March 18, 2015

The Honorable James Inhofe
Chairman
Committee on Environment & Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Barbara Boxer
Ranking Member
Committee on Environment & Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

Re: Response to Critique by Law Professors of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

In a March 16, 2015, letter addressed to you, a group of 25 law professors and other lawyers expressed "serious reservations" with the "Frank R. Lautenberg Chemical Safety for the 21st Century Act," S. 697. For the reasons set forth below, we believe that the reservations expressed in the March 15 letter are misplaced.

As former EPA and Justice Department officials who, during our tenures, were tasked with interpreting and implementing the current Toxic Substances Control Act (TSCA), we believe we bring a unique perspective in analyzing and commenting on S. 697 as proposed by Senators Udall and Vitter, and the important need for such legislation. We believe that S. 697 as a whole represents a substantial and necessary improvement over the current Toxic Substances Control Act, and, in particular, that S. 697's amended safety standard will provide EPA with greater authority to address potentially risky chemical substances in commerce.

1. The "Unreasonable Risk" Standard for Safety Determinations

The March 16 letter focuses principally on the safety standard in S. 697 and asserts that S. 697 "essentially preserves the same inadequate 'safety standard' used in current law." To support this claim, the letter references law review articles critical of the current TSCA. The letter, however, misreads S. 697. While S. 697 incorporates the words "unreasonable risk" as the new safety standard, it makes clear that "unreasonable risk" as included in S. 697 is not to be interpreted as it has been under the existing TSCA. S. 697 defines "safety standard" in pertinent part as "a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a

chemical substance under the conditions of use."[1] Thus, the safety standard in S. 697 would require EPA to determine whether risk management measures are needed for a chemical substance solely on the basis of its evaluation of the risks to health and the environment. The language of S. 697 makes clear that its "unreasonable risk" standard has no role for cost-benefit analysis.

Many federal statutes call for regulation of "unreasonable risk." Language in those statutes has generally been interpreted to combine into one step an assessment of the nature and magnitude of the risk and a risk management decision with respect to reducing that risk, by requiring a balancing of the benefits of regulating against the costs of doing so. For example, the Consumer Product Safety Act directs the Consumer Product Safety Commission to adopt consumer product safety standards, saying that "any requirement of such a standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." [2] The Safe Drinking Water Act requires EPA, when proposing a national primary drinking water regulation, to "publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs."[3]

Under TSCA today, in determining that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must consider the effects of the substance and the magnitude of exposure of human beings, the effects of the substance on the environment and the magnitude of exposure, the benefits of the substance for various uses and the availability of substitutes for those uses, and the reasonably ascertainable economic consequences of a rule regulating the substance.[4]

In contrast, S. 697 would separate a determination of whether or not a chemical substance presents an unreasonable risk from decisions about risk management measures to address a confirmed unreasonable risk. As noted above, in defining "safety standard" S. 697 mandates that there be no consideration of economic costs or benefits:

> The term "safety standard" means a standard that ensures, **without taking into consideration cost or other nonrisk factors**, that no unreasonable risk of harm to health or the environment will result from exposure to a chemical substance under the conditions of use ….

[1] S. 697, section 3(4) (also specifying that the "no unreasonable risk of harm" standard shall apply to the general population and "any potentially exposed or susceptible population" identified by EPA.
[2] 15 U.S.C. § 2056(a). *See, e.g., American Textile Manufacturers Institute v. Donovan*, 452 U.S. 490, 511 n.30 (1981) ("In other statutes, Congress has used the phrase 'unreasonable risk,' accompanied by explanation in the legislative history, to signify a generalized balancing of costs and benefits. See, *e.g.*, the Consumer Product Safety Act of 1972").
[3] 42 U.S.C. § 300g-1(b)(4)(C).
[4] TSCA § 6(c), 15 U.S.C. § 2605(c).

(S. 697, section 3(4) (emphasis added)). Explicit language foreclosing the consideration of costs and other nonrisk factors is not found in other "unreasonable risk" statutes, such as the Consumer Product Safety Act or current TSCA. This provision would compel EPA, and any reviewing court, to interpret the S. 697 safety standard very differently from the way unreasonable risk is interpreted under current TSCA.

We note also that the March 16 letter asserts that "courts would be likely to interpret Congress' intent, as it has been previously construed in case law, as still requiring a cost benefit analysis ([referencing Corrosion Proof Fittings])." This assertion is incorrect. It is black letter law that statutory language is to be interpreted consistent with the clearly expressed intent of Congress as reflected in the plain language of the statute.[5] Where, as here, the statute would clearly state that the safety standard is to be implemented "without taking into consideration cost or other nonrisk factors," a reviewing court would certainly not be likely to interpret this definition as requiring a cost-benefit analysis because the statute expressly precludes the consideration of cost or other nonrisk factors.

Moreover, S. 697 defines "safety assessment" as "an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance." (S. 697, section 3(4)). "Safety determination" is defined as "a determination by the Administrator of whether a chemical substance meets the safety standard under the conditions of use." (*Id.*) Safety assessments and safety determinations are to be "based on information, procedures, methods, and models employed in a manner consistent with the best available science" and "the weight of the scientific evidence (S. 697, section 4). S. 697 clearly would not allow for consideration of costs and benefits under the safety standard, notwithstanding what may at first blush appear to be similarity in wording to the current "unreasonable risk" standard.

2. Consideration of Costs and Benefits for Risk Management

The March 16 letter also incorrectly describes the provisions of S. 697 as they relate to consideration of costs and benefits in EPA's rulemaking procedures. Rather than imposing a

[5] *United States v. Amer. Trucking Assns.*, 310 U.S. 534, 543 (1940) ("There is, of course, no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes."); *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980) (it is a "familiar canon of statutory construction that the starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive.").

heavy burden on EPA by mandating a formal cost-benefit analysis, the bill simply would require EPA to conduct an alternatives analysis during the risk management rulemaking process, using readily available information, which is a requirement applicable to federal rulemaking that has been in effect through executive orders for over 33 years. We believe that this provision is key to rational decision-making and would not be a fundamental obstacle to rulemaking.

Under S. 697, where EPA determines that a chemical substance does not meet the safety standard, the Agency would be required to adopt a rule establishing risk management measures sufficient for the chemical substance to meet the safety standard. (S. 697, section 8(3)). In selecting those measures, EPA would have to consider costs and benefits:

> In deciding which restrictions to impose … as part of developing a rule . . . , the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(*Id.*) A similar provision would apply to consideration of whether to adopt a public interest exemption to a ban or phase-out. (*Id.* p. 74.) S. 697 does not require that EPA select the least costly or least burdensome alternative, but that EPA be aware of and consider the relative costs and benefits of a key regulatory alternative. This provision would simply call on EPA to "consider" costs and benefits so as to develop a rational response to an unreasonable risk.

Consideration of costs and benefits is reasonable and common in regulation of safety and environmental risks. For example, as the Supreme Court concluded in 2009, the Clean Water Act permits EPA to use cost-benefit analysis in determining the content of regulations.[6] There, Justice Breyer noted in his concurrence that consideration of costs and benefits is critical to rational decisionmaking:

> [A]n absolute prohibition [on consideration of costs and benefits] would bring about irrational results. As the respondents themselves say, it would make no sense to require plants to "spend billions to save one more fish or plankton." That is so even if the industry might somehow afford those billions. And it is particularly so in an age of limited resources available to deal with grave environmental problems, where too much wasteful expenditure devoted to one problem may well mean considerably fewer resources available to deal effectively with other (perhaps more serious) problems.[7]

[6] *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208 (2009) ("EPA's current practice is a reasonable and hence legitimate exercise of its discretion to weigh benefits against costs that the agency has been proceeding in essentially this fashion for over 30 years.").
[7] 556 U.S. at 232 (citation omitted).

Moreover, EPA and other agencies have been required by executive order to consider costs and benefits, to the extent permitted by law, ever since President Reagan issued Executive Order 12991 in 1981. Executive Order 12991 directed, "Regulatory action shall not be undertaken unless potential benefits to society for the regulation outweigh the potential costs to society."[8] President Clinton issued Executive Order 12866 in 1993, which provides, "Each agency shall identify and assess available alternatives to direct regulation" and "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[9] Most recently, President Obama issued Executive Order 13563 in 2011, which states that the regulatory system "must take into account benefits and costs, both quantitative and qualitative …. In applying these principles, each agency is directed to use the best available techniques to quantify present and future benefits as accurately as possible."[10] The Office of Management and Budget has issued clarifications to this requirement to consider costs and benefits in Circular A-4, which includes extensive guidance on how to evaluate public health and safety rulemakings.[11]

In other words, S. 697's requirement for EPA to consider costs and benefits is an obligation shared by all Executive Branch agencies in the interest of good government. It is not intended to be an insuperable or even a heavy burden, but rather is consistent with longstanding Agency practice, can be met within existing Agency capacity, and is necessary to ensure that EPA makes rational decisions.

Thus, we conclude that the views asserted by the March 16 letter, with regard to interpretation of the unreasonable risk standard, the likelihood that the statutory definition of unreasonable risk will be ignored or misinterpreted by a reviewing court, and regarding alternatives analysis in rulemaking, are incorrect.

Sincerely,

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[8] 46 Fed. Reg. 13193 (Mar. 8, 1981).
[9] 58 Fed. Reg. 51735 (Oct. 4, 1993).
[10] 76 Fed. Reg. 3821 (Jan. 21, 2011).
[11] Office of Management and Budget, Circular A-4 (2003), http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf.

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