TESTIMONY OF

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on

Strengthening Public Health Protections by Addressing Toxic Chemical Threats

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My name is Tom McGarity. I hold the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law, where I teach courses in Torts and Environmental Law. I am also a member of the Board and immediate past president of the Center for Progressive Reform. I have written several law review articles on federal regulation of toxic substances. In 2008, I published a book entitled *The Preemption War: When Federal Bureaucracies Trump Local Juries*, in which I explore issues involving federal preemption of state common law claims. In that same year, I published, with my co-author and colleague Wendy Wagner, *Bending Science: How Special Interests Corrupt Public Health Research*, in which we explore many issues involving the regulation of toxic substances. I am very pleased to be here to testify on the topic of federal regulation of toxic substances and changes to the Toxic Substances Control Act. Please note that I am expressing my own views and not necessarily those of the University of Texas or the Center for Progressive Reform.

Introduction.

The Toxic Substances Control Act (TSCA) is a broken statute, but S. 1009 is not going to fix TSCA. In fact, it will almost surely make a bad situation worse.

S. 1009 appears to provide a systematic mechanism for prioritizing and evaluating the tens of thousands of grandfathered chemicals that have not been adequately tested to determine the risks, if any, that they pose to human health and the environment. But appearances can be deceiving. The numerous and rather ill-defined procedural and analytical steps that the EPA must take prior to requiring companies to begin testing their chemicals, combined with EPA's perennial lack of resources and the absence of any enforceable deadlines, ensure that we will not see any testing results for high priority chemicals for many years or even decades.

The Bill does not change the tests for requiring additional testing and for taking regulatory action to protect the public and the environment in any significant way. As a result, EPA will face the same daunting difficulties in demonstrating to reviewing courts that testing or other regulatory action is necessary. At the same time, the Bill fails to change the standard of judicial review from "substantial evidence" to the "arbitrary and capricious" standard that Congress generally prescribes for judicial review of informal rulemaking, thereby ensuring that reviewing courts will continue to review TSCA rules more stringently that most federal regulations.

Although the preemption section of the current law has been working well for thirty-five years, S. 1009 changes that section to preempt state data production requirements that are likely to produce the same information as an EPA data production rule, a prohibition or restriction on a subject for which EPA has completed a safety determination, or a significant new use notification requirement for a chemical for which EPA has prescribed such a requirement. The current law allows a state to prohibit the sale of a chemical without regard to any EPA regulation governing that chemical. The Bill will

unnecessarily force states to allow the production, processing and distribution of chemicals that state agencies have deemed to be too dangerous.

Finally, a highly unusual provision in S. 1009 will require state courts to admit EPA safety determinations as evidence in both civil and criminal trials and preclude state judges and juries from concluding that a chemical declared to be safe by EPA is unsafe for purposes of imposing liability on manufacturers, processors and distributors of the relevant chemical. This provision is simply a gift of partial immunity to companies that are fortunate enough to have their chemicals declared safe by EPA in proceedings in which potential victims are not likely to be represented.

The Toxic Substances Control Act: A Failed Statute.

When Congress enacted the Toxic Substances Control Act of 1976 (TSCA), I was a young attorney in the Environmental Protection Agency's Office of General Counsel in the division that was responsible for implementing that brand new statute. Although it took five years for the final version to emerge from Congress, most observers agreed at the time that the statute would for the first time allow the federal government to protect American citizens from the serious risks posed by potentially toxic substances in the environment.

TSCA was supposed to fill in the considerable jurisdictional gaps left by the topical statutes like the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, and the Federal Insecticide, Fungicide and Rodenticide Act. The hope was that EPA would in short order require companies to test the thousands of chemicals for which rudimentary toxicity studies were lacking and would require manufacturers, processors and distributors of risky toxic chemicals to use proper warnings, to limit human exposure to those chemicals, and, in some cases, to take dangerous chemicals off the market altogether.

Thirty-five years later, it has become painfully apparent that, with some modest exceptions, TSCA is a failed statute.

TSCA requires manufacturers of new chemicals to notify EPA of their intent to introduce their products into commerce.[1] This notification aspect of the statute has worked reasonably well over the years, though the process has not always been as transparent as Congress originally envisioned.

TSCA also empowers EPA to promulgate rules requiring the manufacturer to test an existing chemical if EPA can demonstrate that insufficient information is available to evaluate its safety and that human beings or the environment are heavily exposed to the

[1] 15 U.S.C. § 2604

chemical or that the chemical is likely to be toxic.[2] The problem with this "selective interdiction" program is that it places the burden on EPA to justify a testing requirement. Given the toxic substances program's perennial lack of resources, this requirement has effectively driven TSCA's testing function underground as EPA and manufacturers negotiate testing agreements outside of the public rulemaking process envisioned by Section 4 of the statute. More important, only a very few chemicals to which the public and the environment are routinely exposed (sometimes at high levels) have been the object of TSCA's testing requirements. Consequently, thousands of "grandfathered" chemicals have not undergone the full range of testing necessary to determine whether they are safe for human beings and the environment.

TSCA's greatest disappointment, though, is EPA's inability to take effective action under section 6 to ban, label, or otherwise limit exposure to existing toxic substances. Section 6 provides that when EPA finds that the manufacture, processing, distribution, use or disposal of a chemical substance presents an "unreasonable risk of injury to health or the environment," it must issue a rule applying "one or more" of eight requirements "to the extent necessary to protect adequately against such risk, using the least burdensome requirements."[3] When EPA, in an early test of its rulemaking powers under section 6, promulgated a rule providing for a gradual phase-out of the manufacture, processing and distribution of asbestos for most domestic uses, the Fifth Circuit Court of Appeals set the rule aside in an opinion that made it abundantly clear that EPA would be hard-pressed to take effective action to protect the public health and the environment under section 6 in the future.

Based on the expertise of its own scientists and an EPA-appointed panel of experts that examined more than one hundred toxicological studies, the agency had concluded that "asbestos is a highly potent carcinogen" and that "severe health effects occur after even short-term, high-level or longer-term, low-level exposures to asbestos."[4] Relying upon numerous exposure studies the agency concluded that "[r]elease of asbestos fibers from many products during life cycle activities can be substantial" and that "[p]eople are frequently unknowingly exposed to asbestos and are rarely in a position to protect themselves."[5] In electing to ban most uses of asbestos, EPA recognized that it was adopting a very burdensome requirement from the perspective of the regulated industry, but it also concluded that this was the only alternative that would protect adequately against the risks posed by human exposure to asbestos. To ease the burden, the rule provided a vehicle through which persons interested in the continued manufacture and use of particular asbestos-containing products could obtain exemptions from the ban.[6]

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[2] 15 U.S.C. § 2603.

[3] 15 U.S.C. § 2605(a).

[4] 54 Fed. Reg. 29,460 (1989).

[5] Id.

[6] Id.

The Fifth Circuit Court of Appeals, in *Corrosion Proof Fittings v. EPA*[7], remanded the rule to EPA in part because of flaws that it found in "the manner in which the EPA conducted some of its analysis."[8] The court held that before EPA may ban a chemical under TSCA it must first analyze the costs and benefits of all less burdensome alternatives:

> Upon an initial showing of product danger, the proper course for the EPA to follow is to consider each regulatory option, beginning with the least burdensome, and the costs and benefits of regulation under each option. The EPA cannot simply skip several rungs, as it did in this case, for in doing so, it may skip a less-burdensome alternative mandated by TSCA.[9]

Later in the opinion, the court made it clear that this analysis was to include an assessment of the risks of possible substitute products and a comparison of those risks to the risks posed by existing asbestos-laden products.[10]

The statute, as interpreted by the court, sends EPA on a potentially endless analytical crusade in search of the holy grail of *the* least burdensome alternative that still protects adequately against unreasonable risk. The agency can, of course, avoid the analytical nightmare by adopting options that are sufficiently inoffensive to the regulated industry to avoid legal challenge or by giving up the quest altogether. The agency has adopted the latter option. EPA has not initiated a single action under section 6 of TSCA since the *Corrosion Proof Fittings* case was decided, and it is not likely to use section 6 to impose requirements that regulatees oppose until it is amended.

One reason for the court's willingness to substitute its judgment for that of the agency was the odd standard of review that TSCA provides for rulemaking. Although the standard of review in the Administrative Procedure Act (APA) for informal rulemaking is the familiar "arbitrary and capricious" test under which the courts are supposed to defer to the agencies' exercise of expert judgment, section 19 of TSCA provides that the reviewing court shall set aside a rule promulgated under that statute if it is not supported by "substantial evidence in the rulemaking record."[11] This test, which the APA reserves for formal adjudications and formal rulemakings, has been construed by some courts to provide for more stringent judicial review than the arbitrary and capricious test. The court in *Corrosion Proof Fittings* made explicit reference to this point in overturning EPA's asbestos rule.[12]

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7 947 F.2d 1201 (5th Cir. 1991).

8 947 F.2d at 1216.

9 947 F.2d at 1217.

10 947 F.2d at 1221.

11 15 U.S.C. § 2618.

12 947 F.2d at 1213.

One provision in the original statute that is clearly *not* broken is section 18, the statute's preemption clause.[13] That section provides that, with certain exceptions, the courts are not to interpret the statute to "affect the authority of any State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture."[14] The exceptions are for state testing requirements for a chemical after EPA has promulgated a testing rule for the same chemical and state regulations other than outright bans that differ from rules promulgated under sections 5 and 6. Under this relatively straightforward preemption provision, the states and the federal government have effectively stayed out of each other's way for thirty-five years with very little, if any, controversy.

S. 1009 is an attempt to fix some of the problems that have plagued TSCA implementation for the past three decades. As such, the bill recognizes the need for a more systematic approach to testing and evaluating existing chemicals, and it appears to provide a comprehensive mechanism for determining whether additional testing should be required for chemicals to which EPA assigns a "high priority" status. But the numerous and prescriptive requirements that the Bill would impose on EPA before it gets down to actually regulating chemicals ensure that it will be years, or even decades, before the agency begins to see any real progress.

The Bill does nothing to change the threshold, which, according to the court in *Corrosion Proof Fittings*, requires EPA to conduct a detailed analysis of the costs and benefits of all of the regulatory alternatives. It does eliminate the "least burdensome" limitation on EPA's choice of actions to take with respect to a chemical that crosses the "unreasonable risk" safety threshold. But, given the court's interpretation of the "unreasonable risk" threshold, the elimination of that limitation will do little to ease the burden that the statute puts on the agency to justify regulatory action, especially when the environmentally preferable action is to ban or phase out the relevant chemical.

Finally, S. 1009 would replace the current preemption provision with a new federal preemption regime under which existing state regulations would be preempted in some cases by the mere fact that EPA considered the relevant chemical to have a high priority for additional testing. Worse, the bill contains a provision that will make it extremely difficult for local juries to hold manufacturers, processors, and distributors liable for damages caused by their chemicals if EPA has previously determined that the chemical meets its test for safety.

I elaborate on each of these observations in more detail below.

Grandfathered Chemicals.

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[13] 15 U.S.C. § 2617.

[14] 15 U.S.C. § 2617(a).

S. 1009 recognizes that thousands of chemicals will never receive adequate toxicity testing if EPA must meet the burden of demonstrating the need for testing in advance. The best way to ensure that new and existing chemicals get tested is to put the burden on the manufacturer to test prior to putting the chemical on the market and to require manufacturers of existing chemicals to test their products by a statutorily predetermined deadline.

The Bill does place the burden on manufacturers to test "high priority" chemicals for which EPA, by rule or order, requires additional testing. But it accomplishes this improvement through a convoluted process that requires the agency: to develop a "chemical assessment framework" for collecting and analyzing existing information on chemicals; to promulgate criteria for evaluating the quality of individual studies; to identify those studies that do and do not meet the criteria; to explain how the agency used information that does not meet the criteria and indicate the scientific limitations in that information; to develop a "structured evaluative framework" for deciding what action to take with respect to chemicals; to come up with a risk-based screening process (within one year of the date of enactment) for identifying "high priority" and "low priority" "active" chemicals; to prioritize existing chemicals under this screening process (making "every effort" to complete the prioritization of all "active" substances in "a timely manner"); to determine an order for performing safety assessments on all high priority chemicals; and to publish and maintain a list of high priority and low priority chemicals. Except for the one-year deadline for coming up with the screening process, the statute does not impose any definite deadlines for accomplishing these tasks. Instead, the agency is to "make every effort" to complete the prioritization of all active chemicals "in a timely manner."

Much of this work will require the agency to engage in notice-and-comment rulemaking, a process that has become laden with resource-draining and time-consuming analytical and procedural hurdles. For example, in grouping chemicals into the "high priority" and "low priority" categories, the Bill requires the agency to take public comment on an initial list of chemicals and proposed prioritization outcomes before publishing the final prioritization list. The Bill even requires EPA to go through the notice-and-comment process in issuing generally applicable guidance documents to aid manufacturers and distributors in implementing the Bill's rather complex requirements.

Mercifully, the Bill declares that the prioritization process does not constitute final agency action and is not itself subject to judicial review. But this will not prevent regulatees from challenging the prioritization in connection with an testing rule or other regulatory requirement long after EPA has completed the prioritization exercise. For example, a company might claim that a rule requiring it to test a chemical it manufactures should be set aside because EPA's characterization of the chemical as "high priority" was not supported by substantial evidence.

Only after the initial prioritization has been accomplished does S. 1009 require EPA to determine whether additional testing data are needed to perform safety assessments. In making that determination, the Bill requires the agency to publish a rule, a consent

decree, or an order identifying the relevant chemical, identifying the entity required to undertake the testing, specifying procedures for developing the data, and setting a time limit (not to be of an "unreasonable duration") for the completion of the required studies. The rule must be accompanied by a statement identifying the need that the requirement is intended to meet, explaining why existing data are inadequate, and encouraging to the extent possible non-animal testing in complying with the rule. If the agency decides to proceed by order, it must show good cause for not undertaking the considerably lengthier rulemaking process. Surprisingly, the Bill does not address the consequences of a company's failure to complete the studies within the specified time limit. Presumably, the agency will simply give the testing entity more time to complete the required studies.

The requirements for the chemical assessment framework are also quite burdensome. For example, S. 1009 would require EPA to determine "for both cancer and non-cancer endpoints, whether available data support or do not support the identification of threshold doses . . . below which no adverse effects can be expected to occur." This appears to be an attempt to require EPA to go through the exercise of explaining why the uncertainties inherent in carcinogen risk assessment preclude the determination of a definitive no adverse effects level for each chemical that EPA evaluates. Although the day may come when scientists can make more definitive statements about the effects of low-dose exposures to carcinogens, it seems unwise to require EPA to determine whether that day has arrived in the context of each chemical that it evaluates.

S. 1009 requires EPA to conduct a safety assessment for every high priority substance, to make a safety determination based on the safety assessment, and to establish appropriate risk management requirements for those high priority substances that do not meet the safety test. The agency must develop an "appropriate science-based methodology" for conducting safety assessments that meets several statutory specifications.

EPA is required to establish a schedule for completion of safety assessments and procedural rules for the safety assessment determination in accordance with criteria specified in the Bill. The schedule must specify deadlines for the completion of each assessment and determination. The Bill does not, however, place any outside limit on the length of time that EPA gives itself to complete the safety assessments; nor does it specify the consequences of failing to adhere to the deadlines.

In conducting the safety assessments, EPA is required to "use the best available science." After going to great lengths in section 4(c) to make it clear that EPA may employ a flexible "weight of the evidence" approach in evaluating the quality of the available information for purposes of the required risk-based screening process, when it comes to the critical evaluation of available scientific information for the purpose of deciding what regulatory action to take with respect to individual chemicals, the Bill limits the agency to the "best available" scientific evidence. The term "best available science" is defined in section 3(2) to mean science that: maximizes the quality, objectivity, and integrity of information; "uses peer-reviewed and publically available" data; and "clearly documents and communicates risks and uncertainties in the scientific basis for decisions." While these are all highly desirable characteristics of scientific information, it is probably

unwise to make critical regulatory determinations depend on the use of the "best available science," so defined. For example, an attorney for a chemical manufacturer might well challenge an EPA determination with respect to its chemical on the ground that the agency relied on one or more studies that were not published in a peer-reviewed journal.[15] This is the sort of inflexible statutory mandate that makes attorneys for regulatees lick their lips in anticipation of future judicial challenges.

Finally, the agency must determine whether the chemical meets the new safety standard. Curiously, the Bill requires EPA to consider the "weight of the evidence of risk" posed by the chemical, but it also requires EPA to use the "best available science" in making the safety determination. Under the "weight of the evidence" approach, decisionmakers consider all relevant studies and give them greater or lesser weight in the decision, depending on the quality of the studies. Some of the studies may not represent the best science that is available, but the agency considers them for what relevant information they do contain. If this Bill is enacted, the courts will have to clarify this apparent inconsistency.

For chemicals that do not meet the safety standard, the agency must promulgate a rule establishing the "necessary restrictions," choosing from among a list that fairly closely tracks the list of regulatory alternatives in the current statute. In accomplishing this task, the agency must "consider and publish a statement" on: the availability of technically feasible alternatives; the comparative risks posed by the alternatives; the economic and social costs and benefits of the proposed regulatory actions and alternative approaches; and the economic and social benefits of the chemical, alternatives to the chemical, and restrictions on the chemical or alternatives. All of the analytical operations that the statute requires in making the safety determination and risk management prescriptions are subject to judicial review under the statute's "substantial evidence" test.

One fundamental, but perhaps unavoidable problem with the Bill is that imposes a large number of very burdensome new obligations on an agency that is currently struggling to keep up with its existing statutory duties. I recognize that this committee is not responsible for EPA's appropriations, but it should be sensitive to the realities of the appropriations process in these days of budget cuts and sequestrations when it imposes highly prescriptive obligations on the agency to set up new programs and procedures. In deciding whether to force the agency through more procedural and analytical hoops, the committee should bear in mind the limited resources that are likely to be available to the agency, at least in the near term.

Another fundamental problem with the "chemical assessment framework" that the Bill envisions is the lack of judicially enforceable deadlines. The only definitive deadline in the provisions of the Bill prescribing the chemical assessment framework is the requirement that EPA promulgate a risk-based screening process within one year of the

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[15] Since much of the information that EPA receives from industry and other sources to establish the safety of their chemicals is not published in peer-reviewed journals, judicial acceptance of this position could cripple the agency's efforts.

statute's enactment. Otherwise, the Bill requires the agency to act "in a timely manner" and to avoid establishing time limits for completion of testing requirements that are of "unreasonable duration." The Bill does not define either term, both of which are, without further statutory guidance, highly discretionary in nature. Nor does the Bill address the consequences, if any, of failure to act in a timely manner or to complete studies within time limits of reasonable duration. In the absence of statutory deadlines or adverse consequences to give the industry an incentive to move expeditiously and to press EPA to complete its tasks in a timely fashion, the agency will direct its very limited resources to those programs for which it faces deadlines or strong pressure to act expeditiously.

When faced with the very similar problem of pesticide tolerances that had not been evaluated under modern toxicological protocols, Congress in the Food Quality Protection Act of 1996 required EPA to divide all existing tolerances into three groups, and it established specific deadlines for accomplishing the required re-evaluations.[16] The deadlines are backed up by the threat of "action forcing" citizen suits against the agency for failing to meet them. The Committee should consider putting into place a similar deadline regime with respect to existing chemicals that have not been sufficiently tested under the failed TSCA testing program. And the consequences of failing to adhere to the deadlines should be sufficiently severe to induce EPA and regulatees to do their best to adhere to the deadlines.

Overly Risky Safety Test.

S. 1009 requires EPA to determine whether a high hazard chemical meets the Bill's safety standard. Only if the chemical fails to meet the safety standard may the agency require the manufacturer to take action to protect public health and the environment. Thus, whether the Bill represents an improvement over the current law depends in large part on the content of the safety standard. Unfortunately, it seems reasonably clear that the Bill's safety standard represents no improvement at all over the standard in the current statute for taking regulatory action.

The term "safety standard" is defined in section 3(16) as "a standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance." This is virtually indistinguishable from the "unreasonable risk of injury to health or the environment" standard that the current statute employs. The "unreasonable risk" standard has been interpreted by many courts, including the court in *Corrosion Proof Fittings*, to require the agency 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 Bill does delete the requirement that EPA select the "least burdensome" regulatory requirement in making its risk management determination, and this should make it easier

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[16] Food Quality Protection Act, Pub. L. No. 104-170, sec. 405, § 408(q).

for the agency to promulgate protective regulations. But that requirement is not the primary reason that EPA has been unable to regulate toxic substances under section 6. The most debilitating aspect of section 6, as interpreted by the court in *Corrosion Proof Fittings*, is the requirement that EPA engage in an extensive analysis of the costs and benefits of the regulatory alternative that the agency selects as well as all of the other alternative regulatory approaches indentified in the statute. The Bill clearly requires EPA to engage in the very same debilitating analysis of the costs and benefits of a set of alternatives that closely resembles the alternatives identified in the current law. Not surprisingly, EPA has been extremely reluctant to engage in this never ending exercise in the wake of *Corrosion Proof Fittings*, and it will no doubt be equally reluctant to engage in such an exercise under the regulatory regime established in the Bill.

Beyond the analytical difficulties of applying the risk-benefit standard in the real world, the standard itself is insufficiently protective of human health and the environment. Even if EPA had infinite resources to devote to the analytical exercise, the risk-benefit test is inherently biased against protective regulatory action. Although this is not the place for an extended discussion of the infirmities of risk-benefit analysis, suffice it to say that the benefits of a chemical that is already in use are typically obvious and easily exaggerated, while the risks that the chemical poses to health and the environment are often clouded by uncertainty and easily belittled or ignored (especially in the case of environmental risks).[17]

History teaches that sometimes a ban or phase-out is by far the most effective way to reduce the risks that toxic chemicals pose to human health and the environment. The phase-down of lead in gasoline and the phase-out of the pesticide mirex are two examples of situations in which society benefited greatly from forceful action that, in retrospect, had very few, if any, negative effects on the economy.[18]

Reacting to EPA's failed pesticide tolerance setting program in 1996, Congress, in the Food Quality Protection Act (FQPA) adopted a more protective standard than the risk-benefit test for establishing pesticide tolerances. FQPA provides that EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the 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

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[17] 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 (Environmental Law Institute 2004).

[18] See Thomas O. McGarity, Radical Technology-Forcing in Environmental Regulation, 27 Loyola of L.A. L. Rev. 943 (1994).

exposures and all other exposures for which there is reliable information."[19] The test explicitly omits any reference to the benefits of the pesticide.[20]

The Bill states that that the safety determination must be "based solely on considerations of risk to human health and the environment," but the "unreasonable risk" safety standard, as interpreted by the courts, allows consideration of the chemical's benefits. It is unclear how the courts would resolve this apparent contradiction if the Bill were enacted, but Congress could eliminate the ambiguity (and the need for more litigation) by adopting the "reasonable certainty of no harm" standard employed in FQPA (and the food additive provisions of the Food, Drug and Cosmetics Act).

The Bill also fails to take into account the special sensitivities of fetuses, infants and children to chemicals in the environment. The Food Quality Protection Act provides special protections for fetuses and children. In establishing tolerances, EPA must assess risks to infants and children on the basis of "available information" concerning (1) consumption patterns among infants and children, (2) special susceptibility of infants and children, and (3) cumulative effects of exposures to infants and children.[21] More importantly, in the case of threshold effects, the agency must apply an additional "tenfold margin of safety" to take into account "potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[22] If the committee wants to enact a protective risk-based standard, it should similarly ensure that EPA gives special attention to the risks posed by toxic chemicals to fetuses, infants and children.

Unchanged Standard of Review.

S. 1009 makes no attempt to address an anomaly that lies at the heart of the current law's ineffectiveness -- the standard for judicial review. As discussed above, the curious specification of the "substantial evidence" standard for judicial review of TSCA rules has invited the courts to review those rules less deferentially than they would under the "arbitrary and capricious" test that normally applies to judicial review of informal rulemaking. If Congress amended the statute to provide for arbitrary and capricious

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[19] FQPA, (b)(2)(A)(ii), 110 Stat. 1513, 1516 (codified as amended at 21 U.S.C. § 346a(b)(2)(A)(ii) (Supp. IV 1998)) (amending FDCA) (emphasis added).

[20] See Kenneth Weinstein, Jeffrey Holmstead, William Wehrum, & Douglas Nelson, *The Food Quality Protection Act: A New Way of Looking at Pesticides*, 28 E.L.R. 10,555, 10,556 (1998) ("[t]he new standard does not generally allow for the consideration of benefits.").

[21] *See* 21 U.S.C. § 346a (b)(2)(c) (1994 & Supp. IV 1998).

[22] 21 U.S.C. § 346a(b)(2)(C)(ii)(II) (1994). The agency may use a different additional margin of safety, but "only if, on the basis of reliable data, such margin will be safe for infants and children." Id.

review, it would send a clear signal to the reviewing courts that it disapproved of the overly intrusive review demonstrated in the *Corrosion Proof Fittings* case.

Excessively Powerful Preemption.

As noted above, TSCA's preemption provisions are not broken and have in fact been functioning quite well for the past 35 years. S. 1009 would work a fundamental change in the relationship between EPA and the states in the area of toxic substances regulation for no apparent reason.

The general rule under the current law is that courts are not supposed to interpret the statute to "affect the authority of any State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture."[23] S. 1009 would change the general rule to state that "no State or political subdivision may establish or continue to enforce": (1) a data production requirement for a chemical or category of chemicals that "is reasonably likely" to produce the same data and information required by an EPA data requirement; (2) a "prohibition or restriction on the manufacture, processing, or distribution" of a chemical after EPA has completed a safety determination; or (3) a significant new use notification requirement for a chemical for which EPA has required such notification. Unlike the current law, the Bill does not even allow the state to promulgate an identical requirement so that the same requirement would be enforceable under state or federal law.

S. 1009 goes even further to prohibit states from establishing a new prohibition or restriction on a chemical that EPA has identified as a high priority substance or a low priority substance. The preemption of regulatory action against low priority substances is apparently based on the assumptions that: (1) EPA will always assess the risks posed by chemical substances accurately in the first instance; and (2) EPA will continuously update its assessments and priority lists in light of new scientific evidence. Both of these assumptions are misplaced.

As discussed above, EPA does not have sufficient resources to make accurate assessments of substances that are likely to fall within the low priority category. It will probably assign chemicals to low priority status on a generic basis based on information about classes and categories of chemicals, rather than on individual assessments of individual chemicals. And the attention that the agency devotes to these assessments will no doubt be influenced by the fact that it can always change the classification of individual chemicals if information later becomes available suggesting that they should be assigned high priority status. The same lack of resources, however, will insure that the agency is unlikely to revisit its assessments in light of changing scientific information. In sum, there is no good reason to suppose that EPA will fulfill its priority ranking

[23] 15 U.S.C. § 2617(a).

responsibilities so perfectly that the states should be precluded from conducting their own evaluations of the available scientific evidence.

The prohibition on state regulation of chemicals assigned high priority status is even more difficult to comprehend. EPA's assignment of high priority status to a chemical represents the agency's determination that the chemical has the potential for high hazard and/or high exposure. High hazard chemicals are likely to be the very chemicals that states are most likely to identify as in need of further regulation. But once EPA makes the high hazard determination, S. 1009 would preclude any state regulatory action. Given the absence of statutory deadlines, discussed above, it may take EPA years (or even decades) to get around to determining the most effective risk management approach for the chemical. In the interim, no governmental entity will have the authority to protect public health and the environment from the risks posed by the chemical. If potential victims cannot motivate EPA to take effective action against the chemical, which might subject only isolated populations in particular geographic locations to exposures high enough to warrant regulatory action, then they are simply out of luck.

S. 1009 does allow a state to petition EPA for a waiver of federal preemption, but the state must demonstrate: (1) that "compelling" state or local conditions warrant a waiver to protect health or the environment; (2) that compliance with the state or local requirement will not burden interstate commerce in the manufacture, processing, distribution, or use of the chemical; (3) that compliance with the state or local requirement will not cause a violation of any applicable federal law; and (4) that the state or local requirement is based on the best science and supported by the weight of the evidence. It seems highly unlikely that any state will be able to surmount this high threshold in situations other than clear emergencies. And should the state persuade the agency to issue the waiver, the waiver itself would still be subject to judicial review under the substantial evidence test.

Finally, S. 1009 contains a highly unusual constraint on the discretion of local judges and juries in state courts to consider and evaluate evidence that chemical substances or products containing chemical substances are unsafe, dangerous or defective. Section 15(c) provides that once EPA has completed a safety determination for a high-priority chemical, that determination is automatically admissible in any public or private litigation in state or federal court for recovery of damages or equitable relief relating to injury to health or the environment caused by the chemical. Moreover, the safety determination is "determinative of whether the substance meets the safety standard under the conditions of use addressed in the safety determination."

In my thirty-six years of teaching and research in the area of torts, I have never seen a proposal for such an intrusive interjection of federal law into the day-to-day administration of justice at the state level. Not only does the Bill change the state judiciary's procedural rules governing the admissibility of evidence, but it also takes away from state court judges and juries the ability to determine whether a chemical is abnormally dangerous or otherwise unsafe in common law litigation. I have seen no evidence whatsoever that the substantive and procedural rules promulgated by the courts

of the 50 states are causing any problems for the manufacturers, processors and distributors of chemical substances. This provision is nothing less than a gift of partial immunity to manufacturers who are fortunate enough to have their chemicals declared safe by EPA.

Although the public is invited to participate in the administrative proceedings through which EPA makes its safety determination, the potential victims are not likely to be represented, because they do not know who they are until the chemical causes them harm. Yet their rights to compensation for damages caused by the chemical will be determined in that proceeding, and not in the state courts where their lawyers would otherwise have an opportunity, through expert testimony, to prove (often using the company's own documents) that the chemical is unreasonably dangerous or otherwise unsafe.

Moreover, the provision appears to work in both directions by making EPA's determination that a chemical is unsafe determinative in state public and private litigation. If the Bill is enacted, plaintiffs' attorneys will no doubt be on the lookout for chemicals that EPA has found not to meet the safety standard. If a plaintiffs' attorney can prove that such a chemical has caused injury to a plaintiff, the attorney may well be able to persuade a judge to instruct the jury to find the chemical to be unreasonably dangerous or otherwise unsafe.

Either way, the provision makes very little sense from the perspective of state/federal comity or from the perspective of respect for the integrity of state civil and criminal justice systems.

Conclusions.

The Toxic Substances Control Act is badly in need of repair, but S. 1009 is not the way to fix that broken statute. The committee should reject this Bill or amend it in ways that make it more protective of human beings and the environment and less protective of the chemical industry. The Bill could be improved by:

- Providing clear deadlines for the tasks that it assigns to EPA in establishing assessment frameworks, collecting and analyzing existing information, prioritizing chemicals, and deciding whether to require additional testing. It should also provide an outside limit on the deadlines for testing chemicals and specify the consequences of a company's failure to complete the testing by the prescribed deadline.

- Clarifying the conflict between "weight of the evidence" and "best available science." The weight of the evidence approach allows the agency to consider all available evidence, giving great weight to the evidence that meets all of the relevant scientific norms and less weight to evidence that may be deficient in one or more regards. Since few scientific studies are flawless, the weight of the evidence approach, which allows the agency to act on the basis of less-than-

perfect scientific evidence is best suited to a precautionary statute like the Toxic Substances Control Act.

• Replacing the "unreasonable risk" test for safety with a more protective test like the "reasonable certainty of no harm" test used in the Food Quality Protection Act and the Food, Drug and Cosmetics Act.

• Changing the standard of judicial review from "substantial evidence" to the "arbitrary and capricious" test that the Administrative Procedure Act and most environmental statutes employ.

• Leaving the express preemption section of the current statute in place. That approach has worked very well in the past. There is no reason to believe that a more restrictive approach to state regulation and state common law would benefit society, and there are many reasons to believe that the extremely restrictive approach adopted by S. 1009 will leave innocent victims unprotected by state law and without recourse in the courts.