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ABA SEER TSCA Preemption of Private Rights of Action Under TSCA and TSCA Legislation Briefing Paper

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EXECUTIVE SUMMARY[2]

In reviewing the statute, regulations, guidance and case law utilized in implementing the Toxic Substances Control Act (TSCA), the ABA SEER Pesticide, Chemical Regulation and Right-to-Know Committee,[3] with the support of the Section's Special Committee on Congressional Relations, developed this paper on the interplay of federal statutory law and state common law to provide a frame of reference for the selection of statutory language regarding federal preemption, particularly in regards to the effect of the proposed statutory amendments on state tort actions. A tort suit is filed by a person who claims to have suffered an injury from a wrongful act (tort originates from the French phraseology *avoir tort* or "to be wrong"). Plaintiffs in a tort action are seeking compensation for their alleged injuries. These are lawsuits are filed not only to obtain money, but also to discourage certain types of actions and to encourage people not to harm others by their actions.

This paper is presented in three parts. The first section provides a comprehensive overview of the underlying constitutional, federal and common law governing preemption in federal statutes. The discussion commences with the legal basis for federal preemption in the U.S. Constitution's Supremacy Clause, proceeds to discuss the various preemption approaches found in federal statutes, and then reviews how courts and case law have interpreted the preemption provisions of these statutes when presented with state tort actions. In some instances, the Congressional intent and language in federal statutes is clear and court decisions reviewing state tort actions are consistent and predictable. In other instances, the Congressional intent is not clear, the statutory language is open to multiple interpretations, and the case law is muddled. This first section describes the types and range of preemption policy and language choices found in federal statutes and the principles courts have historically used in determining whether or not a particular state tort action was preempted.

The second section of this paper departs from the general historical overview of the law governing preemption, and focuses in on TSCA and other federal product regulatory statutes. This second section identifies the key policy approaches and statutory language choices regarding the issue of preemption of state tort actions being considered in recent Congressional proposals.

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[2] The ABA is a diverse, non-partisan nongovernmental organization that includes legal practitioners from private sector, public sector, non-profit world, and academia, reflecting a wide diversity of political and policy views. As such, the Section has not taken a formal position endorsing or opposing non-ABA policy proposals or legislation.

[3] This report was prepared by Charles L. Franklin, Akin Gump Strauss Hauer & Feld, Group Leader; Lynn Bergeson, Bergeson and Campbell, P.C.; Lawrence E. Culleen, Arnold and Porter LLP; Mark N. Duvall, Beveridge and Diamond, P.C.; Jean Eggen, Widener School of Law; Maureen F. Gorsen, Alston and Bird; Eric P. Gotting, Keller and Heckman LLP; Martha E. Marrapese, Keller and Heckman; Joanne Thelmo, American Cleaning Institute; Kirk Tracy, Paladin Law Group; and Jim Wedeking, Sidley Austin, with contributions from the SEER PCRRTK TSCA Briefing Paper Team, which the authors gratefully acknowledge.

In the third and final section, the paper suggests several drafting tools that current policymakers can use to ensure the legislative language and structure of a bill will reflect and to effectuate the intended possible policy choice.

In sum, it is hoped that this paper will assist Congress by helping ensure that the language of any proposed legislation matches the intent of its authors, and is interpreted by courts in the future as its authors intended.

I. FEDERAL SUPREMACY, STATE FEDERALISM, AND THE DOCTRINE OF PREEMPTION

A. The Legal Basis of Preemption

Under the U.S. Constitution, certain governmental powers are reserved for the federal government, some are reserved for the several states, and some powers are shared.[4] To resolve the inevitable clashes arising under this system of shared power, Article VI of the Constitution states that:

> This Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.[5]

In theory, this principle, known as the "Supremacy Clause," gives Congress authority to preempt state law with respect to certain issues falling within the federal government's areas of enumerated powers and authority. In practice, however, the broad reach, legal complexity, and factual variability of both federal and state legal systems makes it difficult to identify a simple black letter formula when and how courts will find state law to be preempted in any given case or controversy. Instead, lawmakers have developed certain drafting techniques, and courts have adopted certain principles and precedents to determine how and when preemption should apply.

Most importantly, when determining whether a federal statute preempts state law, courts look specifically to the intent expressed by Congress when adopting the statute as the "ultimate touchstone" of preemption analysis.[6] Such intent may be explicitly stated in the federal statute or

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[4] *Compare U.S.* Constitution at Article 1, section 8 (Enumerating powers granted to Congress, including, *inter alia*, the power to "regulate Commerce with foreign Nations, and among the several States" and to "make all Laws which shall be necessary and proper for carrying [such powers] into Execution."); *with id.* at 10th Amendment ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

[5] U.S. Const. at Art. VI, cl. 2.

[6] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

implicitly contained in the statute's structure and purpose.[7] In many statutes, however, Congress's intent is less than clear, leaving it to the courts to choose between multiple interpretations.

There are generally two types of preemption that are relevant to TSCA modernization: express preemption and implied preemption. Express preemption occurs when there is an explicit command from Congress stating a clear intention to preempt state law.[8]

> ***Express Preemption (example)*:** Congress passes a law governing the sale and use of pesticides which provides that a "State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" the act.[9] Pursuant to this statutory provision, EPA adopts a regulation requiring that labels for certain pesticides only use the signal word "CAUTION."[10] Plaintiff A brings a lawsuit claiming that the same pesticide should have been labeled using the signal word "DANGER." The Court concludes that because the desired tort remedy would impose labeling or packaging requirements "in addition to or different from those required" under the federal statute, the claim is expressly preempted by the federal requirement.[11]

Courts can also find that a federal statute preempts state law based on a finding of implied preemption, with respect to an entire field of federally regulated behavior (implied field preemption) or, more commonly, with respect to a more limited range of actions that directly conflict with the federal framework (implied conflict preemption). In the case of implied field preemption, the court must find that the federal regulatory or legal authority is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."[12]

> ***Implied Field Preemption (example)*:** Congress enacts a law requiring that railroad carriers only use locomotives, tender, parts and appurtenances that are found to be in proper condition and safe to operate without unnecessary risk of personal injury, pursuant to Department of Transportation regulations and inspections. A machinist who contracted malignant mesothelioma after exposure to asbestos in locomotive brake systems files suit in state court, asserting that the brake manufacturer and railroad had defectively designed locomotive parts and

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[7] *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). It is also important to note that regulations adopted by federal agencies, in addition to federal statutes, can have preemptive effect. *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982).

[8] *In re Welding Fume Prods. Liab. Litig.*, 364 F. Supp. 2d 669, 676-77 (N.D. Ohio 2005).

[9] *See* Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b).

[10] *See* 40 C.F.R. § 156.64.

[11] *See generally Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 436 (2005).

[12] *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261(2012).

> failed to warn Plaintiff of dangers associated with those parts. Citing long-standing precedent, the court concludes that in enacting the federal law, Congress "manifest[ed] the intention to occupy the entire field of regulating locomotive equipment," and that because the common-law claims for defective design and failure to warn are aimed at the same subject as the federal law, i.e., equipment of locomotives, the claims fall within the pre-empted field.[13]

More commonly, courts will find federal law to have a more limited implied preemptive effect over state law, either because it would be *impossible* for a party to comply with both federal and state law,[14] or because giving effect to the state statutory or common law would stand as an *obstacle* to the achievement of the goals of the federal scheme.[15]

> ***Implied Conflict Preemption (Impossibility) Example:*** Federal law and regulations require generic drug manufacturers to use warning labels that are identical to those approved by the government for their brand-name counterparts. Plaintiff A brings a state tort lawsuit claiming personal injuries resulting from her use of a generic drug and argues that the generic manufacturers should have used stronger warning language on their labels. The Supreme Court has held that such failure to warn claims would be preempted, as it would be impossible for the generic manufacturers to comply with their duty under federal law to use labels identical to those appearing on the brand-name drug while at the same time complying with their state law duty to amend the labels and strengthen the warnings.[16]

> ***Implied Conflict Preemption (Obstacle) Example:*** Federal regulations required auto manufacturers to install passive restraints in some, but not all, of their vehicles, and provided a range of passive restraint devices to be introduced by manufacturers into vehicles gradually over time. Plaintiff A, an injured motorist, brings a state design defect claim arguing that her car should have had a driver's side airbag. The plaintiff's product liability suit would be preempted. The Supreme Court has held that a state tort law requiring airbags in all vehicles would upset the compromise struck by the federal regulations that, on the one hand, attempted to have the auto industry address immediate safety needs while, on the other hand, allowed manufacturers to gradually phase-in a mix of various passive restraint technologies.[17]

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[13] *Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. at 1268-1270.

[14] *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

[15] *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

[16] *See generally PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

[17] *See generally Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861 (2000).

Because of the variety of legal and factual variables at play in the course of individual cases and controversies, the jurisprudence regarding implied preemption is fairly fluid, making it difficult to predict how courts may rule in any give case.[18] For this reason, where regulatory certainty is a priority in an area of regulated activity, policymakers and stakeholders have a strong incentive during the legislative development phase to negotiate and articulate the intended preemptive effect, if any, of the federal legislation with respect to all aspects of state statutory and common-law regulation.[19]

B. State Statutory Environmental Law Versus Common Law Torts

Both the federal government and state governments have broad authority to regulate economic activities that have an impact on human health or the environment, and regulators at both levels can use variety of legislative and judicial tools to regulate environmental, health, and safety in the marketplace. Until the 1900s, Congress largely deferred to the states for most environmental and product regulation. As interstate commerce increased and the US economy became more complex and intermingled during the 20th Century, the federal government assumed a larger regulatory role, first in food and drug law and later in other areas of product regulation. Product manufacturers are now subject to a wide variety of federal and state regulatory requirements addressing both the manufacturing process and the end-use products themselves. Regulated entities must adhere to a variety of mandates that can include: pollution control requirements during the manufacturing process; product design standards and restrictions; testing requirements; risk management provisions; labeling and warning requirements; and recordkeeping and reporting requirements, among others.[20]

But states need not enact affirmative laws, regulations, or popular referenda to affect intrastate and interstate regulation of products. In some states today, and in most states prior to the 20th Century, states would use the judicial system to regulate product risks, based on well-established but always evolving principles of common law for standards. The term "common law" generally "refers to that body of governing principles, mainly substantive, expounded by the common-law courts of England in deciding cases before them."[21] Over time, courts have tweaked, modified, or even created new tort law causes of action in adjusting to modern commerce. For example, the modern law of product liability evolved in response to the

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[18] *See, e.g.*, Jean Macchiaroli Eggen, *The Normalization of Product Preemption Doctrine*, Widener Law School Legal Studies Research Paper Series no. 08-57 (2006) at 1; Charles Franklin and Alison Reynolds, *TSCA Reform and Preemption: A Walk on the Third Rail*, American Bar Association, Natural Resources and the Environment, Vol. 27 No. 1 (Summer 2012) at 1.

[19] *Id.*

[20] Because the Committee is providing an in-depth analysis of preemption as applied to statutory law in a separate White Paper, this document does not address this issue further, and it is the preemption of State tort claims that we turn to next.

[21] *William B. Stoebuck*, Reception of English Common Law in the American Colonies, 10 Wm. & Mary L. Rev. 393 (1968).

changing process of manufacture and distribution of products.[22] The various causes of actions typically found in a toxic tort suit, such as negligence, trespass, strict liability, nuisance, and the like, were fleshed out in this manner and continue to evolve today.[23]

At the heart of any toxic tort lawsuit are allegations by plaintiffs that they were harmed by an exposure to a chemical substance or other hazardous material. But that is where the similarity ends, as toxic tort litigation can take many forms. Plaintiffs may claim they were exposed through the use of a consumer product, while working at a manufacturing facility, or as the result of environmental contamination. The claimed damages can be equally varied, such as bodily injury (*e.g.*, cancer), fear of future bodily injury (*e.g.*, contracting cancer in the future), wrongful death, property damage, or economic loss. And the potential causes of action – including negligence, trespass, strict liability, nuisance, and product liability – all reflect the wide range of circumstances that may give rise to a toxic tort suit.

The following are just a few examples of state common-law tort suits that can raise preemption questions:

- **Negligence:** Neighborhood residents rely on a state's common law (i.e., judge-made law embodied in court decisions) to allege that a manufacturing facility negligently disposed of chemical liquids in an open pit that eventually contaminated drinking water supplies. The residents argue that the defendant breached a common law duty to safely dispose of the materials.

- **Product Liability:** A consumer claims that a manufacturer sold a product that contains heavy metals, which could be absorbed through the skin or inhaled during use. The consumer argues that the product's design was defective (i.e., unsafe) and that the manufacturer failed to warn of the alleged risks.

- **Nuisance:** A landowner alleges that at a manufacturing site adjacent to her property chemicals were stored too close to the property line and are now leaking onto her land. She claims that the presence of the chemicals interferes with her use and enjoyment of her land by contaminating the property and creating a risk of illness.

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[22] For example, courts created a theory of implied warranty running from a manufacturer to a consumer, without any contract between them, making the manufacturer strictly liable for injuries resulting from a defective product. *Jarnot v. Ford Motor Co.*, 156 A.2d 568, 572 (Pa. 1959). A California court later evolved the theory further by completely dropping the notion of implied warranties and simply imposing strict liability on manufacturers as a matter of law "to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57, 64 (1963).

[23] State legislatures can also shape state tort law through statutory mandates that can expand, narrow, or supplement the range of tort claims available to litigants through the courts.

A state tort decision may implicate labeling or warning requirements, product testing protocols, recordkeeping and reporting requirements, use restrictions, or manufacturing and operating processes, all of which may be regulated by the federal government. In such cases, Defendants often maintain that the conduct or product at issue is already regulated under federal law and, therefore, preemption applies. They will argue that a decision in the plaintiff's favor would have the same effect as a state directly enforcing a statute or regulation that governs the manufacture, sale, or use of a chemical substance. Plaintiffs, in turn, will argue that federal regulations fail to consider or address the fact-specific cases raised at common law. They will further argue that the federal regulations should be viewed as minimum standards, beyond which state law may impose additional standards.

To address this potential clash between federal regulation and state common law, most federal product statutes and regulations incorporate specific language addressing the intended relationship between federal and state standards, including duties of care, labeling, and disclosure. Appendix I offers a brief summary of the types of language used by selected federal regulatory statutes to anticipate and address these issues. Notwithstanding such provisions, courts have often disagreed on the interpretation of the language.

C. The Evolving State of Common Law Preemption Jurisprudence

Even where Congress has provided language articulating principles for resolving federal/state conflicts over regulatory standards and liability, it is often difficult to predict how any specific statutory framework, phrase, or saving clause will be interpreted and applied to a specific set of facts. There are certain principles courts follow – in theory if not always in practice – in determining whether a federal statute or regulation preempts state common law actions.

1. Presumption Against Preemption

Courts often say that a presumption against preemption applies, particularly when a case involves matters of public health and safety. The Supreme Court has stated that, pursuant to the Supremacy Clause,[24] "the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress."[25] But the Court has not always clearly followed this rule. This has meant that the Court has rejected or ignored the presumption in cases where it would otherwise seem applicable.[26] Even though the Court has

[24] U.S. CONST. art. VI, cl. 2.

[25] *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947).

[26] *Compare Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870-71 (2000) (refusing to apply the presumption against preemption in a case involving motor vehicle safety) *with Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) (recognizing that the presumption against preemption applies in both the express and implied preemption contexts in a case involving tobacco products).

recently reinforced its adherence to the presumption against preemption,[27] interested parties should remain wary about relying on the force of the presumption in a particular case.

2. Interpretation of Preemption Provisions

Judges employ various interpretive devices when considering preemption provisions and saving clauses. Courts will look to the plain language of the statute and apply rules of statutory construction, such as giving every word or phrase meaning and avoiding interpretations that render statutory text superfluous.[28] Judges consider the overall structure and purpose of the statute, including Congressional findings and statements of intent appearing in the statute's preamble.[29]

3. Role of Saving Clauses

The existence of a saving clause in the federal statute – a provision that excludes some or all state law from preemption – is relevant to both express preemption and implied preemption. Where a saving clause accompanies a preemption provision, it is a complement to the preemption provision and should be interpreted with it under an express preemption analysis. In *Geier v. American Honda Motor Co*., the Supreme Court interpreted the relevant saving clause in that case, stating: "The saving clause assumes that there are some significant number of common-law liability cases to save. And a reading of the express preemption provision that excludes common-law tort actions gives actual meaning to the saving clause's literal language. . . ." The Court went on to emphasize that this interpretation would "leav[e] adequate room for state tort law to operate – for example, where federal law creates only a floor, i.e., a minimum safety standard."[30]

The existence of a saving clause does not necessarily prevent implied preemption from precluding state common-law actions, as *Geier* demonstrated. Although the saving clause in *Geier*, read together with the preemption provision, made clear that common-law tort actions were not intended to be *expressly* preempted, it did not save those same tort claims from being *impliedly* preempted. A longer quote from the *Geier* opinion is germane:

> On the one hand, the pre-emption provision itself reflects a desire to subject the industry to a single, uniform set of federal safety standards . . . and suggests an intent to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create . . . .

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[27] *See Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009) (reasoning that "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action'").

[28] *See, e.g., Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 85 (1992) (O'Connor, J., writing for the plurality).

[29] *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 490 (1996).

[30] *Geier v. Am. Honda Motor Co*., 529 U.S. at 868.

> On the other hand, the saving clause reflects a congressional determination that occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time. But we can find nothing in any natural reading of the two provisions that would favor one set of policies over the other where a jury-imposed safety *standard actually conflicts* with a federal safety standard.[31]

This segment of the opinion recognizes the value of a saving clause, but also emphasizes that it has limits. The *Geier* Court then went on to hold that conflict preemption precluded the tort claims in the case.

Recently, the Supreme Court reinforced this interpretation in *Williamson v. Mazda Motor of America, Inc.*[32] The Court stated: "In light of *Geier*, the statute's express pre-emption clause cannot pre-empt the common-law tort action; but neither can the statute's saving clause foreclose or limit the operation of ordinary conflict pre-emption principles."[33] In both *Williamson* and *Geier*, the Court's express preemption analysis viewed the saving clause in relation to the preemption provision, and it also viewed the saving clause as relevant to implied preemption analysis. This potential use of the saving clause in an implied preemption analysis is all the more reason for including clear and unambiguous language in the saving clause to assist courts in understanding Congressional intent.

4. Consideration of Legislative Findings

Similarly, courts will look to legislative findings when interpreting the preemption provision. Because the touchstone of preemption is the intent of Congress, legislative findings in the statute may be particularly useful for interpreting a preemption provision that is not clear on its face. The role of findings is discussed in more detail below under "Implied Preemption."

5. The Scope of Defined Terms

The Supreme Court has made clear that the term "requirement" in a preemption provision will be interpreted to include common-law tort actions. In *Riegel v. Medtronic, Inc.*, a case involving the preemption provision in the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), the Supreme Court stated: "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties."[34] The

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[31] *Id.* at 871 (emphasis added).

[32] *PLIVA*, 131 S. Ct. 2567.

[33] *Id*. at 1136. The Court also stated: "Since tort law is ordinarily 'common law,' we held that "the presence of the saving clause," makes clear that Congress intended state tort suits to fall outside the scope of the express pre-emption clause. *Id*. at 1135 (quoting *Geier*, 529 U.S. at 868).

[34] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008).

statements in *Medtronic* remain dicta outside the context of the Medical Device Act. Given the parallels between device regulation and regulation of products generally, however, drafters should assume, absent explicit and unambiguous definition otherwise, use of the term "requirements" in a preemption provision will be deemed by courts to include state common law actions.

6. Uncertainty of Implied Preemption Principles

While express preemption language can help clarify legislative intent and reduce the risk of unintended judicial interference at the federal or state level, courts have found implied preemption to apply in statutes with and without stand-alone preemption provisions. Accordingly, implied preemption is something of a wildcard, as it often depends upon the specific statutory provision or regulation in question and the specific issues that arise in the case. The Supreme Court has recognized that even if state law is not preempted by an express preemption provision, implied preemption may nevertheless bar state common-law claims. The Court has stated: "The fact that an express definition of the pre-emptive reach of a statute 'implies' – i.e., supports a reasonable inference – that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption."[35] In *Geier v. American Honda Motor Co.*, the Supreme Court held that although the federal statute's preemption provision did not bar the state tort claims alleged in the case, the claims were nevertheless impliedly preempted.[36]

7. Consideration of Legislative History

Where a preemption provision is ambiguous, courts have looked to the legislative history to determine the meaning of an express preemption provision. In *Cipollone v. Liggett Group, Inc*., the Supreme Court scrutinized the preemption provisions in the two federal cigarette labeling acts relevant to a smoker's personal injury action.[37] The Court interpreted the 1965 preemption provision's language to preempt only state positive law enactments, but interpreted the broader language in the 1969 act's provision to encompass preemption of some, though not all, of the plaintiff's tort claims.[38]

In *Wyeth v. Levine*, the Supreme Court examined the full legislative history of the FDCA since 1906 and concluded that the overwhelming thrust of that act's drug provisions reflected Congressional intent to retain state common law actions.[39] The Court recognized the long-

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[35] *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

[36] *See Geier v. Am. Honda Motor Co*., 529 U.S. at 873.

[37] *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (plurality opinion).

[38] Because the cigarette acts were labeling acts, the 1965 provision stated that "[n]o statement relating to smoking and health shall be required in the advertising [or labeling] of . . . cigarettes which are labeled in conformity with the provisions of the Act." Pub. L. No. 89-92, 79 (1965). In the *Cipollone* decision, the Court interpreted "statement" to mean only state statutes or regulations requiring certain warnings. In contrast, the 1969 act used the language "[n]o requirement or prohibition." Pub. L. No. 91-222 (1970). In comparing the two provisions, the Court held that "requirement or prohibition" was intended to be broader than "statement" and could encompass common-law tort claims. *Cipollone*, 505 U.S. at 522.

[39] *See Wyeth v. Levine*, 555 U.S. at 565-68.

standing role of tort law as an adjunct to the FDA's authority.[40] It ultimately held that neither impossibility preemption nor obstacle preemption barred the plaintiff's failure-to-warn claim involving a drug marketed through the new drug provisions of the FDCA.[41]

The *Levine* decision was fact-specific and turned on narrow provisions of the FDCA, making it difficult to attribute the decision to any single factor. Still, *Levine* illustrates the analytical steps that courts will sometimes take to discern Congressional purposes and goals.

D. Other Considerations in Legislative Drafting

While much of the scholarship on the balance of power between federal and state environmental law has focused on the concepts of express and implied preemption, federal statutes influence the practical viability of common law tort remedies in other ways as well. In practice, the mere act of granting federal administrative agencies the authority to make independent safety assessments and determinations will shape the factual and legal environment judges and juries face in evaluating a tort claim. For example, the typical tort action may involve claims that the defendant acted negligently, failed to warn of a particular hazard, or placed into commerce a defectively designed product. Under any of these theories, the plaintiff bringing a tort suit must first demonstrate "causation" – i.e., that the defendant's conduct resulted in a chemical exposure that harmed the plaintiff. Often, plaintiffs must also show that the injury was "foreseeable" – i.e., that the defendant knew or should have known of the danger posed by the use or handling of its chemical. To the extent that federal law authorizes administrative agencies to consider available data, assess potential risks associated with identified hazards and routes of exposure, and/or make risk or safety-related determinations based on the available data, such determinations may influence whether and how litigants can meet their burdens of proof or persuasion on these and other issues in a number of ways.

1. Influencing the Causation Analysis

The causation piece is often the most complicated and hard fought element in tort litigation. In most toxic tort cases, especially those involving risks to human health, the plaintiff must first demonstrate what is called "general causation" – that the chemical is capable of causing the alleged injury in the general population – and identify the relevant exposure level or dose that triggers injury. Assuming the plaintiff overcomes this hurdle, he/she must then establish what is referred to as "specific causation" – that the chemical exposure was at or above a level sufficient for the jury to draw the inference that the chemical, in fact, caused plaintiff's alleged injury.[42]

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[40] *See id.* at 575 ("[Congress'] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

[41] *Id.* at 573.

[42] *See, e.g., Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010) (discussing Iowa law); Federal Judicial Center, Reference Manual on Scientific Evidence, at 609 (3d ed. 2011).

In the toxic tort context, certain types of evidence are typically introduced to demonstrate whether or not a particular chemical is capable of causing harm. Such evidence might include (i) toxicological studies aimed at "identifying and understanding the adverse effects of external chemical . . . agents on biological systems" (which usually involve exposing cells, tissues, or animals to the chemical); and (ii) epidemiological studies whose purpose is to "better understand disease causation" by looking at the "incidence, distribution, and etiology of disease in human populations."[43] Litigants may also introduce testimony from an expert toxicologist or epidemiologist considering levels of exposure or dose, as well as the mechanisms by which a chemical may cause a certain disease.[44] Based on these disparate sources of information, judges and juries must then make a determination as to whether the evidence supports a finding of causation.

The presence of an affirmative federal safety determination with respect to a specific chemical, product, or use scenario would be a material consideration for a jury pondering causation, regardless of the outcome of the determination. Where an agency has concluded that a chemical does not meet the applicable safety standard, it may be more difficult for the defendant to cast doubt on the plaintiff's general causation case. The plaintiff's expert, for example, may be able to substantially rely on the work done by EPA and the underlying data to establish general causation. It may even be that the safety determination is so compelling that the plaintiff will be able to secure a settlement long before trial. On the other hand, where an agency has concluded that a product, chemical, or use pattern does meet the applicable safety standard for a given use scenario, it may be more difficult for the plaintiff to overcome that finding or somehow otherwise establish general causation. In fact, the safety determination may be so convincing that it will persuade a potential plaintiff not to file a tort suit at all.

2. Influencing the Foreseeability Analysis

A federal safety assessment and determination can also influence the way judges and juries assess the foreseeability of a risk of injury or harm from a specific use. In many states, plaintiffs support arguments that a product's design is defective by submitting evidence that foreseeable risks of harm, such as those associated with chemical exposures, could have been reduced or avoided through a safer design.[45] Similarly, in most states, a design defect may be established by showing that foreseeable risks could have been minimized through adequate use instructions or warnings.[46]

To the extent a federal statute authorizes a federal agency to make safety determinations regarding a chemical, product, or use scenario, the litigants on all sides of a tort suit will look to

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[43] Federal Judicial Center, Reference Manual on Scientific Evidence, at 551, 635.

[44] *Id.* at 635-38, 597-06.

[45] *See, e.g., Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 431-32 (Cal. 1978).

[46] *See, e.g., Bouchard v. Am. Orthodontics*, 661 A.2d 1143, 1145 (Me. 1995).

whether and how they may be able to rely upon or refute the relevance of that finding in arguing whether the defendant manufacturer knew or should have known that the chemical, product, or substance posed a foreseeable risk. How a safety determination ultimately effects the foreseeability element will depend on the facts of each case. For example, where there has been a finding by the agency of no unreasonable risk, the plaintiff may be able to argue that studies conducted subsequent to the safety determination and known by the manufacturer demonstrate foreseeability. Alternatively, where the agency has found an unreasonable risk, the defendant may be able to use the facts of that determination to argue that the plaintiff's exposures were much lower than those considered by the agency during the safety assessment, suggesting the lack of foreseeable danger in that case.

3. Admissibility of Federal Determinations in State Court

The degree to which a safety determination affects state tort suits will also turn, in part, on the federal statute's approach to (and each individual state's rules regarding) the admissibility of evidence showing compliance, or non-compliance, by the defendant with a government standard. Many state courts allow such evidence into the record, but hold that it is not necessarily dispositive evidence of liability.[47] In other words, it is up to the jury to decide how much weight to give to the defendant's compliance record. Thus, the mere fact that a law states that a safety determination is always admissible in a tort suit may not, as a practical matter, have much of an impact in those cases, while a provision preventing consideration of federal safety determinations may significantly prejudice the defense.[48] In contrast, the governing state law in some jurisdictions may limit the admissibility of government safety determinations as evidence in a toxic tort claim, particularly cases involving strict liability claims of a defective product.[49] In those cases, the inclusion of specific language in a federal bill mandating the admissibility of federal safety findings would put plaintiffs at a significant disadvantage relative to status quo ante.[50]

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[47] *See, e.g., Jemmott v. Rockwell Mfg. Co.*, 216 A.D. 2d 444, 444-45 (N.Y. App. Div. 1995) ("While ANSI standards and OSHA regulations may be indicative of what may constitute negligence, neither is dispositive").

[48] Of course, if Congress were to prohibit safety determinations from coming into evidence at all, or otherwise limit the extent to which a jury could consider it as evidence regarding compliance or non-compliance with the safety standard, this would substantially change how most courts deal with this type of evidence.

[49] *See, e.g., Nesbitt v. Sears, Roebuck and Co.*, 415 F. Supp. 2d 530, 534 (E.D. Pa. 2005) ("It is clear that a manufacturer may not introduce evidence of compliance with . . . OSHA standards to demonstrate the absence of a product defect").

[50] Similarly, federal language mandating that federal agency safety findings should be treated as persuasive or determinative could shift, if not fix the burden of persuasion and proof, relative to the state's historic common law jurisprudence.

II. PREEMPTION IN PRACTICE

A. Preemption Under the Current TSCA

TSCA contains a limited express preemption provision at section 18 under which states may regulate chemical substances in a wide range of circumstances.[51] States are generally free to impose restrictions on any chemical substance if EPA has not specifically addressed that substance under the statute.

Only when EPA adopts a test rule under section 4 or otherwise imposes risk management measures for a particular chemical under sections 5 or 6 (*e.g.*, requires specific warning labels or limits the amount of a chemical that may be produced) does TSCA preempt any similar state action.[52] Even where EPA regulates a given chemical, section 18 allows states to, among other things, enforce requirements that are identical to any federal restrictions or ban outright the use of the chemical substance within its borders.[53]

Section 18 is silent as to the preemptive effect of the statute on state tort lawsuits due to chemical exposures. Nowhere in that provision does Congress specifically address to what extent, if any, state tort claims are preempted. Section 20 of TSCA, however, contains a saving clause that preserves the right of citizens to "seek any other relief" under state statutory and common law.[54] Some courts have interpreted this saving clause as permitting a common law tort suit for damages, notwithstanding section 18's preemption provision.[55]

In fact, the Supreme Court has examined a saving clause appearing in the Clean Water Act (CWA) that is worded almost identically to TSCA section 20 and held that it preserves state common law claims related to chemical contamination. In *Int'l Paper Co. v. Ouellette*, the Court considered whether the CWA preempted a common law nuisance suit alleging water pollution in Lake Champlain.[56] The saving clause in the CWA provided that nothing prohibited any person

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[51] 15 U.S.C. § 2617.

[52] *Id.* § 2617(a)(2)(A)-(B).

[53] *Id.* § 2617(a)(2)(B). Section 18 also contains a waiver provision in which a state may apply for a preemption exemption, provided it meets several requirements (*e.g.*, the state law provides for a significantly higher degree of protection when compared to the federal requirement).

[54] *Id.* § 2619(c)(3). "Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this chapter or any rule or order under this chapter or to seek any other relief."

[55] *See, e.g., Chappell v. SCA Services, Inc.*, 540 F. Supp. 1087, 1100 (C.D. Ill. 1982) (holding that TSCA does not preempt a nuisance claim brought by residents involving a nearby landfill containing PCBs); *but see Sanford Street Local Dev. Corp. v. Textron, Inc.*, 768 F. Supp. 1218, 1223-24 (W.D. Mich. 1991), *vacated on other grounds*, 809 F. Supp. 29 (W.D. Mich. 1991) (holding negligence *per se* claim for alleged violation of TSCA preempted by statute).

[56] 479 U.S. 481, 483 (1986).

from seeking "any other relief" under statutory or common law.[57] Although the Court found that "Congress intended to dominate the field of pollution regulation," it also concluded that the "saving clause negates the inference that Congress 'left no room' for state causes of action."[58] It was this similarity between the CWA's saving clause and TSCA's section 20, which led one federal court to hold that TSCA does not preempt common law actions.[59] The court noted that TSCA's saving clause is patterned after the one appearing in the CWA when it held that "TSCA does not preempt state common law nuisance actions for damages."[60]

Courts have not yet ruled on how the establishment of an EPA use restriction on a particular chemical would affect a plaintiff's ability to file a state tort claim implicating the same or similar types of restrictions.

B. Preemption Approaches Under Other Federal Product Regulatory Statutes

Because of the ever-present tension between federal, state, and local regulatory environmental regulation, most of the major federal environmental laws contain specific provisions intended to provide, at least in theory, some directive to the Courts regarding the relationship between federal and state-issued regulatory standards. In addition, it is not uncommon for federal statutes that regulate products containing chemical substances to contain a saving clause provision limiting the law's preemptive effect with respect to prior state statutes and common law. Appendix A to the Paper provides excerpted language from key provisions in five federal product regulatory statutes addressing address statutory and common-law preemption and savings principles.

For example, the Food and Drug Administration Modernization Act of 1997 (FDAMA) modified the FDCA to clarify that, with respect to nonprescription drugs, the federal law does not "affect any action or the liability of any person under the product liability law of any State."[61] Similarly, the Consumer Product Safety Improvement Act of 2008 (CPSIA) provides that the Consumer Product Safety Commission (CPSC) may not construe various statutes as "preempting any cause of action under State or local common law or State statutory law regarding damage claims."[62] Finally, FIFRA has an even broader saving clause, where states may, in most instances, regulate the sale or use of any federally registered pesticide.[63] The Supreme Court has

[57] *Id.* at 485.

[58] *Id.* at 492.

[59] *Chappell*, 540 F. Supp. at 1099-1100.

[60] *Id.* at 1100.

[61] 21 U.S.C. § 378r(e).

[62] 15 U.S.C. § 2051(a) (citing to the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Flammable Fabrics Act).

[63] 7 U.S.C. § 136v(a).

interpreted this provision as allowing state tort actions except where they seek relief related to labeling and packaging that is "in addition to or different from" requirements under the statute.[64]

In several cases, the Supreme Court has given effect to saving clauses and found that they preserve common law tort claims, even in the face of what would otherwise be considered strong preemption language. For instance, in *Geier v. Am. Honda Motor Co., Inc*., the Court held that a common law tort action alleging that an auto manufacturer should be held liable for failing to install airbags was not preempted by the express preemption clause in the National Traffic and Motor Vehicle Safety Act of 1966.[65] That provision prohibited states from establishing safety requirements "which were not identical to the Federal standard."[66] The federal standard governing safety restraints in automobiles did not require airbags and, therefore, any state court decision imposing liability in that case would arguably be preempted.[67] Although the Court acknowledged that the term "standard" could be broadly interpreted as preempting not only positive enactments, but also common law claims, it nevertheless held that a saving clause in the statute preserved plaintiff's lawsuit. That clause provided that "[c]ompliance with" a federal safety standard "does not exempt any person from any liability under common law."[68] The Court concluded that the "saving clause assumes that there are some significant number of common-law liability cases to save."[69]

Similarly, in *Sprietsma v. Mercury Marine*, the Supreme Court held, based on the broad savings clause in the Federal Boat Safety Act of 1971 (FBSA), that at least some common-law claims were not preempted. The Court limited the terms "law or regulation" in the FBSA's preemption provision to mean state positive law enactments and allowed the plaintiff's claims.[70]

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[64] *Bates*, 544 U.S. at 443; *see* 7 U.S.C. § 136v(b) (stating that a "State shall not impose or continue in effect any requirements for labeling and packaging in addition to or different from those required under this subchapter"). Saving clauses, moreover, do not merely extend to tort claims. Federal statutes also contain provisions that "save" state labeling statutes, such as California's Safe Drinking Water and Toxic Enforcement Act, Cal. Health & Safety Code §§ 25249.5-25249.13 (1986) (otherwise known as "Proposition 65"). For instance, both the FDAMA and CPSIA have clauses that exempt from preemption various state consumer product initiatives adopted after a specified date.

[65] 529 U.S. at 868.

[66] *Id.* at 867 (citing 15 U. S. C. § 1397(k) (1988 ed.).

[67] *Id.* at 864-65.

[68] *Id*.

[69] *Id*.

[70] *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002) (discussing the saving clause, which states, "Compliance with this chapter does not relieve a person from liability at common law or under State law.").

C. Preemption Under Recent Modernization Proposals[71]

If the case law surrounding the application of the preemption doctrine to current law is muddled, anticipating the likely treatment of future bills is even more challenging. Even when parties have clear agreement of the intended scope and reach of a statute's preemptive provision, drafting ambiguities and gaps can open the door to unexpected post-enactment arguments and judicial interpretations. This uncertainty creates both legal and policy complications for policymakers and stakeholders involved with the current TSCA modernization effort. In the 113th Congress, two distinct TSCA modernization bills were introduced, reflecting two fairly distinct visions. The bills also provide two distinct approaches to the issue of preemption.

1. The Chemical Safety Improvement Act

The Chemical Safety Improvement Act (CSIA), S. 1009 contains a limited express preemption provision. Like TSCA, preemption under the CSIA would only be triggered when EPA takes some type of action with regard to a specific chemical substance. However, while under TSCA preemption is triggered upon the imposition of risk management measures, preemption under section 15 of the CSIA would be pegged to the prioritization and safety determination process, events likely to occur prior to any final risk management action. In particular, section 15 would amend section 18 of TSCA to provide that "no State or political subdivision of a State may establish or continue to enforce" the following:

- A requirement for the development of test data or information for a certain chemical substance or category of substances if it is reasonably likely to produce the same data or information already required by EPA under sections 4, 5, or 6 of the CSIA, whether by rule, consent agreement or order;

- A prohibition or restriction on the manufacture, processing, or distribution in commerce or use of a chemical substance after EPA has completed a safety determination for that substance under section 6 of the CSIA; or

- A requirement for the notification of a use of a chemical substance that EPA has specified as a significant new use and for which the Agency has required notification under section 5 of the CSIA.[72]

With respect to state prohibitions or restrictions established after the CSIA was enacted, states would not be able to adopt:

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[71] As this Briefing Paper was going to print, lawmakers in the House of Representatives released a bill in "Discussion Draft" form, entitled the Chemicals in Commerce Act. *See* U.S. House of Representatives, *Press Release: Shimkus Unveils Discussion Draft of Chemicals in Commerce Act* (February 27, 2014), available at https://energycommerce.house.gov/press-release/shimkus-unveils-discussion-draft-chemicals-commerce-act. This Briefing Paper does not attempt to analyze this new bill.

[72] S. 1009 § 15(a).

- A prohibition or restriction on the manufacture, processing, distribution in commerce or use of a chemical substance that has been designated by EPA as a high priority substance under section 4 (as of the date on which the Agency publishes a schedule for the safety assessment under section 6); or

- A prohibition or restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance that has been designated by EPA as a low priority substance under section 4.[73]

The CSIA also contains certain preemption exceptions, but they differ from those found in TSCA. The CSIA would not allow states, as does TSCA, to enforce requirements that are identical to federal regulations or ban the use of a chemical substance within their borders. Instead, a state would only be able to enforce "a requirement, prohibition, or restriction" that:

- Is adopted under the authority of any other federal law;

- Implements a reporting or information collection requirement not otherwise required by EPA under the CSIA or other federal law; or

- Is adopted under state law related to water quality, air quality, or waste treatment, and which (i) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of the chemical and (ii) is not otherwise inconsistent with an action taken by EPA under sections 5 or 6.[74]

As to state tort actions, the CSIA would retain the saving clause provision in section 20 of TSCA, governing citizens' civil actions, leaving intact the statement that "Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief."[75] The retention of this language lends support to the argument that the CSIA does not preempt the rights of parties to seek relief through private tort suits.

Still, stakeholders have pointed out that even if tort suits were not expressly preempted under the CSIA, its preemption provision does appear to set limits on the discretion granted to state courts in balancing federal safety determinations against other sources evidence. Specifically, the CSIA's preemption provision addresses the role that certain EPA decisions would have in state tort suits. It explicitly provides that any safety determination for a high

[73] S. 1009 § 15(b).

[74] *Id.* § 15(c). Section 15 would also amend section 18 of TSCA to include a waiver provision under which a state may be exempted from preemption provided it meets several conditions (*e.g.*, the state demonstrates that there are "compelling State or local conditions" warranting such a waiver).

[75] 15 U.S.C. § 2619(c).

priority chemical "shall be admissible" and that it "shall be determinative of whether the substance meets the safety standard under the conditions of use addressed" in the determination.

2. The Safe Chemicals Act

On April 10, 2013, less than a month prior to the introduction of the CSIA, Senator Lautenberg and 29 Democratic cosponsors introduced an earlier TSCA modernization bill, entitled the Safe Chemicals Act of 2013 (SCA) (S. 696). The SCA took a much different approach to preemption. Under section 18 of that bill, TSCA's existing preemption language would be repealed with the exception of allowing states to enforce "any regulation, requirement, or standard of performance" unless it is "impossible" for a regulated entity to comply with both the state regulation and a federal requirement.

By invoking the "impossibility" strain of conflict preemption, the SCA preemption provision is substantially more limited in scope than both TSCA's current preemption provision and that proposed in the CSIA. In weighing preemption under the SCA, "[t]he question of 'impossibility' is whether the private party could independently do under federal law what state law requires of it."[76] Traditionally, this has been a very demanding standard for those seeking to invoke preemption.[77] Given the presumption against the preemption of state police powers,[78] the Supreme Court has stated that courts must work to reconcile state and federal law, whenever possible, to avoid impossibility preemption.[79]

The SCA's "impossibility" preemption provision also would allow states to issue prohibitions or restrictions on a chemical substance regardless of whether EPA characterizes that chemical substance as one that is "likely to meet the safety standard under section 6(d)" while awaiting a safety standard determination[80] or of "very low concern."[81] This is because even if EPA characterized a chemical substance or class of chemical substances as "safe" or presumptively safe, states would remain free to impose more stringent requirements provided that regulated entities would be able to comply with both state and federal requirements.

As with the CSIA, the SCA would largely retain TSCA § 20, the citizens' civil actions provision, enacting only minor changes. In particular, it would retain the savings clause

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[76] *PLIVA*, 131 S. Ct. 2567, 2579.

[77] *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) ("Impossibility pre-emption is a demanding defense."); *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient" to find preemption); *California v. FCC*, 75 F.3d 1350, 1359 (9th Cir. 1996) ("the impossibility exception is narrow").

[78] *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 518 (1992).

[79] *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117, 127 (1973).

[80] *See* S. 696 § 6, adding § 5(b)(1)(C)(i) of TSCA.

[81] *See id.*, adding § 5(b)(2)(D)(iii)(II).

language stating that "Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief."[82] This would leave the question of state tort law preemption in its current state.[83] Unlike the CSIA, nothing in the SCA addresses the use of safety determinations as evidence in tort suits.

III. CONCLUDING STRATEGIES FOR CLARIFYING AND CODIFYING LEGISLATIVE INTENT

As part of the process of adopting TSCA modernization legislation, policymakers and stakeholders will need to consider the appropriate role of state common law tort remedies in a modified federal chemical control framework. Legislation may articulate Congress' intent in ways that will reduce the likelihood of judicial (and stakeholder) confusion in areas such as the following -

- **Legislative Findings:** Use legislative statements of intent to signal intended scope and limits of any preemptive effect.

- **Preemption Scoping Language:** Describe and define preserved and preempted state activities with particularity to reflect intended scope of any preemption, making a clear distinction between state-implemented regulatory powers and judicially-administered causes of action.

- **Saving clause:** Include saving language that specifically identifies and addresses whether and how both state legislatively enacted and common-law tort remedies will be treated under federal law.

- **Legislative History:** Include statements in Senate/House reports and Conference reports reiterating and elaborating on the intended preemptive scope of the law generally, and the intended impact on tort remedies in particular.

To be sure, these general recommendations may do little to help policymakers and stakeholders find consensus on the underlying policy views. ABA SEER hopes, however, that these recommendations, combined with the broader analysis in the White Paper and the collected and distilled examples of preemptive language from federal product regulatory statutes in Appendix 1, may offer potential road signs, if not a road map, for addressing the tort law preemption issue.

Attachment

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[82] 15 U.S.C. § 2619(c).

[83] *See* footnote 39, *supra*, citing contradictory cases on TSCA preemption of state tort law suits.