TSCA Reform Preserving Tort and Regulatory Approaches

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Introduction

In early August 2013, scientists from the University of California, the University of San Francisco, and Washington State University published a study with some disturbing findings: Every sample of umbilical cord blood obtained from the pregnant test subjects contained bisphenol A (BPA), a common endocrine-disrupting chemical used in many consumer products, and more than a third of those samples contained BPA levels at or higher than those shown to produce harmful health effects in animals.¹ This troubling study adds to a rapidly growing body of literature documenting how babies are now born "pre-polluted" by potentially toxic chemicals. A 2009 study commissioned by Environmental Working Group (EWG) found the presence of up to 232 different toxic chemicals in umbilical cord blood samples.² These and other study results led the President's Cancer Panel—appointed by then-President George W. Bush—to warn in 2010 that Americans are "bombarded continually with myriad combinations" of carcinogenic chemicals "even before they are born."³

Chemicals pervade our lives. We encounter them—often unwittingly—in the workplace, the environment, and many consumer products. The exact number of chemicals that are manufactured or used in the United States is unknown, though an inventory maintained by the Environmental Protection Agency (EPA) includes more than 80,000 different chemicals. The number is growing, too, as hundreds more new chemicals enter the marketplace each year.

In the United States, the framework for safeguarding people and the environment against the growing dangers of toxic chemicals comprises three mutually reinforcing legal systems: federal regulation, state and federal civil justice systems, and state regulation. But this three-part framework for protecting against harmful exposures to toxic chemicals does not work as well as it could because each part of the framework has been substantially weakened. Like a threelegged stool with all three legs slowly deteriorating, this framework has become too hobbled to support reliable protections for the public.

Congress is now considering competing bills to fix one leg of the stool—the Toxic Substances Control Act (TSCA), the principal statute governing federal regulation of toxic chemicals. The two bills—the more protective Safer Chemical Act (SCA) and the industry-backed Chemical Safety Improvements Act (CSIA)—both fall short of what is needed to fix TSCA, albeit to a widely varying degree. Of even greater concern, the CSIA would also essentially eliminate the two other legs of the stool—the state and federal civil justice systems and state regulation—which, if successful, would leave the American public even more vulnerable to threats of toxic chemicals.

This CPR Issue Alert explains how each leg contributes to reducing the risks posed by chemicals. Although TSCA is desperately in need of reform, such reform should not come at the price of eliminating either of the other two essential elements of the way in which we protect ourselves against unreasonable risks created by toxic chemicals that are ubiquitous in our lives.

To be sure, TSCA reform is needed. It must strengthen federal regulators' ability to police the manufacture and use of toxic chemicals. In addition, it should seek to preserve and enhance the crucial role that the state and federal civil justice systems and state regulation each play in addressing chemical risks. Measured against these criteria, this Issue Alert finds that existing proposals, such as those currently pending in the Senate, would not offer better protections against toxic chemicals unless they are significantly amended.

The Three-Part Framework for Protecting People and the Environment Against Toxic Chemicals

The three-part protective framework for toxic chemicals includes a TSCA-led federal regulation, the state and federal civil justice systems, and state regulation. When TSCA was enacted in 1976, its objective was to establish a broad federal regulatory program, overseen by the Environmental Protection Agency (EPA), for addressing chemical risks. As the key element of the federal regulatory tool for safeguarding the public against harmful exposures to hazardous substances by granting the EPA broad authority to ban, label, or otherwise limit the manufacture or use of unreasonably dangerous chemicals.⁴

The other two parts of the three-part protective framework—the state and federal civil justice systems and state regulation—also work to prevent harms associated with toxic chemicals, complementing the protections provided by the TSCA-led federal regulatory system. State regulatory systems (and even local regulatory programs) augment public protections by filling gaps in the federal regulatory safety net and by enabling state and local governments to experiment with alternative models of chemicals regulation that might complement the work of the EPA and other federal agencies. State and local governments can also choose to adopt more rigorous protections above and beyond those afforded by federal regulation to address chemical risks that are of particular local concern.

In addition, by deterring unreasonably dangerous products and activities, the state and federal civil justice systems complement the efforts of state and federal regulation to prevent harm. The threat of tort liability can help deter chemical manufacturers from producing dangerous chemicals, and encourage the production of safer alternatives. Likewise, it can discourage chemical end-users from engaging in unreasonably dangerous practices with those chemicals or from failing to use adequate protective measures. This additional deterrent effect is especially important given the unique institutional advantages that the civil justice systems offer. The civil justice systems are available to citizens in every state, whereas effective state regulation might not be.

Moreover, unlike state and federal regulatory systems, state and federal civil justice systems are less susceptible to political "capture" by the chemical industry—that is, when regulated entities come to exert considerable influence over the agencies intended to regulate the industry, and the agency instead works to advance the narrow interests of the regulated entities. The symptoms of agency capture often include ineffectual standards and weak enforcement. The state and federal civil justice systems are nearly impossible to capture because their decision-making authority is spread across a diverse universe of actors and institutions. This arrangement provides some assurance that at least one mechanism for holding the chemical industry accountable will remain relatively uncorrupted by excessive political influence.

The state and federal civil justice systems also play a crucial compensatory role for addressing harms after they occur. Even when functioning properly, the three-part protective framework cannot prevent all harms associated with toxic chemicals; something as complex and inherently dangerous as the manufacture and use of chemicals can never be entirely safe. When harm from toxic chemical exposure does occur, the civil justice systems provide the victims with a possible avenue for seeking compensation from those whose unreasonably dangerous products or activities contributed to the harm.

As it undertakes the critical task of reforming TSCA, Congress must pursue legislative proposals that strengthen all three parts of the protective framework for addressing toxic chemical risks. Both of the proposals currently pending in the Senate fall short of this goal, however, as explained below.

Federal Regulation of Toxic Chemicals

TSCA: A Failed Statute

TSCA has been a dismal failure, incapable of fulfilling its role in the three-part protective framework for safeguarding the public against harmful exposures to toxic chemicals. The failure of TSCA to accomplish even its basic functions has significantly weakened the federal regulation "leg" of the three-part framework described above, leaving people and the environment inadequately protected against potentially harmful chemicals.

TSCA's weaknesses begin with its inadequate provisions for gathering information on the potential hazards of the tens of thousands of chemicals currently on the market, a necessary precondition to managing any public health or environmental risks those chemicals might pose. Since TSCA's enactment, the EPA has succeeded in obtaining comprehensive health and safety information for only a few hundred chemicals. Due in part to TSCA's failure to generate basic chemical toxicity information, the Government Accountability Office (GAO) has placed the EPA's chemical management program on its "High Risk List"—a biennial inventory of federal government programs that GAO has found are "most in need of transformation."⁵

For many chemicals, Section 4 of the statute authorizes the EPA to promulgate rules requiring manufacturers to test a given substance—but only if the agency can *first* demonstrate that it "may present an unreasonable risk of injury to health or the environment."⁶ TSCA's failure to generate much information on the vast majority of chemicals is largely traceable to this provision. Rather than placing the burden on the manufacturer to demonstrate that testing is *not* necessary for a given a chemical, it instead shifts the burden to the EPA to justify any testing requirements. The courts have defined this burden as requiring the agency to demonstrate that the chemical poses a "more-than-theoretical" possibility of an unreasonable risk.⁷ Yet, without the very health and safety data that is being sought, the EPA cannot surmount this high bar in many cases. Consequently, meeting this burden places the EPA in a difficult "Catch 22."

When the EPA does attempt to issue a testing rule under Section 4 of TSCA, the process can be a long and arduous one, lasting up to ten years from development to receipt of the data sought. The task of building a case to support a testing rule is resource-intensive, and the lack of adequate staff and funds often prevents the EPA from undertaking this task in a timely fashion. TSCA also does not impose any statutory deadlines for completing these rules, which might compel the EPA to work more expeditiously on them, assuming the agency had sufficient resources to do so.

Section 5 of TSCA requires manufacturers of new chemicals to provide the EPA with a "pre-manufacturing notification" before introducing their products into commerce,⁸ but this new chemical screening is very weak for several reasons. First, as part of this notification, the manufacturer must submit data to the agency regarding the chemical's potential health and environmental effects, but only if such information is already in the "possession or control" of the manufacturer. In many cases, manufacturers have no health and safety data in their possession or control, and Section 5, as written, imposes no affirmative obligation on them to generate this information as part of the pre-manufacture notification process. Second, though the

manufacturer cannot begin manufacturing the chemical until the EPA has completed a review of these data and subjected the chemical to some basic testing procedures, TSCA also requires that the EPA complete its review of all new chemicals within 90 days. Though the statute provides for short extension under limited circumstances, the short tight frame combined with the EPA's lack of resources makes it nearly impossible to conduct an adequate review of most new chemicals.

As a result, Section 5 implementation has been incomplete at best. Without sufficient testing to allow for meaningful evaluation of new chemicals or sufficient resources for the EPA to review each application completely, the pre-manufacture notification process can allow many unreasonably unsafe chemicals to enter the marketplace before their hazards are properly identified. Indeed, rather than placing the burden on industry to demonstrate that a new chemical is safe, Section 5 places the burden on the EPA to identify potential health and environmental harms, even though the agency typically lacks adequate data and resources for undertaking this task.

TSCA's greatest weakness is the EPA's inability to take effective action under Section 6 to ban, label, or otherwise limit exposure to existing toxic substances. Of the more than 80,000 chemicals in the TSCA inventory, the EPA has used Section 6 to establish limited restrictions on only a handful of toxic chemicals after they went on the market. "Your child has a better chance of becoming a Major League Baseball player than a chemical has of being regulated by EPA" is how H. Fisk Johnson, the Chief Executive Office of S.C. Johnson and Son, characterized the dysfunctional state of TSCA's regulatory program in a recent speech.⁹

Before the EPA can regulate a chemical under Section 6 of the statute, the agency must first demonstrate that it presents an "unreasonable risk" of harm to human health or the environment.¹⁰ This standard creates 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 in determining what regulatory action to take. The "unreasonable risk" standard is therefore inherently biased against protective regulatory action, since the benefits of a chemical that is already in use are typically obvious and easily exaggerated, while the risks that it poses to health and the environment are often clouded by uncertainty and easily belittled or ignored.¹¹ Assuming the EPA can demonstrate that a chemical poses an unreasonable risk, it must then demonstrate that its selected regulatory option is the "least burdensome" means for eliminating that risk.¹²

The federal courts have strictly enforced the Section 6 rulemaking requirements, further limiting the EPA's authority to take effective action under the statute. In particular, the U.S. Court of Appeals for the Fifth Circuit's 1991 decision striking down the EPA's attempt to ban most uses of asbestos sounded the death knell for Section 6's regulatory provisions. Despite overwhelming evidence of health damage linked to asbestos exposure, this important regulatory effort failed to pass muster in litigation. The court held that the EPA not only had the burden of establishing the scientific case that a chemical poses an unreasonable risk of harm to human health or the environment, but also the burden of proving that the proposed Section 6 restrictions were the "least burdensome" option available to the agency.¹³ The court found that the EPA had failed to meet either burden, and in so doing made it clear that crafting a legally defensible rule

would be all but impossible.¹⁴ To pass the court's stringent test, the EPA would have to engage in an information-intensive exercise of incredible complexity, involving a cost-benefit analysis not just on the proposed restrictions, but also on other possible alternatives, in order to demonstrate that its selected option was the least burdensome of all alternatives that still protects adequately against any unreasonable risks. Since this case was decided, the EPA has not initiated a single significant action under Section 6 of TSCA, nor is it likely to make effective use of TSCA's regulatory provisions until they are amended.

As long as TSCA's regulatory program remains mired in hopeless dysfunction, the public and the environment will continue to face the unnecessary threat of harmful exposure to dangerous chemicals, such as formaldehyde. Formaldehyde is a carcinogen, known to cause leukemia and various kinds of respiratory cancer, that is used in a wide variety of consumer products, including cleaning agents, plastics, and building materials that are incorporated into everything from carpet to furniture.¹⁵ With its obvious risks and wide range of uses, formaldehyde is exactly the kind of toxic chemical that TSCA was supposed to address through the comprehensive regulatory programs authorized under Section 6 of the statute. Instead, the EPA has been forced to rely on targeted statutes—including the Clean Air Act and the Formaldehyde Standards for Composite Wood Products Act—to provide more limited, piecemeal protections against harmful formaldehyde exposures. This arrangement subverts the federal regulatory model described above, in which TSCA was intended to serve as the primary regulatory gatekeeper for addressing the most dangerous chemicals.

TSCA Reform: Strengthening Federal Regulation of Toxic Chemicals

The academic literature has identified what needs to be done to make TSCA more effective.¹⁶ Neither of the pending legislative proposals incorporates the reforms needed to enable TSCA to fulfill its role in the nation's three-part framework for protecting the public against toxic chemicals. While Congress is debating some of the following necessary reforms, its efforts thus far fall short of the type of comprehensive reform that is necessary.

Section 4 of TSCA must be reformed to improve the EPA's ability to gather information about existing toxic chemicals. The Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA) offers a useful model for reform.¹⁷ Once a pesticide is on the market, FIFRA gives the EPA broad authority to demand additional information from pesticide registrants. To obtain additional information, EPA only has to demonstrate that it does not have sufficient information about the safety of the product to justify keeping it on the market.¹⁸ This is a much lower burden of proof than TSCA requires under Section 4.

Section 4 of TSCA could be further improved if Congress established a list of highpriority chemicals for chemical risk assessment. The list of high-priority chemicals should come at the suggestion of the EPA, drawing on the agency's past efforts to prioritize chemicals of highest concern.¹⁹ The 1990 amendments to the Clean Air Act included a similar list of 189 toxic air pollutants²⁰ and charged the EPA to implement a comprehensive Hazardous Air Pollutant program that specifically addressed these air pollutants through the use of strict technology-based standards.²¹ Adding this provision to TSCA would provide the EPA with clear legislative authority to focus on those chemicals that are of highest concern in the short term. In addition, Congress should establish statutory deadlines, enforceable through "citizen suits," for completing reviews of existing chemicals under Section 4. Congress has successfully added deadlines to EPA regulatory programs in the past, including through the 1996 Food Quality Protection Act (FQPA) amendments to FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Congress should add a testing schedule similar to that in the FQPA to TSCA. In the FQPA, Congress set a ten-year schedule for the EPA to review pesticide tolerances. Under the schedule, the agency had to complete a third of the reviews by the end of the third year, the next third by the end of the sixth year, and the final third by the end of the tenth year. Although these other statutes provide useful guides concerning the use of statutory deadlines to ensure timely agency action, some of them contain preemption provisions that still unnecessarily limit access to the civil justice system.

To strengthen Section 5 of TSCA, Congress should require manufacturers to bear the burden of testing their products before they enter the marketplace. Accordingly, Congress should authorize the EPA to establish a basic analytical framework that would enable chemical manufacturers to determine that their chemicals' human health and environmental risks meet a strong safety standard that takes into account foreseeable exposure scenarios. Congress should further require the manufacturers to share the analyses and all underlying health and safety information with the EPA, so that the agency can independently verify the adequacy of the testing procedures.

It is also essential that any TSCA reform bill significantly overhaul Section 6 of the statute so that the EPA has greater authority to take effective action to safeguard the public and environment against toxic chemicals. To be more protective of the public, Congress should amend TSCA to place the burden for proving safety on the manufacturer rather than on the EPA. Manufacturers enjoy superior information about their products and also receive the greatest financial benefits from their manufacture; indeed, it is precisely for this reason that FIFRA, the statute governing pesticide regulation, placed the burden on manufacturers to demonstrate the safety of their products. Congress should also amend the "unreasonable risk" standard, since forty years of experience have exposed numerous practical and theoretical problems with conducting a full cost-benefit analysis on a chemical-by-chemical basis. There are a range of alternative standards that will better protect public health and encourage safer chemicals. Congress could, for example, adopt a standard much like the one it adopted in the FQPA. The FQPA directs the EPA to "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the [EPA] Administrator determines that the tolerance is safe," and it goes on to define "safe" to mean "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." Alternatively, Congress could require manufacturers to establish that their chemicals are at least as good as the best available substitute chemicals. Both of these alternative standards should avoid the analytical paralysis and hidden assumptions that characterize the standard cost-benefit approach to product regulation.

Congress should also amend Section 6 to eliminate its requirement that the EPA adopt the "least burdensome" regulatory alternative. This requirement has not only proved unworkable in practice; it also represents bad public policy, since it prohibits the EPA from selecting a

regulatory option that imposes a modestly larger cost on industry even if that option produces significantly greater benefits.

To further enhance protection of the public, Congress should give special attention to the risks posed by toxic chemicals to fetuses, infants, and children. Many of the chemicals to which human are commonly exposed, such as BPA, pose a unique threat to fetuses and children. To address this unique threat, Congress could amend TSCA's provisions—including those related to information gathering for new and existing chemicals and to regulating chemicals that are harmful—to specifically account for this unique threat.

The State and Federal Civil Justice Systems and Toxic Chemicals

The State and Federal Civil Justice Systems Have Emerged as an Effective Backup to TSCA and This Role Must be Preserved

The dismal failure of TSCA has made the supplementary role that state and federal civil justice systems play in the protective framework even more significant. So far, state and federal civil justice systems have been able to respond, because TSCA does not preempt or interfere with their ability to weigh the competing interests that are presented in toxic tort suits and other cases that may affect the use and distribution of chemicals. Moreover, state and federal civil justice systems have played this backup role without imposing undue costs on the manufacturers, processors and distributors of chemical substances.

The reduction in asbestos use provides a good illustration of the important role of the civil justice systems. Even though the U.S. Court of Appeals for the Fifth Circuit struck down the EPA's attempt to ban most uses of asbestos, asbestos use has declined sharply in the United States.²² A primary cause of this decline has been state and federal civil justice systems, as the threat of tort liability has discouraged the development and use of this product and encouraged the use of safer alternatives. More recently, the threat of liability helped to encourage the petroleum refiners to remove MTBE—a potentially harmful chemical that was added to gasoline to improve engine performance and reduce air pollution—from their products.

State and federal civil justice systems are essential in another way: The discovery process in civil litigation has unearthed critical information held exclusively by chemical manufacturers about the dangers posed by their products that the EPA was not able to otherwise obtain through TSCA's limited data-gathering provisions. One notable victory came after the residents of a small West Virginia town filed a lawsuit against DuPont, which operated a plant near the community, for contaminating their drinking water supply with perfluorooctanoic acid (PFOA), a chemical used to manufacture Teflon. While little was known about PFOA at the outset of this litigation, documents produced in discovery revealed the risks posed by the chemical as well as the extent of DuPont's knowledge about these risks. Among other things, these documents showed that DuPont had known for over two decades that PFOA was highly toxic to humans and had been linked to a wide variety of birth defects. These documents also showed that DuPont had violated a provision of TSCA that requires chemical manufacturers to file adverse information with the EPA. Using this information, the EPA was able to impose the largest fine ever under TSCA against DuPont for violating the act.²³

The PFOA case was by no means an isolated victory. Plaintiffs in state and federal toxic tort suits have succeeded in using the discovery process to obtain data about the health and environmental impacts of several toxic chemicals, including vinyl chloride, asbestos, and polychlorinated biphenyls (PCBs). The litigation brought on behalf of victims of asbestos exposure was particularly successful in uncovering crucial risk data that the EPA had otherwise been unable to obtain through its TSCA authorities. The discovery process in these cases produced several internal industry documents demonstrating that manufacturers of asbestos had known about the health risks of asbestos since at least 1934 and had been actively working to keep this information from the public.²⁴ Without this litigation, it is unlikely that the EPA would

have ever obtained this information, given its chronic lack of resources and the weak data gathering provisions in TSCA.

The compensatory role that state and federal civil justice systems play has also allowed victims of harmful exposures to toxic chemicals to seek compensation for their injuries when other legal efforts to prevent those harms failed. For example, while the EPA's efforts to ban most uses asbestos have failed, state and federal civil justice systems have provided the victims of harmful asbestos exposures an important measure of corrective justice. Since the early 20th century, tens of thousands of Americans have died from asbestos-related diseases, and tens of thousands more deaths from these diseases are expected in the coming decades.²⁵ Beginning in the 1970s, civil litigation brought on behalf of people sickened and killed by asbestos exposure has resulted in at least partial redress for the personal and economic injuries they have suffered.

While the state and federal civil justice systems have proved critical in addressing toxic chemical risks, this legal institution is subject to important constraints. Because of these constraints, the civil justice systems work best when the protections they afford serve to complement those provided by a robust federal regulatory system.

Some of these constraints are inherent in how tort law operates and cannot be easily avoided. The most significant constraint is that state and federal civil justice systems generally operate only after harm has occurred. While compensating someone for an injury after the fact is essential, it is obviously preferable to prevent injury from occurring in the first place. Of course, the threat of tort liability can deter future harm from occurring as noted above, but in some cases meaningful deterrence may not take effect until the victims of harm have succeeded in obtaining compensation in a few cases.

Another inherent limitation of state and federal civil justice systems is that proof of causation can be a significant, if not insurmountable, hurdle in many cases involving injuries from harmful exposures to toxic chemicals. The diseases caused by toxic chemicals-including carcinogens such as asbestos and endocrine disruptors such as BPA-often have very long latency periods between exposure and the manifestation of disease. In addition, the complex toxicological mechanisms through which many chemicals cause harm to human health can further cloud the question of causation. For some chemicals, the timing of exposure-for example, during fetal or certain childhood development stages-can make a given dose of a toxic chemical more harmful. Other chemicals can have significant effects at surprisingly low doses that cannot be predicted by their effects at high doses. The chemical industry defendants have succeeded in exploiting the challenges posed by causation to such an extent that the civil justice system now functions best for addressing chemicals that are known to cause a "signature disease," such as mesothelioma, which is uniquely caused by exposure to asbestos.²⁶ In the absence of a signature disease, the state and federal civil justice systems still provide victims of harmful chemical exposures with a critical avenue for seeking corrective justice, but the task deserving plaintiffs face can be significantly more difficult.

At the same time, some wholly unnecessary constraints on state and federal civil justice systems have been imposed by courts and legislatures and need to be addressed through reforms that go beyond overhauling TSCA. These constraints include the growing body of laws—

enacted to further the agenda of the disingenuous "tort reform" movement—that seek to deny citizens effective access to the courts. Among the novel limitations these laws have placed on citizens' access to the civil justice systems are caps on non-economic damages and the creation of overly-broad defenses against products liability claims involving manufacturers of dangerous goods.

In addition, plaintiffs in civil litigation arising from harmful toxic exposures must overcome high evidentiary hurdles, such as the *Daubert* evidentiary standard and other similar state standards, for admissibility of expert testimony. The result of a highly problematic 1993 U.S. Supreme Court decision,²⁷ this standard and others state standards like it have since been used to block potentially reliable scientific evidence that plaintiffs attempt to rely on to prove causation.²⁸ In practice, the excessively high standards that some courts have imposed on the reliability and relevance of scientific evidence have made it exceedingly difficult for plaintiffs' attorneys to prove causation in several cases arising from exposures to toxic chemicals.

TSCA Reform Must Preserve an Active Role for the State and Federal Civil Justice Systems

State and federal civil justice systems play a critical role in the three-part protective framework for safeguarding Americans against toxic chemicals, and it is critical that efforts to reform TSCA do not undermine that role. As noted above, weaknesses in TSCA have prevented the EPA from taking meaningful action to regulate harmful chemicals, and the law's current preemption provisions have therefore not resulted in significant interference with the effective functioning of state and federal civil justice systems. If a TSCA reform bill does strengthen the EPA's regulatory authority, then the law's current preemption provision would also need to be revised to ensure a broad role for state and federal courts that complements, but does not conflict with, applicable federal regulatory safeguards.

One of the reform proposals, the Safer Chemical Act (SCA), would simplify TSCA's existing preemption provision as it relates to the state civil justice systems by allowing state courts to establish different requirements and standards of civil liability as they see fit, unless "compliance with both" the federal and the state or local requirements or standards "is impossible."²⁹

The other proposal, the Chemical Safety Improvement Act (CSIA), takes a much more interventionist stance in trumping the state and federal civil justice systems. The CSIA would put unprecedented restrictions on state and federal courts by making EPA "safety determinations" for a given chemical substance automatically admissible in any private litigation and declaring them "determinative of whether the substance meets the safety standard under the conditions of use addressed in the safety determination."³⁰ The CSIA's preemption of tort law creates an intrusive interjection of federal regulations into the day-to-day administration of civil justice by state and federal courts that is unprecedented among federal environmental statutes. Not only does this provision change state and federal procedural rules governing the admissibility of evidence, but it also takes away the courts' ability to determine whether a chemical is abnormally dangerous or otherwise unsafe in common law litigation.

The practical effect of the CSIA's preemption of tort law is to grant partial immunity to manufacturers who have their chemicals declared safe by the EPA. Public safety would therefore depend on whether and how quickly the EPA can update prior safety determinations in light of new evidence establishing that a chemical is not safe even though the agency had previously determined that it was. The EPA may be slow to update prior safety determinations because of budget constraints, the political influence of chemical manufactures, or for other reasons. In the meantime, the EPA's prior safety determination, though plainly outdated and inaccurate, would still be automatically admissible and determinative in any litigation that involved claims of harmful exposure to the chemical. Even if the plaintiff presented the court with this new evidence demonstrating unequivocally that the chemical at issue had caused serious harm, the court would still be required to rule that the chemical was safe as a matter of law, leaving the plaintiff with no recourse for obtaining corrective justice or for holding the manufacturer accountable.

The most effective way for Congress to preserve the critical backstop role that state and federal civil justice systems play in protecting the public from dangerous chemicals is to enact a savings clause providing that nothing that the EPA does under TSCA shall affect the right of an injured party to sue the manufacturer, distributor, or seller of a chemical substance in a common law court. In particular, the savings clause should make it clear that nothing in the bill is meant to adversely affect the right of an injured party to present information that differs from that relied upon by the EPA in deciding whether or not to regulate the relevant chemical. Adding a savings clause of this sort would make clear Congress' intent to leave the state and federal civil justice systems leg of the stool in place. Enacting the CSIA's preemption provision, on the other hand, would effectively remove that leg from the stool.

State Regulation of Toxic Chemicals

State Regulatory Systems Have Provided Key Safeguards and Its Role Must be Preserved

As with state and federal civil justice systems, state—and even local—regulation has assumed a more prominent role in the three-part protective framework for addressing toxic chemical risks, in large part because TSCA has failed to provide the federal regulatory safeguards that it was supposed to provide. Fortunately, TSCA has very limited preemptive effect over state and local regulations, and this has permitted state agencies and legislatures to develop their own rules to protect people and the environment from toxic chemical hazards. As with state and federal civil justice systems, state regulatory systems have provided important safeguards without significant economic dislocation for the chemical industry.

California has developed several innovative programs that illustrate the valuable complementary role that state regulatory systems can play in protecting people and the environment against harmful exposures to toxic chemicals. Proposition 65 establishes a list of chemicals that the state has determined are carcinogenic or cause reproductive problems. Once a chemical is listed, discharge of the chemical into a source of drinking water is prohibited and businesses must warn people about exposures to the chemical, including warnings about the presence of chemicals in consumer products. The program has already achieved several notable successes, including protecting children from lead in vinyl "bounce houses" that are common at parties and amusement parks, removing arsenic from playground equipment, and discouraging the use of lead in toy jewelry.³¹ The Green Chemistry Initiative authorizes the state's Department of Toxic Substances Control to identify a list of "chemicals of concern" (based on toxicity and presence in consumer products), a list of "priority products" that contain "chemicals of concern" and pose significant risks to health, and establish a framework for performing "alternatives analysis" according to which manufacturers will search for ways to reformulate those products using less toxic ingredients.³²

Since 1989, Massachusetts has implemented the Toxic Use Reduction Act (TURA) program, which regulates facilities in the state that use large quantities of toxic chemicals. This innovative program requires that these facilities track and report the amount of toxic chemicals they use, as well as engage in biennial toxics use reduction planning. The TURA program is credited with significantly reducing the use of toxic chemicals within the state, and it has served as a model for initiatives being implemented in other states to reduce toxic chemical use.³³

Several other states are implementing innovative regulatory programs for addressing chemical risk as well. Maine, Minnesota, and Washington all have programs for identifying "Chemicals of High Concern" and prioritizing those chemicals for study and regulation in the respective states.

While weaknesses in TSCA have prevented the EPA from taking effective action against specific chemicals that have been linked to public health harms, increasingly state and local governments have enacted laws that restrict the use of these chemicals. In recent years, states have passed dozens of bills to ban, phase out, or restrict the use of toxic substances such as

mercury, lead, cadmium, brominated flame retardants, phthalates, and BPA.³⁴ At the same time, cities such as Chicago and San Francisco have taken important steps to ban or restrict various toxic chemicals, including BPA and phthalates. These actions not only provide immediate protections for the citizens in the states or cities, they also create strong market incentives for chemical manufacturers to develop "greener" substitutes or non-toxic alternatives.

As important as state regulatory systems have been in safeguarding the public against toxic chemical risks, this legal institution still functions best when it provides protections that complement those provided by a robust federal regulatory system. State regulation is fundamentally constrained in that the protections it affords are limited to the state's own citizens. For example, states such as Texas, where a lot of industrial manufacturers and users of toxic chemicals are based, have no state-level chemical safety laws that are analogous to TSCA. In states such as these where the protective framework lacks a viable state regulation leg, the need for effective federal regulation is especially acute.

On rare occasions, though, the state regulatory systems can overcome these constraints. If a critical mass of states adopts laws restraining a particular chemical, the manufacturers of goods containing that chemical will be compelled by economic necessity to find a less harmful alternative. For example, 12 states currently have restrictions on the use of mercury in many consumer products. In response, many manufacturers of certain mercury-laded goods, such as thermostats and batteries, have developed and now sell only products without mercury, even in states where they are not required.³⁵

TSCA Reform Must Preserve an Active Role for the State Regulatory Systems

As described above, the state regulatory systems are vital to the effective functioning of the three-part protective framework for safeguarding Americans against toxic chemicals. The provisions of TSCA governing its relationship to state regulations have some limited preemptive effect. If, however, TSCA is amended to empower the EPA to take more effective action, the current preemption provisions may start to crowd out innovative state efforts to regulate the chemical substances that EPA does regulate.

The SCA takes the approach of minimizing the preemptive effect that TSCA has on state regulation. This bill would leave state and local regulatory authorities free to adopt any laws and regulations to address toxic chemicals, provided that simultaneous compliance with these laws and regulations and the requirements of TSCA is not "impossible."³⁶ This provision would allow the EPA to preempt existing state regulations by promulgating a regulation that was inconsistent with the state law.

In contrast, the CSIA would significantly expand TSCA's preemptive effect, undermining the ability of state and local regulators to enact effective safeguards against toxic chemicals. The CSIA would broadly preempt state efforts to request that manufacturers supply data regarding their chemicals.³⁷ Of even greater concern, the CSIA would prohibit state and local governments from controlling the use of a particular chemical in any way once the EPA has made a preliminary determination to classify the chemical as either "high priority" or "low priority" for further assessment purposes.³⁸ Significantly, by taking effect when the preliminary classification determination is made, the CSIA begins preempting state regulation at a very early

stage in the assessment process, well before the EPA would make any concerted effort either to obtain needed data on particular chemicals or to take steps to control their use. Once the classification is made, and preemption takes effect, the EPA is unlikely to take any needed actions to control even those chemicals that are identified as "high priority" for their potential risks to people and the environment, because the CSIA retains a lot of the same barriers to regulatory action that currently exist under Section 6 of TSCA. With federal action all but foreclosed and state regulation preempted, the public would be left without any meaningful safeguards against potentially harmful chemicals. Even in those rare instances in which the EPA does manage to establish regulations for a chemical, the CSIA would prohibit a state from promulgating an identical regulation so that the same requirement would be enforceable under The statute does offer states the opportunity to apply for waivers both state and federal law. from these preemption restrictions, as they do under TSCA's existing preemption clause, but in most cases states likely will not be able to meet the heavy burden that the statute places on them for obtaining a waiver.

The CSIA contains similar troubling language in its "Findings, Policy, and Intent" section. For example, the bill would add a new "finding" to TSCA that states "for the purposes of promoting uniform protections through regulation of chemical substances in commerce, to minimize undue burdens on commerce, and to minimize burdens on States, specified actions by the Administrator should preempt requirements by States and political subdivisions of States that relate to the effects of or exposure to a chemical substance under the intended conditions of use."³⁹ This new "Findings, Policy, and Intent" language seems designed to buttress the preemptive effect that the bill would have on both state regulation and the state and federal civil justice systems.

The authors of the CSIA may have included all of this preemption language in order to clarify that state or local governments are prohibited from issuing regulations that would be impossible for the chemical industry to comply with while remaining in compliance with any conflicting federal regulations issued under TSCA. If that is purpose of these preemption provisions, then they are unnecessary and only likely to cause confusion. The Supremacy Clause of the Constitution already shields the chemical industry against this eventuality by providing that whenever federal and state laws directly conflict, federal law takes precedence.

A better approach to amending TSCA's preemption provisions would seek to preserve state regulatory authority by including a savings clause that allows all state regulations existing at the time of the promulgation of a section 6 rule to remain in effect. With respect to future state or local regulations, Congress should provide that any rules that the EPA promulgates under section 6 are meant to serve as a "floor" for providing public safeguards, and not a "ceiling." As such, this provision should expressly authorize states and local governments to regulate a chemical more stringently than is provided for under existing section 6 regulations, unless the chemical industry is able to demonstrate that simultaneous compliance with both the federal and state or local regulations is impossible.⁴⁰

Conclusion

Chemicals play an important role in the nation's economy and the daily lives of our citizens, and they will undoubtedly continue to do so in the future. But it is critical that we take all necessary steps that are available to protect people and the environment against unacceptable risks that toxic chemicals might pose. To provide these protections will require strengthening the comprehensive three-part framework we depend on for addressing these risks.

Currently, each of three mutually reinforcing legal systems that comprise this framework—the federal regulatory, state regulatory, and state civil justice systems—are not functioning as well as they should be. As a result, the protective framework has become too hobbled to provide the public with reliable safeguards. At the same time, this state of affairs has delivered significant benefits to industrial manufacturers and users of toxic chemicals, which, in the absence of meaningful accountability mechanisms, have largely been free to avoid the costs of carrying their activities in a reasonably safe manner. In fact, industrial manufacturers and users of toxic chemicals would prefer to weaken the parts of this protective framework further still or even eliminate them outright—particularly the state and federal civil justice systems and state regulation, which have done an admirable job stepping up to cover for the weaknesses of TSCA. A completely dysfunctional protective framework devoid of any meaningful accountability mechanisms would afford these industries even greater freedom to maximize their profits at the expensive of public health and environmental protection.

Congress must strengthen the federal regulatory provisions of TSCA, but in doing so it must guard against chemical industry efforts to use the reform process as an opportunity for further undermining the state and federal civil justice systems and state regulation. If industry's views prevail in the reform debate, we risk being left with the worst of all worlds: a protective framework in which all three parts have been rendered ineffectual. Industrial manufacturers and users of chemicals will not be interested in strengthening the federal regulatory provisions in TSCA, but they will be supportive of reforms that expand the preemptive effect of TSCA over the state and federal civil justice systems and state regulation. For example, in its current form, the CSIA largely amounts to a state preemption bill cloaked in the mantle of TSCA reform. To be effective, the protective framework requires all three legs to be available and functioning properly; the CSIA and similar proposals would nevertheless seek to dismantle this framework so that it is reduced to just one broken leg.

As Congress undertakes the critical task of overhauling TSCA, it must aim to strengthen the federal regulatory provisions of the statute while allowing the state and federal civil justice systems and state regulation to play as active a role as possible in safeguarding the public against toxic chemicals. A stronger federal regulatory program to address toxic chemicals is essential, but it must not come at the cost of robust and energized state and federal civil justice systems and state regulation.

Endnotes

¹ New Study Suggests 'Universal Fetal Exposure' to BPA, ENVTL. HEALTH NEWS, Aug. 23, 2013, available at http://www.environmentalhealthnews.org/ehs/newscience/2013/08/2013-0822 bpa-in umbilical cord blood/

² ENVIRONMENTAL WORKING GROUP, POLLUTION IN PEOPLE: CORD BLOOD CONTAMINANTS IN MINORITY NEWBORNS 3 (2009), *available at* <u>http://static.ewg.org/reports/2009/minority_cord_blood/2009-Minority-Cord-</u>

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³ LaSalle D. Leffall, Jr., & Margaret L. Kripke, *Introductory Letter to the President* for NAT'L CANCER INSTITUTE, NAT'L INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW: 2008-2009 ANNUAL REPORT – PRESIDENT'S CANCER PANEL (2010), *available at* http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf

⁴ According to this federal regulatory paradigm, TSCA was to erect a primary defensive shield against harmful chemicals that overlays the piecemeal protections offered in more topical federal regulatory statutes, such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Occupational Safety and Health Act (OSH Act); the Federal Food, Drug, and Cosmetic Act (FFDCA); the Consumer Product Safety Act (CPSA); and others.

⁵ See U.S. GOV'T ACCOUNTABILITY OFFICE, HIGH RISK LIST (2013), available at

http://www.gao.gov/highrisk/overview; U.S. GOV'T ACCOUNTABILITY OFFICE, HIGH RISK LIST: TRANSFORMING EPA'S PROCESS FOR ASSESSING AND CONTROLLING TOXIC CHEMICALS (2013), *available at* http://www.gao.gov/highrisk/transforming epa and toxic chemicals/why did study.

⁶ 15 U.S.C. § 2603. Significantly, the statute does not require the EPA to make the "may present an unreasonable risk of injury to health or the environment" demonstration as part of a test rule for chemicals that ⁷ Chem. Mfrs. Ass'n v. EPA, 859 F.2d 977, 984 (D.C. Cir. 1988).

⁸ 15 U.S.C. § 2604.

⁹ S.C. Johnson's Case for TSCA Reform, INSIDEDEFENSE.COM,

http://insidedefense.com/index.php?option=com_user&view=login&return=aHR0cDovL2luc2lkZWRIZmVuc2UuY 29tLzIwMTEwNjIxMjM2NzczMy9FUEEtQmxvZy9UaGUtSW5zaWRILVN0b3J5L3NjLWpvaG5zb25zLWNhc2U tZm9yLXRzY2EtcmVmb3JtL21lbnUtaWQtOTcuaHRtbA== (last visited Sept. 23, 2013).

¹⁰ 15 U.S.C. § 2605(a).

¹¹ 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).

¹² 15 U.S.C. § 2605(a).

¹³ Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1214 (5th Cir 1991).

¹⁴ *Id.* at 1215.

¹⁵ Safer Chemicals Healthy Families, Resources: Congress Must Provide the EPA With Authority to Regulate Unsafe Chemicals: Formaldehyde, <u>http://www.saferchemicals.org/resources/chemicals/formaldehyde.html</u> (last visited Sept. 23, 2013).

¹⁶ For more on the recommendations for TSCA reform provided below, see Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817 (2009); Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 IND. L.J. 629 (2008); John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721 (2008); John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365 (2008); Thomas O. McGarity, *The Complementary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy Relevant Scientific Information*, 37 ENVTL. L. 1027 (2007); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUMBIA L. REV. 261 (1991); and Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795 (1989).

¹⁷ It is important to note that FIFRA has an express preemption provision, without a savings clause, that prevents states from requiring a different label for pesticides. 7 U.S.C. § 136v(b). Significantly, however, the Supreme Court in *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005), held that FIFRA did not preempt state common law design defect claims.

¹⁸ 7 U.S.C. § 136a(c)(2)(B).

¹⁹ See, e.g., U.S. Environmental Protection Agency, Existing Chemicals, TSCA Work Plan Chemicals, <u>http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html</u> (last visited Oct. 14, 2013).

²⁰ 42 U.S.C. § 7412(b)

²² U.S. GEOLOGICAL SURVEY, U.S. DEPT. OF THE INTERIOR, WORLDWIDE ASBESTOS SUPPLY AND CONSUMPTION TRENDS FROM 1900 THROUGH 2003, 28-32 (2006), available at http://pubs.usgs.gov/circ/2006/1298/c1298.pdf.

²³ McGarity, *supra* note 16, at 1033-47.

²⁴ Environmental Working Group, Asbestos: Think Again, Section 3: Something in the Air, The Asbestos Document Story, http://www.ewg.org/asbestos/facts/fact3.php (last visited Oct. 14, 2013).

²⁵ Jim Morris, Asbestos' U.S. Legacy May Be Half-Million Deaths, MCCLATCHY, July 21, 2010, available at http://www.mcclatchydc.com/2010/07/21/97624/asbestos-us-legacy-may-be-half.html#.UkDtVoashcZ.

²⁶ See Noah Sachs, Blocked Pathways: Potential Legal Responses to Endocrine Disrupting Chemicals, 24 COLUM. J. ENVTL. L. 289 (1999), available at http://www.jdsupra.com/documents/81bc381c-328f-4020-9ce7-

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²⁷ Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993). For a detailed critique of this decision, see Lisa Heinzerling, Doubting Daubert, (Ctr. for Progressive Reform White Paper 511, 2005), available at http://www.progressivereform.org/articles/Doubting_Daubert_511.pdf.

²⁸ See Joseph Sanders, Applying Daubert Inconsistently?: Proof of Individual Causation in Toxic Tort and Forensic Cases, 75 BROOKLYN L. REV. 1367, 1374 ("In no area has the Daubert revolution had a greater effect than in toxic torts. The number of cases in which expert causation testimony has been excluded must by now run into the thousands. Many commentators ... [argue] that the bar has been set too high."). For a listing of articles critical of how *Daubert* has been applied in toxic tort cases, see *id*. at 1369 n.12.

²⁹ Safe Chemicals Act of 2013, S.696, 113th Cong. § 18 (2013).

³⁰ Chemical Safety Improvement Act, S.1009, 113th Cong. § 15 (2013).

³¹ Michael A. Troncoso, Senior Counsel to the Attorney General of California, Kamala D. Harris, Testimony Before the S. Comm. on Environment & Public Works, Hearing on "Strengthening Public Health Protections by Addressing Toxic Chemical Threats," July 31, 2013, at 4-6, available at

http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=952b7db0-fbf3-4559-b111-610799224269.

³² LYNN L. BERGESON, WASHINGTON WATCH – ONE STEP CLOSER: CALIFORNIA PROPOSES SAFER CONSUMER PRODUCT REGULATIONS (2012), available at

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³⁴ Ken Zarker, Pollution Prevention and Regulatory Assistance Section Manager, Washington State Department of Ecology, Testimony Before the S. Comm. on Environment & Public Works, Hearing on "Strengthening Public Health Protections by Addressing Toxic Chemical Threats," July 31, 2013, at 3, available at http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore id=e3d315dc-bc8d-4b44-bed5-

56fa29e83f36. ³⁵ Daniel Rosenberg, Senior Attorney, Natural Resources Defense Council, Testimony Before the S. Comm. on Environment & Public Works, Hearing on "Strengthening Public Health Protections by Addressing Toxic Chemical Threats," July 31, 2013, at 3-4, available at

http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=ac9ffa00-d5fe-4a02-9035-545b047ffc0f. ³⁶ Safe Chemicals Act of 2013, S.696, 113th Cong. § 18 (2013).

³⁷ Chemical Safety Improvement Act, S.1009, 113th Cong. § 15 (2013).

³⁸ Id.

³⁹ Chemical Safety Improvement Act, S.1009, 113th Cong. § 2(b) (2013). Elsewhere, the bill would add a new "Intent of Congress" that states "It is the intent of Congress that the [EPA] Administrator shall . . . implement this Act to protect the health of the people of the United States and the environment in such a manner as not to unduly impede commerce or create unnecessary economic barriers to technological innovation, including safer chemistry." Id.

⁴⁰ William W. Buzbee, Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction, 82 N.Y.U. L. REV. 1547 (2007).

²¹ 42 U.S.C. § 7412 (d)

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