20

Strengthening the Power of Health Care Insurers to Regulate Medical Device Risks

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20.1 INTRODUCTION

There is growing concern over the FDA's persistent failure to prevent the marketing of medical devices that subject patients to previously undetected risks of death, disability, and other serious injuries.[1] Departing from the dominant approach to reform calling for expanding FDA authority and resources, state tort law, and other modes of government oversight, we consider harnessing the regulatory power of market forces, particularly those uniquely exerted by health care insurers ("insurers").[2] Essentially, insurers' regulatory power derives from their market-gatekeeping coverage and purchase decisions that determine the economic fate of all FDA-approved devices; capacity to constantly and comprehensively monitor the market for product-related accidents, including manifestations of new and increased risks; and exposure to paying the medical and other expenses of injured insured patients.

Insurers thus can surpass other nongovernmental as well as governmental forms of oversight (for example, academic researchers, physicians, manufacturers, tort lawyers) in enhancing FDA efforts to protect patients from unreasonably risky product designs, warnings, and usage. They can draw on the continuous inflow of insured-patient requests for payment of medical and other expenses resulting from product-related

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[1] See, e.g., 80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices, N.Y. Times (May 4, 2019), https://www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html?action=click&module=RelatedLinks&pgtype=Article (attributing significant incidence of medical device accidents to the "combination of dubious regulatory approvals, skimpy post-market surveillance, and faltering responses from regulators").

[2] State tort law generally applies the negligence rule, which holds device manufacturers liable for failing to exercise reasonable care in designing the product and warning of its risks. In Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), the Supreme Court preempted enforcement of any state tort claim involving a medical device that had been marketed in FDA-approved form and manner when the allegations of manufacturer misfeasance contradict specific agency findings that the product was safe and efficacious.

injuries to supply the FDA with both a superior source of reliable postmarket data on product risk and efficacy and virtually instantaneous notice of emerging signs of new or increased risks.[3]

Monitoring for emerging device risk is of vital importance to insurers because they will pay the medical and other product-related accident costs incurred by their insured injured patients. Exposure to bearing product-related accident costs drives insurers to include the implicit price of accidents in coverage and purchase decisions. Therefore, insurers operating in the normal course of business select for safer and more efficacious medical devices and uses.[4]

Insurers' risk-rated coverage and purchase decisions can serve as an unmatched means of fortifying manufacturers' incentives to exercise reasonable precautions in developing, testing, and marketing their products. They also supplement FDA-prescribed warnings and informed physician judgments by curtailing overuse of medical devices, evaluating the comparative safety and efficacy of products and other treatments, and better-fitting product benefits to patients' medical needs. Because insurers bear the accident costs of false positives – that is, of curtailing patient access to a device based on an erroneous finding of undue risk – as well as false negatives, they have incentives to make measured and reliable decisions.

Yet, market impediments may prevent insurers from exercising their regulatory powers for maximum social benefit. Depending on market and other factors, sharp competition can be part of the problem. An insurer might delay or refrain from publicly reporting the discovery of an emergent risk to the FDA for fear of competitors freely capitalizing on proprietary information concerning adjustment of its coverage and purchase decisions. While transmission of product-related risk in insured-patient payment requests may not involve great expense, translating that information into risk-rated coverage and purchase decisions is another matter. Deriving reliable implicit risk-rated prices to incorporate into coverage and purchase decisions can involve expensive AI systems and other private sources and methods of aggregating and analyzing data to discern patterns or even signs of new or increased risks; determine causal mechanisms and associations in the various contexts, practices and behaviors that frequently characterize the heterogeneity of health care provider and patient use of the product; and estimate accident prevalence and costs among the patient population.

Most importantly, insurers lack sufficient financial incentives to exercise their regulatory powers for maximum social benefit because two structural features of all insurance systems, private and public, shield them from bearing the total costs of

[3] See Rebecca S. Eisenberg & W. Nicholson Price, Promoting Healthcare Innovation on the Demand Side, 4 J. L. & Biosciences, 3, 12–13 (2017) (describing insurers' wealth of information on product uses, efficacy, and risks).

[4] Analysis of the incentives of US and foreign government insurers to effectively monitor the use and risk of medical devices they supply and to make appropriate coverage and purchase adjustments is beyond the scope of this chapter.

product-related accidents. First, because risk-averse individuals are unwilling to pay premiums or taxes for nonmonetary losses (harm that money cannot remedy, such as death), insurance does not provide coverage for it.[5] Nonmonetary loss, however, represents a real and major diminution of individual welfare that must be included in the total amount of product-related accident costs when determining the reasonable amount of resources to expend in securing maximum social benefit from safety precautions. The second structural constraint is insurance subrogation, the contractually or legally created means by which insurers recoup from insured-patient tort recoveries the amount they have paid out in covering medical and other injury-related expenses.[6] In calculating the product-related accident costs they anticipate bearing – to determine coverage and purchase decisions – insurers rationally discount that burden by the amount they expect to be reimbursed from tort recoveries through subrogation. Cumulatively, these structural constraints relieve insurers of well over half of the total product-related accident costs.[7]

We propose two simple and virtually costless federal statutory reforms to correct these market defects. Pursuant to the first, Congress would require insurers to report medical device accidents to the FDA. This would overcome any market competition constraints on insurers' willingness to publicly disclose proprietary information. The second would have Congress establish a federal rule of manufacturer strict tort liability that is predicated on proof of causation alone and pays damages directly and fully to the US Treasury.[8] For the purposes of removing the structural constraints on insurers' financial incentives to reduce risk, the principal virtue of manufacturer strict liability is that tort damages account for both monetary and nonmonetary losses and – because manufacturers will reflect total expected tort damages in their product prices – thus lead insurers to consider the total costs of product-related accidents in monitoring the market for risk and risk-rating their coverage and purchase decisions. Paying recoveries into the US Treasury eliminates the other market defect of subrogation reimbursement.[9] Initiation of strict manufacturer liability actions would first require FDA validation of the causal connection

[5] See A. Mitchell Polinsky & Steven Shavell, The Uneasy Case for Product Liability, 123 Harv. L. Rev. 1437, 1462 (2010).

[6] For a general discussion of insurance subrogation, see Tom Baker, Insurance Law and Policy 391–407 (2003).

[7] This estimate reflects the roughly equal division in tort recoveries between monetary and nonmonetary losses. See Tillinghast-Towers Perrin, U.S. Tort Costs: 2002 Update 17 fig. (2002).

[8] This type of strict liability rule was introduced in David Rosenberg, A Sampling-based System of Civil Liability, 15 Theoretical Inquiries L. 635, 659 (2014), and developed in Steven Shavell, On the Redesign of Accident Liability for the World of Autonomous Vehicles (2019), http://ssrn.com/abstract=3437474. The federal strict manufacturer liability rule we propose would replace state tort law to the extent it is not currently preempted from regulating medical device risks. For discussion of the regulatory deficiencies of the negligence rule and comparative advantages of strict liability, see infra, at note 23.

[9] Although manufacturers and insurers might address these problems contractually, we know of no such arrangements and do not consider the contractual option here.

between product and injury, and then the decision by the Civil Division of the Department of Justice to litigate claims directly or by auctioning them to private attorneys.

We examine the mandatory reporting proposal in Section 20.2 and the manufacturer strict liability proposal and system for enforcing it in Section 20.3. Section 20.4 concludes.[10]

20.2 MANDATORY REPORTING

Currently, Congress requires only manufacturers (or importers) and device user facilities (end-users) such as hospitals to report medical device accidents. In this section, we address whether insurers should be included.

Driven by financial self-interest and informed by the constant flow of insured-patient payment requests, insurers have the unrivaled capacity to monitor the market continuously and comprehensively for incidents of product-related accidents generally, and signs of emergent danger especially. Insurers are thus uniquely equipped to serve FDA market surveillance objectives, particularly as early warning "watchdogs."

Undoubtedly insurers are motivated to voluntarily report newly detected risks to the FDA. Insurers, like other participants in the health care system, embrace the ethos of "doing no harm." Further, in accelerating FDA investigation and intervention, insurers' reporting will reduce accident risk and hence their outlays for medical and other expenses, and relatedly their costs to analyze risk data and adjust coverage and purchase decisions accordingly. Expedited FDA intervention has the further beneficial effect of preventing insurers from perversely competing for market share by delaying or otherwise manipulating coverage and price responses to newly discovered risks.

Competition gives rise to concern that insurers may lack optimal reporting incentives. Despite benefiting from accelerated FDA intervention, insurers may hesitate to report newly discovered risks in some cases. Doubtless, insurers will not think twice about reporting accidents that directly implicate readily determinable defects or risky features of a widely sold or frequently used product. In such cases, no competitive advantage is likely to accrue from delayed reporting, as other insurers probably would be experiencing similar accidents and making corresponding adjustments in coverage and purchase decisions. A different case arises when accidents are sporadic or the insurer incurs substantial expense in generating proprietary information to discover the risk, determine its nature, estimate product-wide accident incidence and costs, and based on that analysis, make risk-rated coverage and

[10] Many reform proposals call for expanding the scope of FDA surveillance and tort liability. To our knowledge, none consider the basic reforms advanced in this chapter; nor are any designed to strengthen the regulatory power of health care insurers.

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purchase decisions. The prospect of competitors free riding on this investment may dull the insurer's incentive to immediately notify the FDA.

Congress can address this problem simply by subjecting insurers at minimum to equivalent investigation and reporting requirements as those presently applied to manufacturers and end-users. That mandate casts a broad discovery net for any information the reporter may have or can reasonably obtain that suggests that use of, or exposure to, a medical device caused, contributed to, or had been a factor in causing or contributing to the injury of a patient (or health care employee, or another person). The source of the risk is also defined capaciously to include product malfunction, failure, manufacturing or labeling defects, or user error. The mandate applies to major product accidents involving death or other serious injuries – defined as posing a threat to patient life, danger of permanent impairment of body function or structure, or need for medical intervention to prevent such fatality or impairment.[11]

Generally, in choosing between voluntary and mandatory reporting of adverse information, the system designer considers the relative social value of the former motivating discovery of more information for private use and the latter motivating discovery of less information for public use.[12] Regarding insurers, both factors point unambiguously in favor of mandatory insurer reporting.

The key variable affecting the quantity of reported information is whether insurers' concerns about adverse effects from public disclosure might lead them to ignore or underinvest in discovering product-related risks. Normally, such perverse incentives arise when the adverse information triggers administrative agency and tort liability sanctions. Contrary to manufacturers and end-users, insurers face no such adverse consequences from reporting product-related risks to the FDA. The only potential cost is competitor free riding, which affects manufacturers to a far greater extent. Moreover, insurers' marginal cost, if any, will likely be negated by the benefits of FDA intervention and the fact that the entire industry is subject to the mandatory disclosure rule. Regardless, insurers will hardly find wilfully reducing monitoring efforts worthwhile, as this increases the chance of paying large, unexpected accident costs and only prevents the possibility of a temporary and usually small competitive disadvantage.

Regarding the second factor, the question is whether greater regulatory benefits accrue from private party use of more discovered information than from public regulator use of less disclosed information. Greater discovery efforts under a voluntary disclosure regime might result in manufacturers detecting product-related risks that they can

[11] In requiring hospitals and other end-users to report product accidents, Congress has implicitly found no administrative difficulty applying the mandate to entities other than device manufacturers, with whom the FDA has a general regulatory relationship. Extending the reporting requirement to insurers – the gatekeepers of the medical device market who purchase the products from manufacturers and provide them to end-users – will significantly improve the efficiency and effectiveness of the agency's postmarket surveillance program.

[12] A. Mitchell Polinsky & Steven Shavell, Mandatory versus Voluntary Disclosure of Product Risks, 28 J. L. Econ. & Org. 360 (2010).

remedy, for example, by recalling the device before anyone else recognizes the problem. Yet, as Congress apparently decided in mandating manufacturer disclosure, the prospect of voluntary recall – which might well be small given the high costs exacted by competitive market forces, including bankrupting a firm with few revenue-generating products – was outweighed by the regulatory benefits from disclosure, including spillover gains in agency knowledge and experience for overseeing similar products and benefits from its independently remedying the problem with the product in question. Extending the mandate to insurers is not a close call, as there is no conflict of interest in the public and private use of product-related risk information. Quite the contrary, their complementary use of the information synergistically enhances joint regulatory benefit.

20.3 STRICT LIABILITY

This section explains the purpose and evaluates the cost-effectiveness of the proposed rule of strict liability and the system for enforcing it.

The regulatory function of civil liability, like that of the FDA and other government and nongovernment modes of controlling medical device risks, is motivating risk-controllers (manufacturers) to invest in reasonable precautions. Reasonable precautions result from manufacturers optimally adjusting two principal interrelated risk-control factors: level of care (for example, improving product design to facilitate sterilization) and level of risky activity (for example, reducing resorts to CT scans). In threatening manufacturers with paying for a patient's total product-related monetary and nonmonetary losses – to the extent measured and monetized in tort – civil liability induces the manufacturer to take reasonable precautions by adjusting the interrelated care and risky activity levels to avoid creating and marketing an unreasonably dangerous product.[13]

Because the straightforward threat of bearing total accident costs motivates manufacturers to exercise reasonable precautions, strict liability achieves this regulatory objective without entangling courts and litigants in a misbegotten fact-finding process of determining what interrelated levels of care and risky activity constitutes reasonable precautions and whether the manufacturer took such precautions in fact. Manufacturers will consider all relevant dimensions of care – from the salient matters of product design to the many less conspicuous but no less critical choices in the scope of research, including the performance of nonmedical devices; methods, types, setup, and management of safety studies; qualifications, training, and compensation of researchers and managers; extent of premarket tests and other efforts to discover the potential for latent risks; and investigation of countless

[13] In other words, strict liability motivates manufacturers to take reasonable precautions against accidents to minimize the sum of their costs of avoiding harm, bearing risk, and, in the event of accident, paying damages and litigation expenses. As such, manufacturers' pursuit of maximum profit vicariously maximizes the social value of their risk-control (regulatory) powers.

scenarios of how, when, and where the product will be used, including consideration of differences in end-user abilities and behavior. Similarly, the manufacturer will make the socially appropriate investment in moderating its risky activity level. For example, it may reduce excessive sales – exposing a sub-group of patients to a risky device for little or no offsetting gain in medical benefit – by toning down advertising and refraining from engaging in problematic promotional tactics. Beyond that, strict liability has the singular activity level-reduction benefit of compelling manufacturers to internalize expected damages and incorporate the anticipated total accident cost in their product prices. Thus, strict liability engenders a "price-signaling" effect that lowers demand, reducing unnecessary use of a risky product, and, ultimately, the incidence of injury.

Health care insurers, functioning as expert buyers with gatekeeping market power, make the medical device market ideal for the use of strict liability to regulate product risks. Strongly motivated to monitor for, and incorporate, the implicit cost of expected product-related accidents into their coverage and purchasing decisions, insurers will be highly attuned to the price signals from strict liability.[14] Far from price takers, insurers would respond to those signals with speedy and deliberate adjustments of coverage and purchase decisions, effectively reducing risky product sales, use, and hence patient injury.[15]

Strict liability and health care insurers mutually reinforce their power to regulate medical device risk. Insurers improve the regulatory coherence of strict liability pricing signals. Risk-neutral, rational, and expert insurers will be free of the risk misperception and demand elasticity problems that may distort the effects of price signals on ordinary consumers.

Regarding insurers, strict liability per se, through its price-signaling effect, closes the major gap in their accident-cost exposure for product-related injuries, in addition to saving them the cost of calculating the implicit price of accident risk. Threatening liability for total expected accident costs, strict liability leads insurers to internalize nonmonetary as well as monetary losses, and to adjust their coverage

[14] Price signals will relieve insurers of much of the burden of determining and incorporating in purchase and coverage decisions the implicit product-related accident cost. Nonetheless, the need will remain for insurers to proactively modify coverage and purchase decisions, given the inevitable delay between the emergence of a new or increased risk from general market use of a product and related changes in FDA regulatory prescriptions and manufacturer prices. Moreover, insurer coverage and price decisions will still be required to fine-tune manufacturer price signals which normally reflect a product's average risk in the relevant patient population. By tailoring a risky product's use to the medical needs of individual or subgroups of patients, these decisions augment the precision medicine effects of FDA warnings and advisories and physician prognoses and judgments.

[15] Patients switching insurance plans might vary the amount of product use and risk among insurers, but it will not diminish or otherwise distort the proposed rule's deterrent effects. The product's aggregate expected accident cost that patients incur will remain unchanged, and hence so will the manufacturer's total, strictly enforced expected liability and the resulting insurance industry-wide price-signaling effect on coverage and purchase decisions.

and purchase decisions accordingly, thereby maximizing the social benefit of their regulatory power.

However, the proposed strict liability rule is needed to fully correct structural market defects. This is because, under conventional strict liability, insurers retain subrogated reimbursement for outlays to cover monetary losses. Subrogation reimbursement substantially reduces insurers' financial incentives to maximize regulatory benefits both by offsetting their coverage exposure and by diluting strict liability's price-signaling effects for monetary losses. The proposed rule corrects this market defect, effectively eliminating subrogated reimbursements, by requiring payment of all recoveries directly and in full to the US Treasury. Ending the prospect of subrogated recoupment will spur insurers to take full account of total expected accident costs – nonmonetary and monetary – when determining the implicit risk-rated price of a device they are considering covering and purchasing.

The system we envision for enforcing the proposed rule of strict manufacturer liability should assure its reliable, measured, and socially appropriate use. Prospective claims would proceed through two stages of merits screening. First, the FDA would, in the normal course of investigating and considering its regulatory response to reported incidents of serious device-related accident, verify the nature, extent, and harmful consequences of the causal connection between product use and patient injury.[16] The manufacturer probably would be notified that the investigation is ongoing and, when needed, required to disclose relevant information and otherwise participate and cooperate fully in the investigatory process. Only positive determinations of causation and harm would send the case to the next stage. At any point in this process, the FDA can exercise its normal regulatory power to control the product risk, including order recalls, curtail marketing, and require new or amplified warnings.

The Civil Division of the Department of Justice would conduct the second stage of merits screening. Division lawyers will formulate and review the merits of the strict liability claim and appraise its expected recovery value net of litigation cost. To avoid wasting government, manufacturer, and court resources, the claim would be dropped (or converted into a fixed fine) unless its expected net recovery value exceeds some minimum threshold amount, best set by Congress. Before litigation commences, the manufacturer may present contradictory or mitigatory evidence and seek settlement.

When the case goes to court, the government could sue directly or auction the claim to private attorneys. If the claim is auctioned, the winning bidder will pay the bid amount to the US Treasury and retain any recovery from successfully litigating the case. To reduce the complications and costs of litigation, Congress could give

[16] The real-time availability and quality of information from insurers will enhance the reliability of FDA causation determinations, particularly in augmenting as well as facilitating use of trend analysis. For pertinent FDA oversight authority and process see, e.g., Food, Drug, and Cosmetic Act, 21 U.S.C. § 360i-l; 21 C.F.R. § 810.1, 810.2, 810.10, 822.2, 822.3.

FDA findings of a causal connection the evidentiary force of a rebuttable presumption establishing a prima facie case of liability on the causation element and promulgate a schedule of damages that would replace ad hoc and disputed case-by-case litigation and recoveries.[17]

In sum, the combined effect of strict liability price-signals and, with the elimination of subrogation reimbursements, exposure to paying insured-patient economic losses will lead insurers to optimally risk-rate coverage and purchase decisions. This, in turn, will reinforce manufacturers' incentives to take reasonable precautions in developing, testing, and marketing medical device products. The inflow of insured-patient bills will also enable insurers to inform the FDA of product-related accidents, including those indicating emergence of increased and new risks. Based on their current and comprehensive knowledge and estimates of the therapeutic and accident experience of products on the market, insurers' coverage and purchase decisions can disaggregate the generalizations of FDA warnings and statistical models of academic researchers to supplement physician judgments in fine-tuning the fit between comparative product benefits and patients' medical needs.[18]

Two questions about the cost-effectiveness of the proposed strict liability rule and its enforcement system warrant attention: first, as with any reform proposal, whether expected social benefits exceed administrative and substantive law enforcement costs; and second, more specifically, whether the strict liability rule would better promote social welfare by paying damages as compensation to injured patients, rather than to the government.[19]

20.3.1 *Administrative Costs*

The dispositive answer to this question is that the administrative-cost footprint of our proposal is virtually nil. Enforcing the proposed strict liability rule generally entails no complicated legal and factual issues. All courts, and hence the government and manufacturers, need to know is the causal connection between the patients' product

[17] Congress could adapt for use in enforcing strict manufacturer liability a version of the schedule of damages and evidentiary presumptions employed by several federal compensation programs. See Peter H. Meyers, Fixing the Flaws in the Federal Vaccine Injury Compensation Program, 63 Admin. L. Rev. 795 (2011) (comparing the cost-saving benefits of damage scheduling and evidentiary presumptions in the vaccine and other federal compensation programs).

[18] The one regulatory gap that the proposed system does not completely close relates to possible insurer investments in affirmative oversight by undertaking postmarket product testing for new or increased product risks. Insurers apparently conduct such evaluations. See Blue Cross Blue Shield Association Works with FDA And Manufacturers To Accelerate Patient Access To New Medical Devices (2016), https://www.bcbs.com/news/press-releases/blue-cross-blue-shield-association-works-fda-and-manufacturers-accelerate; see also Eisenberg & Price, supra note 3(proposing that insurers evaluate device efficacy based on their extensive holdings of claims and other data on product performance). However, given the lack of nonmonetary loss coverage, insurers might not have sufficient financial incentive to invest optimally in product testing.

[19] Space limitations prevent comparative assessment of such alternatives as enhancing FDA premarket oversight.

use or exposure and the resulting accident losses. These are straightforward matters in most cases.

This no-cost assessment holds even though our proposal extends civil liability to medical devices that Supreme Court preemption rulings currently shield from state tort law, and could give rise to disputes over causation and nonmonetary loss in some cases.[20] The reason is that the litigation of all strict liability claims hinges on FDA findings of causation, and the FDA (with manufacturers typically participating) will continue to investigate and determine that question exactly as it currently does in carrying out its regulatory function in every case of serious product-related injury for all classes of device.

Disputes will be especially likely to settle quickly and inexpensively in the proposed system. Expecting FDA causation findings to strongly influence the outcome of adjudicated claims and leery of chancing juries awarding high nonmonetary damages, manufacturers will almost surely forgo follow-on litigation in favor of settlement. Moreover, because strict liability damages will be levied and distributed solely for deterrence purposes, and therefore can be assessed on average rather than for individual patients, courts could readily employ collectivized modes of adjudication, such as class actions and sampling, to resolve any causation and nonmonetary loss disputes.[21] Congress could further reduce administrative costs, as noted above, by giving FDA causation findings the force of a rebuttable presumption establishing a prima facie case for strict liability and promulgating a schedule of damages.

Some might think, mistakenly, that strict liability damages will inflate manufacturers' costs of doing business and inhibit their investment in device innovation. The proposed rule merely shifts the burden of bearing accident costs from patients to manufacturers, who would otherwise have borne them but for the defective medical device market. Indeed, manufacturers could never successfully dump such accident costs on well-informed patients purchasing medical devices in a well-functioning market. In correcting the defective medical device market, the proposed strict liability rule thus revokes a subsidy that perversely increases manufacturers' profit margin at the expense of patients' safety.[22]

[20] Our proposal avoids problems that led Congress to preempt state tort law claims. By holding manufacturers liable for product-related accident costs on FDA-determined causation grounds alone, the proposed strict liability rule does not implicate or conflict with any FDA findings of safety and efficacy, however specific their nature. Whether Congress should grant federal and state courts concurrent jurisdiction to enforce the rule is a matter beyond the scope of this chapter.

[21] See Rosenberg, supra note 8.

[22] Even if subsidy were needed to promote innovation, relieving manufacturers of efficient regulatory controls and thereby putting patients at greater unreasonable risk of serious personal injury is a socially dubious means to the end. Many cost-effective options exist for subsidizing innovation without jeopardizing the lives and health of patients, for example encouraging breakthrough discoveries with special patent protections, tax credits, research grants, priority and expedited FDA review, and prizes.

20.3.2 *Substantive Costs*

It would also be a mistake to think the negligence rule is more cost-effective than strict liability. The negligence rule suffers from long-recognized and well-documented fundamental regulatory failings.[23] In requiring courts to determine whether a defendant manufacturer exercised reasonable precautions, the negligence rule entails an enormously expensive regulatory inquiry, one that is inevitably misguided and socially wasteful. Primarily, high-cost barriers prevent courts from obtaining and analyzing evidence of critical relevance regarding multiple dimensions of care and risky activity. Deprived of this evidence, courts cannot reliably make the complicated factual findings on which the basic questions of negligence liability must turn: first, establishing the optimal, interrelated adjustment of levels of care and risky activity that defines the standard of reasonable precautions governing the case; and second, determining whether the manufacturer's actual precautions satisfied the standard. Consequently, enforcement of the negligence rule systematically fails to confront manufacturers with sufficient sanctions – that is, with a threat of liability for damages equaling total accident costs – and hence fails to create optimal legal incentives for them to take all reasonable safety precautions in developing, testing, and marketing their products.[24]

Compared to the negligence rule, strict liability produces superior regulatory results because courts can enforce it without undertaking the costly task of establishing and applying a standard of reasonable precautions and making the resultant complicated factual findings. As Holmes observed in explaining the policy supporting use of strict liability rather than negligence, "as there is a limit to the nicety of inquiry which is possible in a trial, it may be considered that the safest way to secure care is to throw the risk upon the person who decides what precautions shall be taken."[25] The same advantage of strict liability applies with added force to avoiding even greater cost barriers to determining the far more complex questions regarding the reasonable level of risky activity, and ultimately, the reasonable combination of care and risky activity levels.[26]

Many think the negligence rule has a possible litigation-cost advantage because only claims evincing both negligence and causation will be filed compared to strict liability allowing suit on causation alone. The plausibility of this conjecture, however, is undermined because it never accounts for the costs of plaintiff-lawyers necessarily investigating the entire pool of plaintiff device-caused injuries to

[23] The following comparative evaluation of strict liability versus negligence is drawn from Steven Shavell, Economic Analysis of Accident Law (1987).

[24] The significant chance courts will erroneously determine the optimal levels of care and risky activity can also create excessive deterrent effects.

[25] O.W. Holmes, The Common Law 117 (1881).

[26] Holmes also intuited strict liability's use in moderating (including through price-signaling) the level of risky activity. See David Rosenberg, The Hidden Holmes: His Theory of Torts in History 139–40 (1995).

determine which among them involve sufficient evidence of negligence, while the proposed strict liability rule entails no such need and cost. It also fails to account for strict liability's superior deterrent effects that reduce the number of injuries and hence resulting claims. Even assuming some marginal filing-cost advantage of the negligence rule, it is doubtful that the savings would come close to negating the rule's disadvantages of great trial and settlement expense, and, most importantly, of regulatory deficiencies and resulting unpoliced device risk.[27]

20.3.3 *Compensation for Injured Patients*

Regarding payment of damages to injured patients rather than the government, the question, essentially, is whether patients would be better off under the conventional tort system of compensation than the proposed strict liability rule. The short answer is that under the conventional tort system the costs of the increased risk of harm far exceed the benefits of possible compensation. This would be so even if the tort system employed strict liability. Paying damages to patients would preserve subrogation reimbursement, shielding insurers from bearing total accident costs and resulting in their insureds incurring otherwise avoidable unreasonable risk of product-related accident, as well as higher insurance premiums to cover it.

Moreover, patients who suffer medical device injuries are already insured for their medical and other monetary losses from product-related injuries. Even if some patients need supplemental coverage, they surely would not willingly, let alone rationally, turn to tort liability to supply it. "Tort insurance" imposes exorbitant overhead costs – far greater than the cost for comparable coverage from public or private insurers – amounting to a dollar or more charge on every dollar recovered (before subrogation deduction).[28] Nor would risk-averse individuals, in need of insurance, willingly pay for taking the wildly variable chance of winning a lawsuit to cover pressing medical needs (for example, ICU stays for COVID-19 patients), with recovery depending not only on the fact of medical and other monetary loss (which alone suffices for true insurance) but also predominantly on the lucky alignment of such unlikely litigation contingencies as tortiously (as opposed to non-tortiously) caused injury, solvent tortfeasor, and net expected damages high enough for a competent plaintiff-lawyer to profit from taking the case.[29] Any suggestion that

[27] And, by paying damages to the government, the proposed rule also avoids the moral hazard problems of conventional strict liability rules that necessitate use of a highly expensive and factually complicated contributory negligence defense, which can diminish the strict rule's litigation cost and regulatory advantages over the negligence rule.

[28] See Polinsky & Shavell, supra note 5, at 1470.

[29] We emphasize "willingly pay" because, contrary to the conventional portrayal of the purported supplemental insurance value of product-related civil liability damages as free for, and freely chosen by, injured parties, it is neither. Insured patients (like all product consumers) pay a civil liability "premium" in the purchase price of the device (or other product) equal to the manufacturers' expected liability and litigation cost in the event of accident and suit – plus, implicitly, the price

patients might willingly buy tort insurance coverage of nonmonetary loss is refuted by evidence showing that despite the annual expenditure of trillions on premiums and taxes worldwide for public and private insurance, no insurer provides such coverage. The reason is simple: no one is willing to pay for it.[30] On top of all of that, tort liability imposes a grossly regressive "premium" tax for coverage of risk in the price of standardized products such as medical devices. While all patients (and other consumers) pay the same premium charge in the product price, tort recoveries greatly vary according to plaintiffs' relative wealth. This alone is sufficient to justify characterizing "tort insurance" "insurance fraud."

20.4 CONCLUSION

In closing, we note several possible refinements of the proposed system for correcting the market to further strengthen insurers' regulatory power. First, to increase operating efficiency, the system might make use of non-judicial administrative tariffs rather than judicially enforced strict manufacturer liability damage awards. Earmarking recoveries (or tariff levies) for deposit in Social Security rather than the Treasury might provide true insurance value without compromising the objective of eliminating subrogation and exposing insurers to the total monetary costs of product accidents. Finally, the proposed system could well be employed for all FDA-approved medical goods, pharmaceuticals as well as devices.

for their own expected legal fees and expenses. And "willingly pay," they do not. Product liability cannot be waived by contract, even for an appropriate reduction in product price.

[30] See Polinsky & Shavell, supra note 5.

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