehensive discussion of these issues. The overarching message of the report is that the existing frameworks on safety and liability can cope with many aspects of these emerging technologies, but there are important gaps that policy makers need to address to ensure consumer protection and to encourage technological innovation. Without intending to be exhaustive, we dive deeply into two historical settings involving Computed Tomography (CT) scanners and medical implants. These settings capture some of the key features of many novel technologies during their early development and commercialization stages. First, many risk factors related to the ways in which humans interact with machines, the ways in which different components and different products interact with each other, and the ways in which consumers are harmed may be difficult to predict ex-ante. Second, a multitude of players are involved in the supply and distribution chain, many of which provide general-purpose inputs and services (e.g., data, sensor, and connectivity providers). Third, many end-product producers are small innovators that may not be able to sustain the liability costs of unexpected (and uninsured) harms.

### **Risk Perception, Learning, and Innovation**

Our first case focuses on the Computed Tomography industry. Judged by primary care physicians as one of the most important innovations in medicine, more than 62 million CT scans were performed in the U.S. in 2006, compared to about three million in 1980. What we describe below illustrates how new information about risk and changes in consumers' concerns about safety may affect firms' innovation incentives and technological progress.

### **Over-radiation Accidents using CT Scanners and the Development of Risk-mitigating Technologies**

On October 8, 2009, a large 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 scans. The error had been made a year before when the hospital had reconfigured a scanner to improve doctors' ability to see blood flow in the brain. Media outlets nationwide reported on the accidents. Most prominently, starting on October 15, the *New York Times* published more than 20 articles in two years making the newspaper a 2011 Pulitzer Prize finalist on this and other medical over-radiation accidents using imaging and radiation therapy devices. After a year-long investigation, the Food and Drug Administration (FDA) concluded in October 2010 that GE Healthcare and Toshiba, the two companies whose CT scanners were involved in the above and other accidents uncovered by the investigation had not violated FDA regulations: these scanners, had they been used according to the manufacturers' specifications, would not have resulted in overexposure. Because the errors were due mainly to misconfigurations by the hospitals, the courts also cleared the manufacturers of their legal liabilities. However, the extensive media coverage of these accidents led to a significant increase in the public's attention to medical radiation risk. Even for medical professionals, survey evidence prior to these accidents showed that physicians tended to underestimate the amount of radiation patients are subject to with various imaging tests, whereas survey

evidence after these accidents showed that physicians became much more aware. In our research (Galasso and Luo, forthcoming), we examine the impacts of these accidents and their extensive media coverage on the development of risk-mitigating technologies that enhance safety.

Drawing on the detailed patent classification scheme developed by the U.S. Patent and Trademark Office, we show that radiation diagnostic device producers increased their innovation efforts substantially on addressing radiation safety, compared to other quality dimensions such as image quality. In particular, our analysis shows that, relative to other technology classes of radiation diagnostic technologies, the average number of patent applications in technology classes related to radiation safety increased by over 100 percent in the period 2010-15 compared to the period 2005-09. With the collaboration of major industry players, Medical Imaging and Technology Alliances (MITA), the industry association, launched a series of new industry standards aimed at preventing over-radiation accidents. These fixes were in line with what the FDA recommended based on their investigation, including the addition of a dose display, alert and notification systems for doses exceeding pre-assigned thresholds, standardized dose-recording software, and redesigned use protocols for certain procedures. But CT producers' innovation in radiation safety did not stop at preventing accidents. All of the major producers also reintroduced and invested heavily in a long-shelved image-reconstruction technique that differed substantially from the then-dominant method. While the reintroduced technique required a significant sacrifice of speed (due to its computational intensity) and image quality and textures that radiologists had been trained with, it allowed for levels of radiation dose reduction (up to 80-90 percent, depending on the applications) that were not achievable by simply 'tweaking' the then-dominant method.

### **General Lessons about Risk Perception and Learning as a Demand-pull Force of Innovation**

Our findings highlight the importance of market forces in driving innovation. In particular, our research suggests that consumer learning about the risk of using new technologies can be a powerful driver of safety innovation. Most products are characterized by multiple quality dimensions, and the intensity of demand for these various dimensions drives producers' innovation efforts. When the risk is not perceived to be high and when there is a trade-off between safety and other quality dimensions demanded by the market, there may be under-investment in safety. In the case of CT scanners, prior to these accidents, "the main drivers for technological improvements have been the physicians' demand for improved image quality, speed, and new clinical applications." The CT scanner is a textbook example of the trade-off between safety and other quality dimensions. With the image-reconstruction technology that dominated the industry for 30 years prior to the accidents, image quality depended critically on the amount of radiation dose used. The alternative technology deployed after the accidents broke this trade-off between image quality and radiation dose but was computationally intensive and could not satisfy the demand for speed.

Our understanding of the risks associated with emerging technologies improves over time, shaped by scientific progress and accidents. When there is a large increase in risk perception,

which is often driven by high-profile accidents or lawsuits, users are often willing to experiment with technologies and products that are high on safety but low on other quality dimensions. This may lead firms to innovate to enhance safety beyond the level required by regulators or by industry standards. During the current COVID-19 pandemic, we have witnessed such willingness to experiment. In a wide variety of settings, firms have adopted and developed digital and automation technologies that fare less well in important dimensions but are critical for mitigating contagion risk. These experiments, in turn, have generated learning, changed behavior, and provided opportunities for further innovation. Changes in risk perception tend to go beyond a particular product or a specific producer, spilling over to other products in the entire category or even to related product categories that use similar technologies. Our results show that, following the accidents, innovation responses in the CT industry were industry-wide and came both from firms directly involved in the accidents as well as firms that were not.

Our research also shows that the largest industry players had a crucial role in the development of risk-mitigating technologies: they were faster in introducing new products that require substantially lower radiation doses and applied for more patents related to radiation safety. This is not surprising, as larger market shares provide greater incentives to internalize the liability and reputation costs. Moreover, because safety-related stocks tend to raise consumers' willingness to pay for safety beyond the directly implicated products, large firms are also better able to appropriate returns from investments in safety across a wide range of products and customer segments. Agreement over new safety standards is also easier to reach in oligopoly markets compared to fragmented industries. This suggests that changes in market structures such as mergers and acquisitions between dominant firms or the entry of smaller players might affect an industry's overall incentive to invest in safety.

### **Tort Liability and Innovation Incentives**

The case discussed above suggests that market forces work well when safety risks are clear and when consumers are aware of such risks and can make informed decisions. In many settings, however, these conditions are not met. Before delving into our second case, we discuss the role that policies can play in such circumstances.

Public policies such as safety regulation and product liability law are important to complement market incentives to promote safety. Product liability, in particular, raises the costs to firms that sell unsafe products by awarding damages to injured parties. This, in turn, incentivizes firms to produce safer products. Other tort liabilities such as medical malpractice law that governs professional negligence by physicians serves a similar goal of deterring harmful behavior.

Theoretically, the impact of liability risk on innovation depends on the characteristics of the technologies and the economic environment. While a greater liability risk increases firms' incentives to enhance safety, it may chill their incentives to develop products that perform well on other quality dimensions but that carry a greater risk of harm or injuries. Extra challenges arise with novel technologies including those that will ultimately make us safer as many of

their risks are hard to predict, even for the producers or other experts when they are initially developed and commercialized. Such uncertainty may lead to problematic judgments subject to hindsight or difficult-to-predict court outcomes and, thus, may suppress innovation incentives. The overall impact of liability risk on innovation is, therefore, an empirical issue and depends on the relative importance of these different effects.

Despite the importance of this question, existing large-sample empirical evidence is scarce. In a pioneering study, Viscusi and Moore (1993) examine the relationship between product-liability insurance costs and firms' research and development investments, using data on large U.S. manufacturing firms in multiple industries between 1980 and 1984. They show that, in a wide range of sectors, when the liability insurance costs are not exceptionally high, greater product liability risk promotes firm investment in product safety (likely through product redesign, as the linkage between liability costs and product research and development is greater than that for process research and development).

Galasso and Luo (2017) examine how state tort reforms that limit the liability exposure of physiciansthe users of medical technologiesaffect a state's medical device patenting. The paper investigates a demand channel: changes in the liability risk faced by physicians (i.e., the direct users of medical technologies) affect their demand for different types of technologies, which, in turn, affects the innovation incentives of medical device producers. Innovation incentives of a wide range of products such as monitoring and diagnostic devices and devices used in complex procedures that help physicians reduce the likelihood of adverse events may not respond to changes in product liability (because these products are less likely to be dangerous or defective themselves) but will become more profitable as physicians face a higher exposure of malpractice liability. We find that relative to states without law changes, states that passed laws that *limit* (i.e., lower) physicians' liability exposure experienced a significant *reduction* in medical device patenting. These effects are the strongest in medical fields in which the probability of facing a malpractice claim is the greatest.

Thus, with different conceptual frameworks and different empirical designs, both of the above-cited studies arrive at a similar conclusion that, on average, greater liability risk incentivizes investment in safety. This does not support the argument that the U.S. tort liability system leads to an often-proposed chilling effect on innovation. That said, there are conditions, at least theoretically, under which the chilling effect may dominate. For example, liability risk is likely to reduce innovation activity when the damages are exceptionally high; when technological possibilities for safer products are limited or economically prohibitive; and when court outcomes and the litigation processes themselves are highly uncertain. It is important for policy makers to understand these conditions, to distinguish them empirically, and, if necessary, to design targeted policies that help mitigate large chilling effects on innovation.

### **Allocation of Liability Risk across the Vertical Chain**

Our second case, which focuses on the early development stages of medical implants, describes a scenario in which liability risk reduced innovation incentives. As we discuss below,



the key reason is the withdrawals by large input suppliers from the implant market as a result of a surge in supplier liability risk.

### **Unexpected Surge in Supplier Risk and Impacts on Innovation**

In the late 1980s, a series of unexpected and widespread problems arose with temporomandibular joint (TMJ) jaw implants and silicone breast implants. Vitek, the leading producer of TMJ implants at the time, filed for bankruptcy in 1990. This induced TMJ implant recipients to file more than 600 lawsuits across 44 states against DuPont, which was Vitek's polymer supplier. Contemporaneously with the TMJ litigation, problems also surfaced with silicone breast implants, with numerous recipients reporting joint soreness and body pain allegedly related to leakages. Also due to widespread litigation, one of the leading implant manufacturers, Dow Corning, eventually filed for bankruptcy in May 1995. Silicone suppliers, including Dow Corning's parent companies Dow Chemicals and Corning and others, such as General Electric, were targets of litigation in these lawsuits.

Common law generally protects component and material suppliers via the 'component parts' and 'sophisticated purchaser' doctrines, which stipulate that the suppliers are not liable unless the component or material per se is defective or if the suppliers are sufficiently involved in the design process of the final product that causes the adverse effect. These litigations in particular, a large number of lawsuits against DuPont, a pure input supplier substantially changed how raw material producers assessed their liability when supplying to implant manufacturers. The events raised the perceived liability risk for all material suppliers selling to medical implant manufacturers, not only those directly involved in the lawsuits or those supplying jaw and breast implant producers. As a consequence, many suppliers drastically changed their supply policies. DuPont refused to sell materials to *all* manufacturers of permanently implantable medical devices and restricted the supply to temporary implants. Their policy for non-implant devices was not changed. Several other major suppliers also exited the market around the same time. According to a survey commissioned by the Health Industry Manufacturers Association at the time, about 60 percent of surveyed polymer suppliers were unwilling to supply medical implant producers and identified the fear of product liability suits as their primary reason. The remaining suppliers required purchasers to execute strong indemnification agreements. They also required proof, in advance of sales, that buyers had enough insurance coverage and other assets to honor those agreements. Because the use of polymeric materials is extremely common in implants and their components, and because DuPont and Dow Chemicals were the primary suppliers, these market-wide withdrawals affected a wide range of products, from sutures and fracture fixation devices to pacemakers and heart valves. The reluctance to supply was said to go beyond polymeric materials. For example, Paul Citron, at the time a senior vice president at Medtronic, said that certain well-established manufacturers of integrated circuits refused to supply chips for implanted devices.

In our research (Galasso and Luo, 2020), we examine how this surge in liability risk faced by upstream suppliers affected innovation incentives for downstream implant producers. Because the supply policies for non-implant medical devices did not change, we use non-implant medical devices to control for the common trends in innovation incentives of the

medical device industry more generally. We find that medical implant patenting experienced a significantly slower growth after 1990 when the surge in the lawsuits against DuPont began relative to patenting of non-implant medical devices. The relative decline was economically large: about 35 percent less than the level implant patenting would have been if it had maintained a similar growth trend as non-implant patenting during the same time period. In addition to the invention stage, which is measured by patenting activities, we also find a large negative impact on the commercialization stage, with a large decline in the number of FDA applications for implant relative to non-implant devices. To link the relative decline in implant innovations to the withdrawal of large material suppliers, we draw on a collective set of evidence in the paper, isolating and controlling for alternative explanations such as concerns about implant failures more generally, implant producers' perceiving a greater liability and bankruptcy risk for themselves, and more-stringent FDA regulations around the time.

### **General Lessons about Liability Risk Spillover through the Value Chain and Innovation**

Many emerging technologies share some of the features the medical implant industry demonstrated in the 1980s and 1990s. Producers are often small and likely to resort to bankruptcy when liability claims exceed their firm's value. The likelihood of product failures and the extent of harms are not well-understood, which, together with information asymmetry, makes it difficult to use insurance markets or contract provisions to protect other transacting parties from liability risk. In these cases, a crucial policy question is whether entities other than the producers should be held liable for defective products. Hay and Spier (2005) study this issue theoretically. They argue that it is a preferable policy to make the suppliers responsible for the shortfall in the liability costs that plaintiffs cannot fully recover from insolvent producers if the suppliers can efficiently manage and absorb this risk. For example, when the suppliers have a good understanding of the safety and solvency levels of the producers, suppliers can charge higher input prices, thereby reducing the number of harmful products produced, accordingly. However, when producers are highly heterogeneous, it may be difficult for suppliers to identify the most-unsafe producers. This may lead them to resort to indiscriminate policies that also raise the costs for producers who either produce safe products or can withstand the liability costs themselves. When this leads to an efficiency loss that outweighs the social gains from greater safety, it may be preferable to impose liability on the producers alone.

Information asymmetry between suppliers and buyers is severe in the medical implant industry. Large suppliers provide general-purpose inputs to a wide variety of downstream markets. Thus, it is prohibitively expensive for them to acquire the specialized knowledge or private information possessed by the downstream firms in order to understand how their inputs are used and to know the risk levels of various products. Such information asymmetry, combined with other transactions costs, may prevent differential pricing or contractual remedies that can pass the upstream liability costs to downstream firms in a way that is specific to the safety levels of the final products.

Moreover, when the total profits from supplying a risky market (medical implants in this case) are sufficiently small relative to other revenue sources, the easiest way for large, deep-pocket

suppliers to protect themselves is to withdraw from supplying this market completely. Such drastic measures raise costs for all downstream firms, including those that are unlikely to be insolvent and whose products are safe. Thus, while some of the foregone innovations could have been harmful and shouldn't have been developed or marketed in the first place, it seems reasonable to conclude that the material supply shortage in the 1990s had deprived consumers of many beneficial innovations in medical implants.

### **Conclusion and Policy Implications**

A fundamental challenge to many novel technologies is that many risks are hard to predict. It is, therefore, important for policy makers to maintain and harness the incentives of various types of players, including media, experts, and firms, to produce and disseminate new information about risk. CT scanner producers' innovation responses to the extensive reporting of medical radiation risk show that when safety risks are clear to consumers, market forces tend to incentivize firms to enhance safety. Systems and procedures need to be in place to monitor, report, document, and assess new risks that are not foreseen by the manufacturers and the regulating authorities in their initial risk assessment. For artificial intelligence and robotic technologies, for example, these include the safety impacts of new ways humans use or misuse these novel technologies, new ways machines interact with each other, and new functionalities or behavior of autonomous products and self-learning algorithms. Existing post-market surveillance and reporting systems for many more-traditional technologies like medical devices, drugs, railway, and airline transportation provide useful examples. Manufacturers and operators are required to report product failures, adverse effects, and accidents to a centralized depository at the relevant agency.

Media play a crucial role in disseminating information on health hazards to the general public, thereby influencing the demand for safety. For example, the congressional and public attention to medical radiation risk that we examine in our study began with a series of effective investigative reporting by *The New York Times*. Pro-corporate or anti-corporate biases and the tendency to sensationalize are all likely to have important consequences on consumer risk perception. The economics literature on media bias suggests that competition policy and regulations aimed at fostering media plurality and independence are important for reducing many of these biases and maintaining the accuracy and objectivity of reporting. Moreover, social media algorithms that perpetuate echo chambers may also lead to more extreme perceptions of risks. Transparent algorithms and platform designs that encourage interaction among diverse users may be beneficial in this respect.

Regulators may complement industry standard-setting by providing clear guidance, making technology users more informed, and demonstrating a clear threat of formal intervention if the industry does not do enough. In the CT scanner case, even though the FDA chose to let the industry take the initiative to revise safety standards, the agency also provided i) a clear set of suggested improvements to the industry association of equipment manufacturers and ii) recommendations to medical professional associations that govern imaging facilities, radiologists, and radiologic technologists on how they may best prevent additional cases of excess radiation exposure. The latter made the users of technologies (the medical



professionals) more informed about radiation risk and their own liabilities, further incentivizing producers to enhance safety by increasing the demand for safety.

Policy makers should also consider how to best utilize learnings from the use and accident of products already placed in the market to help assess the risk of future technologies *before* they are allowed to enter the market. This may be achieved by tasking the relevant agencies or standard-setting organizations to codify these learnings in ways that can be generalizable to similar and related technologies. As discussed above, it seems effective if such learning can be clearly codified and communicated to the market, including the consumers, the operators of these technologies (such as physicians and other healthcare providers for medical devices), the courts, and the media. Keeping these parties more informed can increase firms' incentives to leverage the market demand for safety.

Apart from producing and disseminating risk information, safety regulations and tort liability systems are also tasked with incentivizing safety when market forces are not sufficient. The literature has shown that tort reforms and other changes in the liability systems have effects that go beyond their short-term impact on consumer safety through affecting the availability and profitability of products that already exist in the market. They also have long-term effects on the rate and the direction of technological change. Recognizing these dynamic effects is crucial to evaluating the costs and benefits of policy reforms. While our and others' research suggests the current tort liability system, generally, seems to achieve the policy goal of incentivizing firms to enhance safety, policy makers need to pay attention to conditions under which the chilling effect on innovation potentially outweighs social gains from greater safety and adjust the existing legal frameworks with targeted policies.

The material shortage experienced by the medical implant industry in the 1990s suggests that large and deep-pocketed suppliers of general-purpose inputs may restrict their supply to applications in which liability risk and uncertainty are the highest. While smaller suppliers may step in, the costs may be higher (due to the lack of scale or scope) and quality control may be inconsistent. In the case of artificial intelligence, the Internet of Things, and robotic technologies, given the importance of economies of scale and scope, many data and software providers are likely to be general-purpose input and technology providers. When their concerns about liability risk make them reluctant to supply to risky but economically and socially critical applications, policies targeted at reducing this uncertainty could be crucial in sustaining the development of new technologies.

In the case of medical implants discussed above, to restore the supply incentive of raw-material producers, the U.S. Congress passed the Biomaterial Access Assurance Act (BAAA) in August 1998. The Act provides liability exemption to the suppliers of bulk components and raw materials for permanent implants, as long as they do not engage in the design, testing, and production of the implants and the inputs themselves are not dangerous or defective. It is important to note that the BAAA is based on the same principles underlying common law protections for component and material suppliers. While these common-law provisions were in place throughout our entire sample period, a federal-level policy may effectively reduce the

uncertainty and expenses associated with the litigation process—for example, material-supplier plaintiffs may invoke the Act to request early dismissal from the courts as well as the complications that may arise from different state laws. Our analysis shows that medical implant innovation recovered a few years after the enactment of the BAAA. This is consistent with the idea that targeted federal-level policies that reduce uncertainty and litigation costs help to restore supply incentives, which, in turn, restore downstream innovation. Such liability exemption policies should be used in only a targeted fashion, as the downside is that suppliers would lack the incentives to adjust their supply policies—e.g., by increasing input costs or by tightening customer screening—to reduce the number of harmful products in the market. As discussed in the previous section, it would be a preferable policy to make suppliers liable for the shortfall in the liability costs not covered by insolvent producers when suppliers can effectively pass through these costs to producers or screen out unsafe ones without incurring too much loss for producers who might look risky but are not actually problematic.

While our study focuses on the trade-off of holding suppliers liable for unsafe products, the question of whether to hold non-producers liable when producers are insolvent is quite general and also applies to other critical players in the value chain. For example, large platforms, system integrators, and connectivity providers also provide critical and potentially generic inputs and services that facilitate the interactions between producers of these emerging technologies and consumers. While the value chain and system integration of these emerging technologies may raise novel scenarios, similar guiding principles and the associated trade-offs as discussed above should also apply.

For novel technologies such as artificial intelligence, the Internet of Things, and robotic technologies, many of the underlying hazards are difficult to predict ex-ante but will become clearer with expanding use. The research surveyed in this article highlights that when risks are clear to users, market demand for safety may drive the development of risk-mitigating technologies. Public policies that can complement such market forces include systems and infrastructures that collect and validate data on health and safety hazards both before and after market entry, communicate risk information to the general public, and promote data access to government agencies, research institutions, and firms. The important roles of general-purpose input and service providers, platforms, system integrators for these products also raise the question of whether these actors should be held liable for unsafe products that are not produced by them. Our research has documented how, in some circumstances, liability uncertainty can make them reluctant to supply or integrate risky but economically and socially critical products. This suggests that policies targeted at mitigating such uncertainty could be critical to preserving innovation incentives.

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