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WENDY E. WAGNER

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Nick Abraham
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Shimkus,

Thank you for your request for more information regarding S.1009. My answers to the questions raised by the Honorable Henry A. Waxman are provided below. Please do not hesitate to let me know if you have any further questions.

- 1. Given the requirements you have identified, do you expect EPA to take action to assess or regulate any chemicals in the near future? Can you estimate how long you think the delay could be before regulatory action would be taken under this bill?**

Under S.1009, EPA's regulation of chemicals could be even more sluggish than it is under TSCA. The bill narrows the aperture for the scientific evidence the agency may consider to justify regulation (see my written and oral testimony on the "Best Available Science" provision at the Nov. 13, 2013 hearing), while at the same time establishing new hurdles for the agency in demanding additional testing from manufacturers. See #6 below. The bill also imposes an entirely new set of procedural requirements on the agency as a prerequisite to regulation. See #5 below. These cumulative impediments add to the high burden already required of the agency to regulate chemicals under TSCA. If over the last thirty-five years, EPA has managed to regulate only five existing chemicals, then one might expect still less progress under S.1009, equating to perhaps to regulatory action on only about one existing chemical every ten years.

- 2. Does the bill provide resources to EPA to meet the procedural requirements you identify?**

No. To my knowledge, there is no provision in the bill for added resources to enable EPA to implement the bill's many added requirements.

3. Would companies required to test chemicals under TSCA have a financial incentive to challenge a testing requirement?

Companies will have a financial incentive to challenge EPA's rules requiring more testing, even in cases where the companies do not expect to prevail in court. Litigation-backed comments appear to lead to the weakening of proposed rules, at least when the comments are submitted by regulated industry. *See, e.g.,* 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). Moreover, with respect to litigation, a simple, rational actor model predicts that a company will invest as much in litigating an EPA regulation as it expects to derive in profits as a result of the added delay of regulation. If litigation delays EPA's regulation by five years, for example, then a company may find it beneficial to challenge that rule if the cost of the litigation is less than the financial gains (e.g., interest from forgone testing, delay in regulatory restrictions) that it expects to recoup as a result of the delay. *See, e.g.,* Gordon C. Rausser et al., *Information Asymmetries, Uncertainties, and Cleanup Delays at Superfund Sites*, 35 J. ENVTL. ECON. & MGMT. 48, 49 (1998) (arguing that potentially responsible parties at Superfund sites may use their asymmetric information regarding their contributions to a site to delay EPA investigation and cleanup because delay brings great cost savings); Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729, 737-39 (making the case for how increased profits resulting from delay in regulation make it profitable in many cases for industry to judicially challenge regulatory requirements, regardless of the expected outcome on the merits).

Past experience also reveals that in many cases litigation against the agency is not brought by a single company but instead by trade associations on behalf of many members. To the extent this pooling of resources occurs for litigation, the company's individual financial benefits from litigation will be much lower to justify a rational investment in litigation. This financial calculation, moreover, brackets the possibility that the litigation might yield favorable precedent for the companies that could have positive spillover effects for other features of their businesses.

4. Is this type of scientific determination well suited to court review?

No -- judicial review of EPA's decisions to demand more testing or to regulate existing chemicals are not well suited to judicial review. The courts have struggled over the last three decades to identify the appropriate level of deference to afford agency scientific and technical choices, and their decisions have varied widely in the level of deference they afford to the agencies. *See, e.g.,* Howard A. Latin, *The Feasibility of Occupational Health Standards: An Essay on Legal Decisionmaking Under Uncertainty*, 78 NW. U. L. REV. 583, 583 (1983) (arguing that courts lack adequate conceptual framework for dealing with factual uncertainties); Richard J. Pierce, Jr., *Two Problems in Administrative Law: Political Polarity on the District of*

Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 DUKE L.J. 300, 311 (arguing that courts often require “that agencies ‘find’ unfindable facts and support those findings with unattainable evidence”). In fact, one of the most criticized cases from within this larger set is the Fifth Circuit’s review of EPA’s effort to regulate asbestos under TSCA. *See, e.g.*, Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525, 548 (1997) (“In the six years that have passed since the Corrosion Proof Fittings opinion, the EPA has not initiated a single action under section 6 of TSCA....”). The courts’ approach to the judicial review of science has also led to various perverse incentives for agencies to be even less transparent in their rulemakings. *See, e.g.*, Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUMBIA L. REV. 1613 (1995). Since the standard for judicial review under S. 1009 is the 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).

5. What other scientific determinations would the bill make judicially reviewable, and do you have concerns about the ability of courts to effectively review those decisions?

S. 1009 imposes a number of science-intensive methodological and procedural requirements on EPA, including: 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.

Some of these steps appear to be judicially reviewable – for example, the promulgation of procedural rules governing safety assessments – and other steps might be insulated from judicial review, particularly in cases when the agency does not promulgate a final rule. Yet the bill is ambiguous about which steps are judicially reviewable and which are not (*see, e.g.*, S. 1009 § 6(b)(6)(B)). This ambiguity, in and of itself, is thus likely to lead to additional litigation over which regulatory products can ultimately be challenged in court. In addition and discussed in #4, the challenge that courts face in reviewing science-intensive rules is well-established in the literature.

6. Given the instruction to use the best available science, do you think it will be difficult for EPA to effectively demonstrate that additional data is needed?

Under S. 1009, EPA must establish the need for data as a condition for demanding more testing. Manufacturers could attempt to argue in opposing such a demand that EPA lacks a legal basis for requesting new data since the “best available evidence” is good enough for purposes of regulation. Hopefully such a circular and counterproductive reading of the bill will not prevail in court, but there is no guarantee in this regard.

It is also difficult to imagine how EPA will justify the need for new testing when it is not clear, absent that testing, what the new information will reveal. Regardless, the requisite showing of need threatens to impose an added evidentiary burden, and a potentially heavy one, on EPA before it can collect additional data from manufacturers. Already the Section 4 requirements of TSCA have led to a Catch 22 since EPA must establish that the chemical “may present an unreasonable risk of injury to health or the environment” as a prerequisite to requiring more testing, even for chemicals for which nothing is known. *See, e.g.,* Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1799 (1989). As a result of this burden, EPA has issued only 200 test rules over thirty years (there are roughly 80,000 existing chemicals in the inventory). By imposing possibly an even heavier evidentiary burden on the agency to acquire added testing under S. 1009, one could expect EPA to be still less successful in acquiring information upon which to base its regulatory decisions.

Respectfully,

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