The Role of Health and Safety Evidence in Regulation and the Civil Justice System: Preserving Protection of the Public

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Introduction

For several decades, corporations intent on avoiding accountability for the harm their products cause have waged a fierce campaign against citizen access to the state and federal civil justice systems. Their lobbyists have pressed Congress to preempt state tort law, and exhorted federal regulatory agencies and the courts to extend the doctrine of federal preemption so that not just federal statutes but federal regulations can preempt state law, including regulations governing pharmaceuticals, consumer products, and automobiles. In addition, corporate interests have pushed to make it easier for corporations to get suits against them dismissed before courts even have a chance to hear the merits. Finally, corporations have lobbied heavily in state legislatures and in Congress for bills containing such “tort reforms” as arbitrary caps on non-economic damages and the creation of overly broad defenses against product liability claims.

Recently, the chemical industry has devised yet another tactic for advancing the long-running campaign to weaken citizens’ ability to make effective use of the civil justice system: “evidentiary preemption.” The industry is supporting a Senate bill to overhaul the Toxic Substances Control Act (TSCA)—the primary law governing federal regulation of toxic chemicals. This bill—the Chemical Safety Improvements Act (CSIA)—would, among other things, fundamentally alter applicable evidentiary doctrines in many tort cases involving claims of harmful exposures to toxic chemicals. The CSIA would charge the Environmental Protection Agency (EPA) with making “safety determinations” for certain chemicals. The evidentiary preemption provision of the CSIA would then make these safety determinations both automatically admissible in any litigation and force both federal and state courts to recognize the EPA’s conclusions as “determinative of whether the substance meets the safety standard under the conditions of use addressed in the safety determination.” In other words, once the EPA makes a formal determination that certain uses of a particular chemical are “safe,” courts would be “preempted” from considering any additional evidence that might lead them to conclude otherwise.

The CSIA’s evidentiary preemption provision would overrule decades of state tort law allowing juries to determine on an independent basis, with specific consideration to the facts surrounding how a person was injured, whether a manufacturer fulfilled its duty to make reasonably safe products. Government safety standards have always been relevant for jury decisions in these types of cases because they establish a clear standard of conduct, but juries in appropriate cases remain free to conclude that a manufacturer should have gone beyond the standard set by the government in cases where the standard is met. The civil justice system follows this approach because, among other things, safety standards may become outdated or inadequate in light of newly available information—information that some manufacturers might otherwise ignore. Moreover, because of the difficulty of updating standards, once a standard is in place, resource-starved agencies are unlikely to devote the staff time to updating them, despite the need to do so. Besides becoming outdated, government standards may be inadequate because
regulatory agencies have become “captured”—or unduly coopted or influenced by the industries that they are supposed to regulate—with the result that an agency may adopt a weak and ineffective standard of protection. The civil justice system has long been a bulwark of protection against agency capture because it provides individuals with the opportunity to demonstrate that a defendant’s product was not reasonably safe, even if it complies with minimum standards set by the government.

Industry interests see evidentiary preemption as a powerful new weapon for bending the civil justice system to their own ends—one that could easily be adapted to matters unrelated to chemical safety. Evidentiary preemption would replace the sensible approach that the civil justice system has employed for more than a century with one that would, in effect, create immunity for industrial manufacturers.

Maintaining a vibrant civil justice system is especially important for safeguarding the public against hazardous chemicals. The industrial manufacturers and users of toxic chemicals face strong competitive pressures to ignore or downplay the risks that these substances pose to public health and the environment. Virtually all of the incentives that drive the marketplace in which these corporations operate discourage them from taking adequate steps to address these risks. Together with federal regulation and state regulation, the civil justice system forms a protective three-part framework that serves to counter these pressures—but only if all three of these legal institutions are permitted to function effectively.4 Rather than considering bills that would further weaken the civil justice system, Congress should instead explore ways to simultaneously strengthen federal regulatory safeguards while preserving Americans’ legal rights to access the courts.
Evidentiary Preemption: A New Line of Attack On the Civil Justice System

The Current Role of Regulatory Standards in the Civil Justice System

For at least a century, the generally accepted common law rule has been that a defendant is not automatically insulated against tort liability simply because he was acting in compliance with applicable regulatory standards when he caused harm to the plaintiff. As the Restatement (Second) of Torts puts it, “[c]ompliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.” In other words, compliance with applicable regulatory standards may be suggestive that the defendant acted reasonably, but the matter ultimately remains an open issue for the jury to decide. The plaintiff, for example, may introduce other evidence suggesting that the appropriate standard of care demanded more than simple regulatory compliance, and the defendant may seek to rebut this claim with his own evidence. It is ultimately the job of the jury to weigh and consider this competing evidence in determining whether the defendant should be held liable.

The more specific field of products liability follows a similar rule, which the Restatement (Third) of Torts: Products Liability summarizes in the following terms:

A product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

As with the general tort law rule, evidence of regulatory compliance is merely suggestive that a product is not defective for the purposes of determining liability, but this evidence is not conclusive.

The basis for the prevailing approach to the use of regulatory standards as evidence in tort actions stretches back well over a century to the U.S. Supreme Court’s decision in Grand Trunk Railway Co. of Canada v. Ives. This case arose from an incident in which the plaintiff was struck and killed by the defendant’s train while crossing over the defendant’s track in a horse-drawn carriage at a grade crossing. Under state law at the time, the state railroad commissioner determined whether railroad companies were required to take special precautions, such as the use of gates or flagmen, to prevent accidents at grade crossings. Despite the unique hazardous conditions at the crossing where the accident occurred, the state railroad commissioner did not require the defendant to take any special precautions. Accordingly, the defendant argued that it was in compliance with applicable law and regulations at the time of the accident, and thus could not be held liable. On appeal, the Supreme Court rejected this argument:

The underlying principle in all cases of this kind which requires a railroad company not only to comply with all statutory requirements . . . , but many times to do much more than is required by positive enactment, is, that neither the legislature nor railroad commissioners can arbitrarily determine in advance what shall constitute ordinary care or reasonable prudence . . . . [E]ach case must stand upon its own merits, and be decided upon its own facts and circumstances, and
these are the features which make the question of negligence primarily one for the
jury to determine, under proper instructions from the court.9

As indicated in the Court’s opinion in Ives, the basic rationale for not treating regulatory
compliance as a safe harbor against tort liability is that the requirements of applicable law will
often fall short of the appropriate standard of care for a given situation.10 Therefore, juries
should be permitted to conclude that the defendant should have taken additional steps to protect
potential plaintiffs. The need for this additional jury scrutiny is especially acute now, given the
current state of dysfunction afflicting the U.S. regulatory system. Burdened by the destructive
combination of outdated statutes, inadequate resources, and withering political interference, the
EPA, the Food and Drug Administration (FDA), the National Highway Traffic Safety
Administration (NHTSA), and other regulatory agencies are increasingly prevented from
accomplishing even their core statutory missions of protecting public health, safety, and the
environment.11 As a result, these agencies are unable to respond to the most obvious and
pressing threats to the public interest in a timely fashion, if at all. The few safeguards that do
emerge from the gauntlet-like regulatory process are often too diluted to provide meaningful
protections.

By preserving citizens’ ability to make effective use of the courts, the current approach to
using regulatory compliance as evidence in tort suits also takes full advantage of the civil justice
system’s unique role in addressing threats to public health, safety and the environment. If
regulatory compliance with inadequate standards immunized potential defendants from tort
liability, then citizens would be effectively denied meaningful access to the courts in many cases,
and the myriad advantages offered by the civil justice system would not materialize.

The civil justice system complements the protections afforded by state and federal
regulation by seeking to hold individuals and businesses financially accountable for the harms
their actions cause. The threat of being forced by courts to pay compensation to injured
individuals deters individuals or firms from putting others at risk of harm, and this deterrent
effect reinforces the efforts of the regulatory system to prevent harm caused by unreasonably
dangerous products and activities.

The civil justice system also plays a key information-gathering role that enhances the
effectiveness of the regulatory system. The discovery process in civil trials can uncover critical
new risk information about regulated products and activities that the federal agencies can use
either to strengthen existing standards or to support the adoption of new ones. In addition,
discovery can help to uncover instances in which a regulated entity has failed to comply with
regulatory requirements mandating the disclosure of certain risk information about its products
or activities. The success of some regulatory programs—such as those that address
pharmaceuticals or pesticides—depends on the timely and accurate disclosure of this
information. By helping to police industry compliance with disclosure responsibilities, the civil
justice system plays a key role in ensuring the effective implementation of these regulatory
programs.

The current approach further strengthens state and federal regulations by ensuring that
many different legal institutions have a role in preventing and addressing harms to the public,
which can help counter the problem of agency capture. Agency capture occurs when regulated entities are able to exert outsized influence over the agency that oversees them. The symptoms of agency capture often include ineffectual standards and weak enforcement. In contrast, the locus of power in the civil justice system is more widely dispersed over many courts and judges, and it is thus less susceptible to capture by industry. Under the current approach, even if a regulated industry is able to secure lax regulatory standards from a captured agency, the courts still stand ready to hold industry accountable if their unreasonably risky actions or products cause harm to others.

Finally, the current approach preserves the compensatory function that the civil justice system provides. Even when functioning well, state and federal regulations cannot prevent all harms. In these unfortunate instances, the civil justice system offers the victims an opportunity to seek compensation for their injuries from those who are responsible. Even if an individual or firm’s unreasonably risky actions are otherwise in compliance with applicable regulatory standards, the civil justice system still offers injured parties hope for recourse against the wrongdoer.

Despite the many advantages the current approach offers, corporations that wish to avoid accountability are strongly opposed to the century-old rule that compliance with applicable standards does not grant them total immunity for harming Americans. They have pushed, with little success so far, to limit the rule’s application in many cases. For example, a 1991 study commissioned by the American Law Institute (ALI) recommended that common law courts recognize a “government standards” or “regulatory compliance” defense that would provide a liability shield for products complying with the regulatory requirements of a state or federal agency.12 Significantly, however, the ALI did not pursue this recommendation, and the courts have not moved perceptibly in that direction.13

**Evidentiary Preemption Would Fundamentally Change How the Civil Justice System Uses Regulatory Evidence in Determining Liability**

The CSIA’s evidentiary preemption provision would replace the current approach in cases arising from harms caused by toxic chemicals with a new paradigm in which the safety determinations that the EPA makes under the statute could be used to insulate industrial chemical manufacturers and users against tort liability. Specifically, the CSIA would provide that the EPA’s safety determination for a given chemical is automatically admissible in all litigation and it would require the court hearing the case to treat the safety determination as “determinative of whether the substance meets the safety standard under the conditions of use addressed in the safety determination.”14 Under this new approach, the ability of common law juries to engage in their traditional role of weighing other competing evidence in assessing the reasonableness of the chemical company’s actions would be greatly restricted—in many cases, the EPA’s safety determination would take this matter out of their hands.

The cornerstone of the CSIA’s evidentiary preemption provision is the safety determinations that the EPA would make under the statute. A safety determination is simply the EPA’s judgment whether the intended or reasonably anticipated use of a given chemical poses an “unreasonable risk” of harm to public health or the environment.15 The courts have interpreted this “unreasonable risk” standard as establishing a very weak protective benchmark that requires
the EPA to balance the benefits of the chemical against the risks that it poses to human health and the environment. A safety determination would thus turn on the EPA’s assessment of both the hazards that a particular chemical poses under its intended or reasonably anticipated uses and the benefits of that chemical. If the EPA were to conclude that the risk of harm is too great, then the CSIA would authorize the agency to take steps to prevent that harm by developing regulations that would control how that chemical is manufactured or used. In contrast, if the EPA were to determine that the normal manufacture and use of particular chemicals is safe—that is, if no unreasonable risk exists—then the chemical industry could continue to engage in those activities generally free of regulatory controls.16

The establishment of safety determinations is just one step in the incredibly complex and resource-intensive process that the CSIA mandates for assessing and instituting controls for toxic chemicals. First, the EPA must undertake several steps to develop a “chemical assessment framework” for collecting and analyzing information on existing chemicals.17 Second, the EPA must develop a “structured evaluative framework,” which the agency must use to guide its decision-making under the statute.18 Third, the EPA must develop a risk-based screening process for categorizing chemicals as either “high priority”—which require additional safety assessments—or “low priority.”19 Fourth, consistent with the chemical assessment framework and the structured evaluative framework, the EPA must use the risk-based screening process to categorize chemicals.20 Fifth, the EPA must establish a schedule for performing safety assessments on all chemicals that are categorized as high priority.21 Sixth, the EPA must perform the safety assessments on high priority chemicals.22 And, seventh, based on those safety assessments, the EPA must make safety determinations regarding the chemicals.23

If, on the basis of a safety determination, the EPA finds that an unreasonable risk exists, the agency may then institute different types of controls on the manufacture or use of the chemical to eliminate that unreasonable risk.24

Given the EPA’s perennial lack of resources, this process would likely take many years to complete for the 84,000 chemicals in commerce in the United States, if indeed it is ever completed. Except for the one-year deadline for developing the risk-based screening process, the legislation does not impose any definite time limits for accomplishing these tasks. Instead, the CSIA only charges the agency to “make every effort” to complete most of these steps “in a timely manner.” Moreover, much of this work will require the agency to engage in notice-and-comment rulemaking, a process that has become laden with resource-draining and time-consuming analytical and procedural hurdles.

At the end of this whole process, when EPA finally makes a safety determination the CSIA’s evidentiary preemption provision would explicitly provide that the determination is automatically admissible as evidence in all civil actions.25 Even in the absence of this provision, though, most common law courts would likely find that a particular safety determination meets the basic requirements of relevance and is not otherwise excludable under the standard rules of evidence. Thus, as long as the defendant chemical company could establish that the actions at issue in a tort lawsuit are related to the safety determination in some meaningful way, the court would likely deem the safety determination to be admissible evidence anyway.
The real controversy with the CSIA’s evidentiary preemption provision is that it would make the EPA’s safety determinations the sole basis for judging whether the chemical manufacturer’s product posed unacceptable risk of harm to the plaintiff. If an EPA safety determination has concluded that the defendant chemical company’s use of the chemical is safe, then that company would be immunized against all accountability. Given the key role that safety determinations play in the CSIA’s evidentiary preemption scheme, the EPA risks leaving the public inadequately protected if it erroneously concludes that particular uses of hazardous chemicals do not pose unreasonable risks. As discussed in the next section, the risk that the EPA will make improper safety determinations is quite high.
The CSIA’s safety determinations would likely understate the public health or environmental hazards posed by harmful chemicals, because they would be set in reference to the same weak “unreasonable risk” safety standard that currently guides regulatory decision-making under TSCA. In practice, the unreasonable risk standard has erected a significant barrier against meaningful regulatory action under TSCA. The standard is inexorably biased against effective safeguards because the benefits of a chemical that is already in use are typically obvious and easily exaggerated, while the risks that it poses to public health and the environment are often clouded by uncertainty and easily belittled or ignored.

The EPA’s attempt to ban most uses of asbestos under TSCA illustrates the problems with the unreasonable risk standard. The record that the EPA relied on in developing this rule contained overwhelming evidence of the health damage linked to even low levels of asbestos exposure. Nevertheless, the U.S. Court of Appeals for the Fifth Circuit struck down the rule, holding that the EPA had failed to demonstrate that the rule’s health benefits would justify its restrictions on continued asbestos use. The court’s overly stringent review of the agency’s assessment of the rule’s costs and benefits made it clear that almost any agency action to protect public health and the environment against chemical hazards was unlikely to satisfy TSCA’s unreasonable risk standard.

Aggravating the risks of an under-protective standard is the practical reality of regulation-writing. The agency sets standards based in significant part on the input it receives from interested groups. If the EPA’s safety rules determine not only how chemicals are regulated but also set preemptive standards for tort liability, chemical manufacturers and their trade associations are likely to invest even greater effort and resources in influencing the EPA’s regulatory decisions. Research reveals that this type of concentrated investment by affected industry pays off; the agency’s rules get weaker when industry dominates the rulemaking process. Yet, individuals, who do not yet know that they have a stake in the regulatory proceedings and would likely face impediments to keeping up with industry even if they did, will be bound by whatever standards emerge from this lopsided administrative process.

Despite the flawed “unreasonable risk” standard at the heart of the CSIA, EPA determinations under this standard would provide the sole basis for judging whether the defendant chemical company had acted in a reasonably safe manner for the purposes of determining liability in cases arising from harmful exposures to the defendant’s chemical. Because of the CSIA’s evidentiary preemption provisions, juries would be prohibited from considering any other available evidence that might lead them to hold the company liable. For example, the plaintiff might acquire through the discovery process crucial new risk information from the company’s files that was unavailable to the EPA at the time it made the safety determination but that demonstrates that a particular chemical is more far more hazardous than previously believed. Alternatively, evidence regarding the unique circumstances of the case might persuade the court that even though the defendant used a chemical as intended, additional steps for preventing injury to the individual were reasonably available. In either case, the court
would be forced to exclude the evidence, and the defendant chemical company would be improperly shielded from liability.

To make matters worse, even if subsequent evidence reveals that the EPA’s judgments were flawed or sloppy, the public will have little recourse to ensure that the EPA properly revises this determination before it is relied on again in future tort suits. The CSIA would empower citizens to petition the EPA to revise inaccurate safety determinations, but this process does not offer an effective remedy. As a preliminary matter, any revisions to the safety determination would still have to be set according to the inherently weak “unreasonable risk” standard. Even with better evidence, this standard might well prevent the EPA from making a safety determination that correctly concludes that the normal uses of the chemical pose an unacceptable risk to public health and the environment.

More important, the process for bringing a successful petition to fruition under the CSIA is complex, time-consuming, and full of pitfalls. If the EPA denied the petition, a citizen could appeal that decision to a federal district court, but the citizen would face an onerous burden there to demonstrate why the petition should be granted. Even if the citizen prevailed in this appeal, the CSIA still grants the EPA wide latitude to indefinitely defer any action in response to a court order. Once the EPA did initiate an action to review and possibly revise an inaccurate safety determination—either in direct response to a petition or under court order—the agency would have to do so through the standard notice-and-comment process. Unfortunately, the regulatory process has become so ossified through the proliferation of new analytical and procedural requirements that a controversial and technically complex rulemaking—such as one to revise a safety determination—could take several years at best to complete. An EPA action to revise a safety determination also constitutes a final action, and would thus be subject to judicial review, a process that would add still more years of delay. All the while that the citizen petition was pending, the chemical industry would continue to enjoy the safe harbor provided by the original inaccurate safety determination.

These dangers posed by evidentiary preemption could easily be introduced into other policymaking contexts as well, if Congress incorporated provisions similar to those of the CSIA into the statutes governing the EPA’s other regulatory activities or into the statutes that govern the activities of other regulatory agencies, such as the Consumer Product Safety Commission (CSPC), the FDA, or NHTSA. As it does with toxic chemicals, the civil justice system plays a critical role in responding to the public health and safety hazards addressed in those statutes. The civil justice system, and its capacity to hold corporations accountable for the harms they cause, would thus be severely undermined if simple compliance with weak regulatory standards issued under those statutes served to insulate corporations from tort liability.
Congress should reject industry efforts to include evidentiary preemption provisions into TSCA reform proposals or into any other bills to update existing environmental, health, and safety statutes. Along with state and federal regulation, the civil justice system plays a critical role in the three-part legal framework for protecting people and the environment against harmful chemicals, and it must be permitted to function effectively. The CSIA’s evidentiary preemption would severely weaken the civil justice system’s role in this protective framework by undercutting its ability to hold industrial manufacturers and users of chemical accountable for harming public health or the environment.

As it approaches TSCA reform, Congress should strengthen all three parts of the protective framework, including the role that the civil justice system plays. To preserve the civil justice system, Congress should adopt a TSCA reform bill that includes a strong savings clause. In addition, the reform bill should also make clear that all findings, assessments, determinations, or other actions the EPA undertakes pursuant to TSCA do not have the effect of preventing a plaintiff from introducing evidence that might be different from or contrary to the information relied upon by the EPA. These measures would help to ensure that the civil justice system can continue to play an active role in responding to chemical hazards.

The CSIA’s evidentiary preemption provision is the latest front in the corporate war against the civil justice system. Policymakers must resist industry efforts to introduce evidentiary preemption into policy arenas outside of chemical safety. The current approach to using regulatory standards as evidence in tort suits must be preserved to ensure that citizens continue to have access to an effective civil justice system. In turn, maintaining citizen access to an effective civil justice system is essential for protecting the public interest and holding corporations to account for the harms their products and activities cause to human health and the environment.
Endnotes


3 Chemical Safety Improvement Act, S.1009, 113th Cong (2013).


5 RESTATEMENT (SECOND) OF TORTS § 288C; see also DAVID G. OWEN, PRODUCTS LIABILITY LAW 93-94 (2005).


7 144 U.S. 408 (1892).

8 Both the road used by plaintiff and the defendant’s railway were known to be heavily used. Several buildings and large trees were situated near the crossing, making it difficult to see any approaching cross traffic. Shortly before the accident another train had passed the crossing. Evidently, the sound of the first train prevented the plaintiff from hearing the defendant’s train as it approached the crossing. Id. at 410-11.

9 Id. at 427.


12 OWEN, supra note 5, at 886. See also Rabin, supra note 10, at 2051-52; Richard B. Stewart, Regulatory Compliance Preclusion of Tort Liability: Limiting the Duel-Track System, 88 GEO. L. J. 2167, 2168 (2000).


15 Specifically, the CSIA defines “safety determination” as “a determination by the [EPA] as to whether a chemical substance meets the safety standard under the intended conditions of use.” Chemical Safety Improvement Act, S.1009, 113th Cong. § 3(4) (2013). Elsewhere, the CSIA defines “safety standard” as a standard that guards against “unreasonable risk.” Id.

16 Chemical Safety Improvement Act, S.1009, 113th Cong. § 6(2) (2013). Alternatively, the EPA may make a judgment that there is not enough information to conclude whether or not the intended or reasonably anticipated use of a given chemical will result in harm to public health or the environment. For this kind of safety determination, the CSIA charges the EPA with taking additional steps to acquire the information necessary for making this conclusion. Id.


18 Id.

19 Id.

20 Id.

21 Id.

22 Chemical Safety Improvement Act, S.1009, 113th Cong. § 6(2) (2013).

23 Id.

24 Id.
26 Id.
28 For an extended discussion of the practical and theoretical difficulties and biases inherent in cost-benefit analysis, see Thomas O. McGarity, Sidney A. Shapiro, & David Bollier, Sophisticated Sabotage: The Intellectual Games Used to Subvert Responsible Regulation (2004).
31 Chemical Safety Improvement Act, S.1009, 113th Cong. § 17(2) (2013).
33 Id.
About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. CPR is grateful to the American Association for Justice Robert L. Habush Endowment for funding this report, as well as to the Bauman Foundation and the Deer Creek Foundation for their generous support of CPR’s work in general. CPR also thanks the Orange County Community Foundation, Passport Foundation, and Bellwether Foundation for the support of projects that underscore the need for improvements to toxics regulation.

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