TESTIMONY OF

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on

S. 1009: The Chemical Safety Improvement Act

Energy & Commerce Committee’s
Subcommittee on Environment and the Economy
U.S. House of Representatives

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One page Summary of Wagner Testimony

My testimony will focus on the various good science provisions in S.1009 and how they are likely to impact EPA’s use of science. I will make the following points in my remarks:

1. The Senate bill contains dozens of unprecedented requirements that limit the scientific evidence EPA can consider when developing regulations and how this evidence can be used. Yet despite the detailed level of scientific prescription in the Bill, it is not clear what problem the Bill is trying to fix. While there have been many failures associated with the Toxic Substances Control Act (TSCA) over the years, they are generally not connected to EPA’s failure to make use of the best available science when promulgating regulations.

2. By contrast, there is broad consensus that the primary problem crippling EPA’s regulatory efforts under TSCA is the dearth of information about chemicals. The Senate Bill not only appears oblivious to the scarcity of toxicity and related information on most chemicals, but may aggravate the problem by preventing EPA from considering research that has the potential to inform EPA’s assessments in scientifically acceptable ways.

3. The various good science requirements and procedures are also loaded with ambiguities, creating numerous “attachment points” that present opportunities for a steady stream of legal challenges to EPA’s rules. If history is any guide, entities with the most at stake (e.g., manufacturers of the least effective and least safe chemicals) will use these attachment points to delay EPA’s implementation or force EPA into negotiations before, during, or after a rule is published. Senate Bill 1009 also lacks enforceable legislative deadlines to counteract this inevitable delay for most provisions. The Bill also makes fails to provide procedural protections that will prevent or at least illuminate these compromises that fall outside the formal processes and out of the public eye.

4. Protracted delays in implementation, with corresponding, potentially high costs to protection of the public health, seem inevitable from the cumulative problems with the good science provisions in S. 1009.

5. Chemical regulation will be effective only if it provides incentives for the manufacture of safer and more effective chemicals. The Senate Bill does not provide these incentives.
My name is Wendy Wagner. I hold the Joe A. Worsham Centennial Professorship at the University of Texas School of Law, where I teach courses in Environmental Law, Law and Science, and Torts. In addition to my academic responsibilities, over the last ten years I have served on several National Academies of Science committees, the Bipartisan Policy Center Committee on Regulatory Science, and as a consultant to the Administrative Conference of the U.S. (ACUS) on a study of the agencies’ use of science. I am also a founding member scholar of the Center for Progressive Reform. I have published dozens of articles on regulatory science and two books, *Bending Science: How Special Interests Corrupt Public Health Research* (with Tom McGarity 2008) and *Rescuing Science from Politics* (with Rena Steinzor 2006).

I am pleased to testify on Senate Bill 1009, entitled the Chemical Safety Improvement Act (CSIA). I have been asked to analyze how the Bill might affect the EPA’s ability to find and use scientific information. My views are wholly my own and are not necessarily those of the University of Texas or other organizations with which I am affiliated.

As I discuss in more detail below, while I applaud the Senators’ goal of attempting to ensure that the science that informs the regulation of chemicals is rigorous, I have a number of questions and concerns about the approach taken in the bill.

**I. The Good Science Requirements in S.1009 impose unnecessary restrictions on the types of Scientific Evidence that EPA can Consider and How it Analyzes that Evidence**

The Chemical Safety Improvement Act provides a number of detailed requirements that govern EPA’s use of science in chemical regulation. These constraints
impact the type of information EPA can consider (the inputs) and the processes by which EPA synthesizes the evidence (the processes).

On the input side, the Chemical Safety Improvement Act limits the evidence EPA can consider by demanding that EPA may use only the “best available science” in conducting chemical safety assessments and determinations. This “best available science” provision thus operates as a gateway that filters the information available to EPA to regulate chemicals. Moreover, in CSIA, “best available science” is defined as science that “(A) maximizes the quality, objectivity, and integrity of information, including statistical information; (B) uses peer-reviewed and publically available data; and (C) clearly documents and communicates risks and uncertainties in the scientific basis for decisions.” Section 3(2). Each prong of this three part test must be met. The test is thus much more restrictive than best available science requirements contained in the Endangered Species Act, the Safe Drinking Water Act, and the Information Quality Act (and the Office of Management Budget’s IQA guidelines).

CSIA also sets forth a series of new, detailed analytical requirements that specify how EPA should synthesize the qualifying evidence. These procedures serve as prerequisites that EPA must fulfill before it can conduct safety assessments or regulate chemicals. An incomplete list of these new procedural requirements include the: 1) development of a “structured evaluative framework” before initiating its chemical oversight work; 2) publication of criteria for evaluating all data and information on which it relies to make any decision; 3) establishing a risk-based screening process for designating chemicals high or low priority for review; 4) development of a strategic plan to promote the development and implementation of alternative test methods and to
promote non-animal tests; and 5) promulgation of procedural rules governing safety assessments EPA will conduct for each “high priority” chemical.

Even EPA’s pursuit of additional research must pass through additional hoops. If EPA determines additional data is required, it must first establish there is a need for the data and provide an opportunity for interested persons to submit the additional information. By contrast, the analytical and evidentiary demands placed on the manufacturers who sell the suspect chemicals and have superior information about their risks and benefits are negligible in the Bill, and these requirements are conditioned by close attention to the costs of testing.

By my count, at least forty pages of Senate Bill 1009 are dedicated to developing these legislative constraints on the types of evidence EPA may consider (the inputs) and how it must use this evidence (the process). This level of detailed legislative prescription is unprecedented to my knowledge. The cumulative effect of these requirements seems likely to cause significant delays in implementation and a string of unintended consequences that could product regulatory results quite different from those sketched out in the Bill’s opening goals.

II. It is not Clear what Problem the Elaborate Good Science Requirements are Intended to Fix; at the same time, these provisions threaten to make other, well-known problems associated with TSCA considerably worse

Given this unprecedented level of scientific legislative prescription, one would expect that there would be a large literature documenting problems with EPA’s scientific analyses in implementing the Toxic Substances Control Act (TSCA).\(^1\) But in my

\(^1\) There is a documented problem with the quality of private research that informs regulation, at least in cases when a sponsor contractually controls the research. Since this
research, I could not identify the underlying problems with EPA’s implementation of TSCA that justify this ambitious set of new requirements.\(^2\)

   The literature does reveal a central and noncontroversial reason for the failure of TSCA – the lack of basic toxicity information on chemicals and the tendency of this regulatory program to perversely create incentives that perpetuate this ignorance.\(^3\)

Virtually every prominent expert panel convened to consider the topic has expressed alarm at the dearth of basic toxicity information on chemicals in commerce.\(^4\) For

problem is largely ignored in the good science of provisions of Senate Bill 1009, as discussed in Part IV.A., however, it does not appear to be among the problems the Bill attempts to fix. This particular problem is also one that occurs very early in the production of research, not in EPA’s own analysis of the available information; the latter is the primary focus of S. 1009.


   Perhaps the most glaring omission is the absence of criteria and information for gauging the benefits to be achieved by implementing the bulletin (that is, a benefit-cost analysis). Although OMB has implied that the agencies currently do not meet the standards that it seeks to establish, it has not established a baseline of each agency’s risk assessment proficiency, including the extent to which generally satisfactory and high-quality risk assessments are produced or how some agencies fall short of the specified standards. Specifically, OMB has not established which agencies do not appear to know what good practices are and which agencies do not have the ability, resources, or incentives to meet the standards. Similarly, OMB has not identified the costs that could be encountered in implementing the bulletin. Thus, OMB has not determined the impact of the bulletin on federal agencies.


\(^4\) See, e.g., National Research Council, Grand Challenges in Environmental Science (2000); National Research Council, Building a Foundation for Sound Environmental Decisions (1997); National Research Council, Review of EPA’s Environmental Monitoring and Assessment Program: Overall Evaluation (1995); National Research Council, Research to Protect, Restore and Manage...
example, as of 1984 no toxicity testing existed for more than eighty percent of all toxic substances used in commerce, and by 1998, at least one-third of the toxic chemicals produced in the highest volumes still failed to satisfy minimal testing standards recommended by an international expert commission.\(^5\) See bar chart.

### Toxicity Testing Information Available on Seven Categories of Chemicals

<table>
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<tr>
<th>Category</th>
<th>Size of Category</th>
<th>Estimated Mean Percent in the Select Universe</th>
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<tr>
<td>Pesticide and Inert Ingredients of Pesticide Formulations</td>
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<tr>
<td>Cosmetic Ingredients</td>
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<tr>
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<td>Food Additives</td>
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</tr>
<tr>
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<td><img src="chart5.png" alt="Chart" /></td>
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<tr>
<td>Chemicals in Commerce: Less than 1 Million Pounds/Year</td>
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</tr>
<tr>
<td>Chemicals in Commerce: Production Unknown or Inaccessible</td>
<td>21,752</td>
<td><img src="chart7.png" alt="Chart" /></td>
</tr>
</tbody>
</table>

NRC, Toxicity Testing (1984), at page 118 fig.2.

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Senate Bill 1009 seems curiously oblivious to this well-known failure of TSCA. Instead, its elaborate new provisions are positioned to aggravate the pervasive ignorance surrounding chemicals. The best available science requirement in CSIA, by definition, limits the evidence that EPA can consider in conducting safety assessments and safety determinations, leaving it with less information to assess chemicals than is currently the case under TSCA. Such information filtering might not be problematic in data-rich areas, like the setting of standards for criteria air pollutants, but in chemical regulation, the best available science requirements may filter out so much research that EPA is left empty-handed. For example, the limited test data that EPA has acquired over the years under its test rule authority may not meet this “best available science” requirement since that research is generally not published, does not appear to be peer reviewed, and the data may not be publicly available. Most substantial risk reports required under Section 8(e) of TSCA would also seem likely to fail the “best available science” requirements, since this manufacturer-supplied information does not appear to be peer reviewed and again, in some cases, the raw data is not publicly available.\(^6\) It seems paradoxical that Congress would require manufacturers to alert EPA to substantial risks from their chemicals, many of which are badly under-tested, but then bar (or at least significantly impede) EPA from considering this same, seemingly relevant information in conducting its safety assessment.

In fact, given EPA’s dependence on private research to inform its oversight of chemical safety, this best available science hurdle could even be used perversely by manufacturers to obstruct the agency from using their own in-house research and data

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\(^6\) These individual reports are posted at [http://www.epa.gov/opptintr/tsca8e/index.html](http://www.epa.gov/opptintr/tsca8e/index.html).
when that research suggests worrisome risks. Manufacturers who discover that their chemicals are unduly toxic, for example, could attempt to slow or even exclude these damaging studies by ensuring the research is not peer reviewed or publicly available. In such cases, it would be up to the EPA, using its scarce resources, to subject this research to the necessary peer review and data disclosure requirements.

CSIA also handicaps EPA’s effort to acquire new information by adding still more procedural requirements to EPA’s ability to demand new test data. In the nearly thirty years of regulatory authority, EPA has issued testing mandates for only about 200 chemicals. Most of the remaining chemicals, roughly 80,000 chemical substances, are effectively unrestricted and often unreviewed with regard to their health and environmental impacts. The primary explanation for this apparent underutilization of EPA’s test rule authority is TSCA’s requirement that EPA must first making a regulatory finding that the chemical “may present an unreasonable risk of injury to health or the environment” as a prerequisite to requiring more testing. Although CSIA does eliminate this Catch 22 in EPA’s test rule authority, it appears to replace one problem with another by demanding that EPA establish that the data is needed as a condition to requiring toxicity testing, as well as imposing other constraints on EPA’s test authority. Like the “best available science” restriction, these new prerequisites do not seem destined

8 For the total chemicals in EPA’s TSCA inventory, see http://www.epa.gov/opptintr/newchems/pubs/inventory.htm. EPA estimates that for new chemicals, only 15 percent of the premanufacture notices contain any information on health and safety testing. See, e.g., GAO, OPTIONS, at 12.
9 See TSCA, § 2604(e).
to expedite EPA’s ability to acquire more toxicity research from manufacturers and may ultimately impose more limitations on EPA’s ability to acquire new data as compared with TSCA.

III. The Good Science Provisions are Rife with Ambiguities that invite litigation and are likely to significantly delay implementation and lead to invisible compromises between EPA and high stakes groups

The “best available science” and related analytical prerequisites are not simply benign, motherhood and apple pie provisions; instead they present real risks of impeding agency regulation, with the attendant loss of health protection that follows from this obstruction.

A. The Bill Creates Dozens of New Attachment Points for Litigation brought by opponents of regulation

Because the bill imposes dozens of new requirements on EPA, each of which is afflicted with its own set of ambiguities, there will be no shortage of disagreement about what these new prerequisites and requirements mean. As is the case with most regulatory programs, these disagreements will generally be resolved through litigation. Courts will referee the acceptable meaning of these ambiguous terms and procedures, and the litigation will be brought, or at least threatened, by the high stakes players who have the most to lose from added regulatory oversight. Since the standard for judicial review is the potentially higher “substantial evidence” standard, moreover, EPA may face a less deferential judicial panel in the courts’ review of its interpretation as compared to the “arbitrary and capricious” standard of the Administrative Procedure Act (APA).
The “best available science” requirement is illustrative of the nature of these attachment points that afflict the good science provisions in Senate Bill 1009. As mentioned, the best available science requirement imposes three mandatory tests for the evidence EPA is able to consider in assessing and regulating chemicals. Since EPA will presumably seek to interpret these exclusionary provisions generously, its resulting interpretations are likely to spark significant litigation. It is important to note, too, that since the “best available science” provision serves as the gateway for all evidence that may be considered by EPA under Section 6 (and perhaps also under Section 4, depending on how you read the requirements), EPA will not be able to sidestep these ambiguities in the “best available science” definition, but instead must confront them head-on.

Senate Bill 1009 specifies, for example, that “best available science” is only science “that uses peer-reviewed and publicly available data.” Section 3(2). But how does one peer review data, as opposed to the studies that use that data; does this peer review of data require replication of the study itself? Perhaps what is meant by “peer reviewed . . . data” is that the studies reporting on the data have been peer reviewed; but in that case, the court will need to allow for an agency interpretation that deviates from the plain language of the statute. It is also not clear what this “peer review” entails. The legislation could be read to suggest that as long as one “peer” (perhaps even an expert hired by the sponsor of the study under contract) reviews the “data”, it meets the requirements of the Act, yet EPA will presumably seek to ensure that these expert reviewers are independent and not contractually controlled by the sponsor of the research. On the other hand, the peer review test – particularly when coupled with the “publicly available” requirement – could be read to imply that published research is the only
science that meets “best available science” requirements, a hurdle that will choke out much of the evidence otherwise available to EPA. Such an interpretation, for example, would eliminate most if not all test data, substantial risk reports, and a variety of other scientifically relevant information that forms the basis for EPA’s assessment of the risks of high priority chemicals.

“Best available science” in CSIA also requires that each piece of “science” must “clearly document and communicate risks and uncertainties”. But there are a series of National Academies report and a very robust academic literature cited in those reports that offer dozens of different ways to think about this requirement, without any clear convergence in what it means to clearly document and communicate risks and uncertainties. The literature does converge, however, on the reality that such an endeavor is very expensive. Like the first requirement, this second mandatory screen for “best available science” not only subjects EPA to still more potential for litigation given the range of credible interpretations, but threatens a significant, added resource burden on EPA, with no corresponding burden on the manufacturers who produce at least some of this research.

Each of the ambiguous analytical prerequisites in “best available science” creates a new “attachment point” – a credible litigation challenge that can be used strategically by vested interests to delay the program or force EPA into negotiations before, during, or after a rule is published. By and large, these and dozens of other ambiguities in the good science procedures mandated in Senate Bill 1009 are likely to be exploited by some high stakes players. And these high stakes players are likely be comprised of a subset of the chemical industry that produce the least effective and most unsafe chemicals. Whether
the end result is delay or compromise, or a combination of both, the Bill’s good science provisions are likely to undercut the ability of EPA to conduct safety assessments, require toxicity testing, and advance chemical regulation.

Despite the seemingly high likelihood of added delays from these various good science requirements, however, CSIA does little to anticipate or counteract them. Although there are numerous new requirements and findings required of EPA, only one of these requirements is backed with a legislated deadline. Otherwise, EPA is instructed only to avoid “unreasonable delay,” an instruction that will be difficult to enforce in court except in cases of protracted agency inaction. The failure of Senate Bill 1009 to keep EPA’s nose to the grindstone stands in stark contrast with other statutes, like the Endangered Species Act, that hold agencies to short, legislative timeframes in implementing the “best available evidence” provisions.

B. EPA will negotiate with high stakes players to avoid some of the delays and resource drains posed by litigation, and these compromises will be largely outside public view

Senate Bill 1009 seems to presume that imposing various legislative constraints on the types of evidence EPA can consider will be sufficient to keep EPA from overstepping in its regulatory role. Yet the literature reveals that precisely the opposite risks are likely from legislation decked with such elaborate, mandatory requirements.

Research in administrative law reveals that a great deal of the agency’s decisions can occur outside the formal notice and comment and traditional record-keeping stages of the rulemaking process. In our empirical study of EPA’s setting of technology-based standards under the toxic air provisions of the Clean Air Act, for example, there was an unexpectedly high level of communications between EPA and industry before EPA
issued the proposed rule – on average about 80 informal communications (170 total communications) -- per rule. See Bar Chart below. At least some of this interaction can be attributed to EPA’s effort to develop a proposed rule that satisfies industry in order to stave off litigation. EPA, in other words, may be compromising at a very early stage in the rulemaking process – one that falls outside the APA notice and comment process – in order to maximize the chances for the survival of its rules. In much more preliminary research on TSCA test rules, we see an even greater amount of industry-exclusive negotiations and discussions recorded in the docket prior to the notice and comment period.

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Interest Group Participation in the Section 112 MACT rules of the Clean Air Act, from Wagner, et. al. Rulemaking in the Shade at 124.

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10 See generally Wendy Wagner, Katherine Barnes, and Lisa Peters, Rulemaking in the Shade: An Empirical Study of EPA’s Air Toxic Emission Standards, 63 ADMINISTRATIVE LAW REVIEW 99 (2011); see also Wendy Wagner, Administrative Law, Filter Failure, and Information Capture, 59 DUKE L. J. 1321 (2010) (discussing the literature on these pre-NPRM negotiations in the literature more generally).
One tentative lesson that emerges from this research is that EPA (or other agencies for that matter) will negotiate proposed rules with the most litigious groups before publishing a proposed rule. Thus while Congress attempts to add more and more embellishments to the “front door”, the back door remains wide open, and elaborate analytical requirements offer little more than window dressing that could actually serve to further obscure this rulemaking reality. As Prof. Elliott observes based on his experience as General Counsel of EPA: “[n]otice-and-comment rulemaking is to public participation as Japanese Kabuki theatre is to human passions – a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues.”

Despite the likelihood of these pre-rule negotiations and compromises under the shadow of the dozens of new requirements and procedural hoops imposed by Senate Bill 1009, the bill does nothing to restrict these inevitable interactions, nor does it require EPA to document them. EPA thus appears free to engage in unlimited meetings, telephone calls, and even written correspondence with the highest stakes group to “work out the details” before a proposed rule or interpretation is published – all without logging this information into the record. Senate Bill 1009 also does not require EPA to record its substantial involvement with other federal agencies, including those that will be adversely affected by its rules, or by the influential Office of Regulatory and Information Affairs.

As a result, the “best available science” provisions and other elaborate good science requirements of Bill 1009 are likely to translate, in practice, into a bonanza for

the manufacturers (and their attorneys and trade associations) that make the most unsafe, least effective chemicals. These groups have the highest stakes in the outcome and can be expected to invest the most resources towards threatening litigation and launching other types of time-delaying tactics.

IV. The Bill Does Not Produce Incentives for Better Private Research or The Development of Safer Chemicals; It Should!

The dozens of pages of scientific prescription not only run the risk of unintended adverse consequences, but they ignore the more promising paths for using regulation to encourage manufacturers to do better. There are undoubtedly many ways that Congress could create positive incentives for private research and chemical innovation. I list only a few for purposes of illustration.

A. Creating Positive Incentives for Independent Private Research on Chemical Risks

The best available science provisions in Senate Bill 1009 are directed at the EPA, yet to extent there are documented problems with the quality of the science used by EPA in TSCA, these problems occur much earlier in the scientific pipeline – in the course of producing the research itself. There are scores of books and articles that document problems with sponsored research,12 yet most of this sponsored research is produced by

manufacturers and trade associations, sometimes voluntarily and sometimes not. The literature reveals that some sponsors will contractually control this research by inserting nondisclosure clauses and other mechanisms to control how a study is designed, how the data is collected and analyzed, and how the research is reported. Meta analyses of studies in biomedical medicine reveal statistically significant evidence of a “funding effect”, in which research funded by a sponsor produces research outcomes that are much more favorable to that sponsor than research produced independently.

Senate Bill 1009 ignores these well-documented problems with the integrity of private research. While the Bill does require EPA to demand information from submitters about the source of funding for studies (note that the bill is silent on penalties if the submitter refuses to provide this information – the requirements apply only to EPA), information on funding alone tells us very little about the nature of sponsor influence. Under the Bill’s approach, the responsible manufacturers are lumped in with manufacturers who strategically manipulate research – the only question asked about private research is who “funded” it, not the much more telling question of whether the sponsor reserved the contractual right to influence the study or researcher.

13 Only some of this research is governed by relatively stringent protocols developed by EPA that limit sponsor discretion; other scientific information is informative, but not governed by a predetermined protocol or methods.
Biomedical journals require that the researchers disclose the nature of sponsor control.\textsuperscript{16} In order to make regulatory research more consistent with scientific standards, the Bipartisan Policy center and the Administrative Conference of the U.S. both recommended that private sponsors should be required to disclose whether they reserved the contractual right to influence the research they sponsor.\textsuperscript{17}

Rather than settling for an uninformative disclosure of funding as Senate Bill 1009 requires, Congress should require that the sponsors disclose whether they reserved the right to influence the research they sponsored. Congress should also require that all underlying data that informs regulation be shared with the general public – on a public database. Such a legislative amendment would complement the existing requirements on federally funded research. (A similar proposal has also been endorsed by both ACUS and the Bipartisan Policy Center.)\textsuperscript{18} CSIA already notes the importance of publically available data in its definition of “best available science,” but the bill does not appear to provide any financial or infrastructure support for a public database.


\textsuperscript{17} See, e.g., BiPartisan Policy Center, Improving the Use of Science in Regulatory Policy 42 (Aug. 2009); ACUS Recommendation 2013-3, available at 78 Fed. Reg. 41,352, 41,357

\textsuperscript{18} See also id.
B. Providing Incentives for Manufacturers to Produce Safer, More Effective Chemicals.

TSCA and the Senate bill both fail to create meaningful incentives for manufacturers to develop more effective and safer chemicals. Instead, manufacturers need only ensure that their chemicals are better than the very worst on the market.

Rather than focus on the worst, EPA should be required to seek out the best performers and hold all other chemical products to these higher standards. Such an approach follows the forty-year old model set in the pollution control statutes—the technology-based standards—which calibrate the nation’s pollution standards to what the best industries are already accomplishing in practice. Such a comparative exercise requires much less information than is currently demanded by TSCA or CSIA to regulate a chemical. EPA would need only to examine the relative toxicity, cost, and effectiveness of chemicals—a full-blown cost-benefit analysis that quantifies every risk and benefit of thousands of chemicals on the market would no longer be required.

Legislation that directs EPA to hold chemical manufacturers to the high standards of their competitors could transform U.S. chemical policy. Such an approach should create powerful incentives for innovation and competition, currently absent in our federal programs; raise product standards that in turn catalyze higher international standards; and lead to more streamlined and expeditious regulation that will better protect the public health and environment. EPA will be liberated from the current approach that forces it to

19 This more incentives-approach to chemical regulation is sketched out in Wendy Wagner, Using Competition-Based Regulation to Bridge the Toxics Data Gap, 83 Indiana L.J. 629 (2008) and “Racing to the Top: How Regulation Can be Used to Create Incentives for Industry to Improve Environmental Quality” (forthcoming FSU Journal of Land Use and Environmental Law).
conduct exhaustive cost-benefit analyses on thousands of chemicals only to find it has authority to eliminate only the bottom one-tenth of one percent of toxic chemicals in commerce.

Thank you again for the opportunity to testify on Senate Bill 1009. I look forward to your questions.