REGULATORY CHECKBOOK

August 10, 2011

Sen. Barbara Boxer
Chairman
Senate Environment and Public Works Committee
Washington, DC 20510-6175

Sen. James M. Inhofe
Ranking Member
Senate Environment and Public Works Committee
Washington, DC 20510-6175

Dear Sens. Boxer and Inhofe:

I am pleased to provide answers for the record to several questions posed to me in your letter dated August 3, 2011.

1. **Would S. 76 give the EPA Administrator limitless discretionary authority over what could be labeled a "disease cluster" and what the "potential causes of a disease cluster" could be?**

S. 76 would establish by statute an exceptionally broad definition of "disease cluster" and give the EPA Administrator unlimited discretion to expand it. The proposed statutory definition has no scientific content, and the Administrator would not be required to base any expansion of the definition on science.

In contrast, S. 76 would narrowly define "potential cause of a disease cluster" based on EPA's portfolio of legal authorities and give the EPA Administrator considerable discretion to expand the depth of the definition, if not its breadth. The bill would give her the authority to include environmental pollutants and toxic substances if they appear "in any other form," such as in occupational settings, consumer products, and food. The proposed statutory definition has no scientific content, and the Administrator would not be required to base any expansion of the definition on science.

In circumstances where one of these statutory definitions yielded foolish results, the Administrator would have no authority to waive it.

The statutory definition of "disease cluster" would be exceptionally broad and nonscientific. § 5(4)(A) uses a highly inclusive statistical rule: the occurrence of a "greater-than-expected" number of cases within (a) any group of individuals, (b) any geographic area, or (c) any period of time, would be deemed by law to be a "disease cluster." A single case could constitute a "cluster" if the expected number in any group of individuals, geographic area, or period of time is less than one. Moreover, a

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greater-than-expected number of cases is a common phenomenon. The modifier "any" permits individuals to be grouped an infinite number of ways. With mildly creative interpretation, no case of disease would escape inclusion within at least one statutorily-defined "disease cluster."

The EPA Administrator would have no discretion to overrule the statutory definition of "disease cluster." Nothing in S. 76 allows the EPA Administrator to determine that cases meeting the definition in subparagraph (A) do not merit designation as a "disease cluster," such as for scientific reasons. She could not use new scientific knowledge, no matter how persuasive, to withdraw or rescind a statutorily-defined designation. For example, even proof beyond a reasonable doubt that an observed greater-than-average number of cases is a spurious cluster would be insufficient to overcome the statutory designation because the statutory definition allows no exemptions.

The EPA Administrator would have unlimited discretion to expand the definition of "disease cluster." § 5(4)(B) would allow the EPA Administrator to establish an unlimited number of supplementary criteria defining "disease cluster." Cases need only "meet[] such other criteria, as the Administrator … may determine." She also could establish a lower numeric threshold than "greater-than-expected. Incidence need only to be as great as "such number of cases … as the Administrator … may determine." To be concrete, she would be permitted to endorse a famous folk superstition and decide that any collection of three events constitutes a "disease cluster."

"Potential causes of a disease cluster" would be limited to what EPA regulates, but only in part. The definition in § 5(7)(A)-(G) is limited to pollutants, chemicals, and substances regulated by EPA under existing statutory authorities. Thus, "disease clusters" are presumed to have only environmental origins, and among environmental origins, only those which are regulated by EPA matter.

While the domain is limited to pollutants and substances that EPA regulates, this is true only in part. The catch-all provision in clause (H) includes

> any other form of environmental pollution or toxic substance that is a known or potential cause of an adverse health effect, including a developmental, reproductive, neurotoxic, or carcinogenic effect (emphasis added).

The boundaries of this text are difficult to plot, but some idea of its unstated breadth can be seen by walking through a couple examples. Benzene is clearly a "potential cause" because it is a regulated pollutant in air, water, and soil, and a regulated constituent in motor gasoline. Clause (H) would enable EPA to expand the domain of "potential cause" to include side-stream and second-hand tobacco smoke, neither of which it otherwise regulates, because both contain benzene in "[an]other

"form." Similarly, EPA could decide that fine Bordeaux is a "potential cause of a disease cluster." It contains ethanol in "[an]other form," which EPA regulates under the Clean Air Act. Charting the boundaries of this text ex ante may be impossible because the array of "other forms" cannot be measured. EPA regulates formaldehyde, and formaldehyde is present at part-per-billion levels in human breath. Could people be deemed "potential causes of a disease cluster" because they exhale? Much like the Clean Air Act defines air pollutant capaciously ("any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and byproduct material) substance or matter which is emitted into or otherwise enters the ambient air" [42 U.S.C. § 7602(g)]), S. 76 specifies no limit to the potential breadth of the "any other form" provision. The only things clearly excluded from the definition are the three most important actual causes of disease—genetics, behavior, and aging. EPA-regulated substances may be involved at cellular levels, but they are exempt because genetics, behavior, and aging are not environmental phenomena.

One of the more troubling aspects of the proposed definition is the adjective "potential" preceding "cause." As I noted in my testimony, only technical feasibility could logically preclude something from being a "potential" cause. Even technical infeasibility is not necessarily a bar under some established regulatory definitions of adverse effect. For example, EPA sometimes considers exposures below the threshold for biological effect to be nonetheless adverse because they may reduce a person's ability to withstand challenges from otherwise non-adverse exposures to other substances. (In this model, everything is adverse because it contains potential risk.)

2. Would S. 76 grant the EPA Administrator an unlimited scope of delegable authorities to Regional Response Centers and Teams?

S. 76 would require the EPA Administrator to delegate certain authorities to Regional Response Centers and Teams. It also would allow her considerable discretion to delegate other authorities. Some authorities could not be delegated. Credibly ascertaining the scope of Response Team authority requires resolving a pair of key uncertainties— what is meant by the mandatory delegated authorities to (1) "investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters" and (2) "address the potential causes of disease clusters."

The EPA Administrator would be *required to delegate* certain authorities. § 7(b)(3)(B) would require the EPA Administrator to delegate to Regional Response Centers and Teams authorities that range from promotional ("making guidelines, protocols, data, and other relevant information and expertise available to State and local officials and the public") to investigative ("investigating suspected or potential disease clusters, environmental pollutants or toxic substances associated with those

disease clusters, and potential causes of disease clusters") to remedial ("addressing the potential causes of disease clusters").

The scope of these mandatory authorities, particularly the investigative and remedial, is not clear. With respect to the investigative authorities, for example, S. 76 would not explicitly authorize Response Teams to seek subpoenas, issue unilateral orders, or enter private property and collect data without permission. S. 76 also would not explicitly authorize Response Teams to require that persons suspected of being part of a disease cluster involuntarily provide biological or other data. On the other hand, the bill does not forbid Response Teams from undertaking any of these activities, and a plausible case could be made that they "are consistent with achieving the goals of the Act."

Similarly, S. 76 is unclear concerning the scope of the Response Teams' mandatory remedial authorities. A general principle of statutory construction is to assume that a text has practical meaning. Without any authority at all, however, the requirement to "address[] the potential causes of disease clusters" would be an empty one. Thus, the questions unresolved by the text of the bill are (1) what does it mean to "address" a "potential cause of a disease cluster"? and (2) what actions would exceed Response Teams' delegated authority?

It should be noted that the definition of a "potential cause of a disease cluster" implies the identification of a person, firm, or other entity that is a *source* of a regulated pollutant, chemical, or substance (though "source of a potential cause of a disease cluster" is not defined in the bill). These identifications require no particular scientific evidence, as S. 76 includes no scientific standards for causation. Moreover, the database EPA would be directed to establish and maintain would not be constrained by scientific standards. It would include every phenomenon the EPA Administrator deemed to be a "disease," and every legislatively or administratively deemed "disease cluster" and "potential cause of a disease cluster."

The EPA Administrator would not be able to delegate certain S. 76 authorities to Response Teams. Several new authorities could not be delegated, including (a) the authority to establish additional criteria for defining "disease clusters"; (b) the authority to "establish criteria for the consideration of petitions" seeking an investigation of a potential disease cluster; (c) the responsibility for acting on such petitions; and (d) the responsibility of compiling and regularly updating the database of disease cluster reports and related information.

S. 76 would authorize the EPA Administrator to direct Response Teams to take investigative and remedial actions based on her own judgment ("that the Administrator determines should be investigated or addressed") or because she is dissatisfied, for whatever reason, with the efforts of State and local governments ("that the Administrator determines State and local officials need assistance in investigat-

ing or addressing"). Thus, S. 76 would authorize the EPA Administrator to overrule the judgment of State and local government officials with respect to matters that, with rare exception, are not federal in scale or scope and for which federal authorities do not have presumptively superior knowledge or insight.

The EPA Administrator *may* be able to delegate certain S. 76 authorities to Response Teams. § 7(b)(3)(A) directs the EPA Administrator to "establish the scope of activities for Response Teams to ensure that the activities are consistent with achieving the goals of the Act." Nothing in the bill would prohibit her from re-delegating authorities delegated to her by other statutes. For example, the EPA Administrator has certain authorities to seek subpoenas, issue unilateral orders, and enter property to collect data without permission. If she determined that these authorities were needed to "ensure that the activities [of Response Teams] are consistent with achieving the goals of the Act" and re-delegation was not otherwise prohibited, she might be able to authorize Response Teams to undertake them.

It appears that the EPA Administrator could not delegate to Response Teams the authority to decide on their own which investigations to undertake. Among the Response Teams' mandatory directives is to "respond[] rapidly to a petition" by "investigat[ing] suspected or potential disease clusters…" and "address[ing] the potential causes of disease clusters…" However, Response Teams do not appear to gain any explicit authority to commence these activities absent prior authorization by the Administrator. Still, nothing in S. 76 forbids Response Teams from undertaking these activities prior to or in anticipation of such a decision, nor does the text forbid the Administrator from delegating the authority to conduct provisional investigations prior to making a decision whether to investigate formally.

The EPA Administrator also might be able to delegate to Response Teams the authority to review petitions seeking federal investigation. Because Response Teams would be incentivized to maximize false positives, they would be conflicted in conducting such reviews. S. 76 forbids direct or indirect conflicts of interest in the selection of Response Team members (§ 7(b)(1)(B)), in the selection of Community Disease Cluster Advisory Committee members (§ 7(c)(3)), and in the procedures for peer review of guidelines for environmental investigations of disease clusters (§ 6(b)(5)), though what constitutes a direct or indirect conflict of interest is not stated. But there is no prohibition against a Response Team reviewing a petition on which it is demonstrably conflicted. This could happen, for example, if one or more Team members had assisted in preparing the petition, which they are implicitly encouraged to do via the provision of technical assistance (see §§ 6(B)(3)(iv) and 7(c)(4)).

3. **In your opinion, are CDC and NIEHS the more appropriate agencies to deal with disease clusters than EPA? If this work is not properly being**

done by those organizations, wouldn't it be more appropriate to work on any deficiencies within their framework rather than shift so much authority to EPA?

I regret that I cannot comment on which agency would be "more appropriate" to define and investigate potential disease clusters. Such a judgment lies beyond my technical expertise in risk analysis. What I can say with near certainty, however, is that S. 76 would fail to achieve its stated purposes irrespective of whether its authorities were delegated to EPA, CDC, NIEHS, or another agency.

Failure is assured because S. 76 would subordinate science to politics, and thereby undermine the scientific integrity of every disease cluster investigation. Critical terms defined in S. 76 lack scientific merit, and the absence of a scientific definition for "disease"—even though everything in the bill hinges on it—likely would result in science becoming functionally irrelevant to the program from the outset.

If there are scientific deficiencies in existing CDC and NIEHS programs, they have not been identified. In my testimony, I asked: *Is there a government failure for which S. 76 is a reasonable solution?* The question was not rhetorical; answering it is an essential prerequisite for rational policymaking in this area.

S. 76 appears to be founded on several crucial assumptions: (1) existing programs operated by CDC and NIEHS have failed scientifically; (2) these institutional failures cannot be remedied, but their programs should not be reduced or terminated; (3) existing CDC and NIEHS programs would be enhanced if a large new program were established under EPA's auspices; and (4) a large new program operated by EPA would likely succeed scientifically where existing programs operated by CDC and NIEHS have not.

I am aware of no credible evidence supporting any of these assumptions. In addition, no credible evidence was presented at the March 29 hearing. Rather, among proponents of the bill, there appears to be a desire to abandon science because it has not succeeded in reaching what they regard as obvious conclusions.

I encouraged Congress to take a step back, and first make a persuasive case of government failure:

> Before agreeing to such a radical change, Congress might want to investigate the extent to which CDC and NIEHS have failed to address disease clusters in a scientifically credible manner.

I stand by that advice.

4. **In your testimony you mention that under S. 76, "substantial public and private resources will be misallocated based on political rather than**

scientific concerns." Do you think that if this or similar legislation were passed it could actually harm the ability of the federal government to better understand and address disease clusters due to this misallocation of resources?

If S. 76 or a similar bill were enacted into law, the ability of the federal government to better understand and address bona fide disease clusters cannot escape being severely damaged, if not ruined. This damage would result because resources would be reallocated from investigating whether scientifically plausible phenomena are actually disease clusters to hunting down culprits for legislatively deemed disease clusters. The principle victims would be those who belong to real disease clusters. Few resources would be available to investigate their cases because the vast majority of effort would be spent pursuing wild goose chases. S. 76 also would require EPA to produce intentionally misleading risk assessments, thereby destroying the Agency's scientific credibility.

S. 76 would ensure that public and private resources are allocated based on political rather than scientific considerations. The bill invites mischief by lacking either a scientific definition of "disease" or a requirement that EPA define the term scientifically. EPA currently defines as "adverse effects" an increasing wide swath of phenomena, including things that are reversible, transient, or even unobservable. Thus, the EPA Administrator should be expected to define "disease" very broadly. Whatever definition she promulgated, it would be virtually impossible to challenge.

S. 76 would require scarce public resources to be diverted to wild good chases. Government epidemiologists would be so overwhelmed investigating statutory disease clusters that they would not be able to focus on investigating those clusters with the greatest likelihood of being scientifically genuine. Indeed, S. 76 would define the term "disease cluster" in a way that maximizes such "false positives." Because the apparent success of each Response Center and Team would depend on the number of "disease clusters" identified and purported to be associated with one or more "potential causes," each Center and Team would be highly motivated to identify as many false positives as possible. Because politics would govern every material aspect of this new program, Response Centers and Teams inevitably would become rentseeking political actors rather than disinterested scientific investigators.

Fostering wild goose chases misallocates private resources. Entities regulated by EPA because of a legal connection to an enumerated pollutant or substance would be implicitly targeted as a source of a "potential cause of a disease cluster." (Indeed, it seems likely that the definition of a "potential cause" would morph from pollutants or substances enumerated § 5(7) to a "potential source of a potential cause.") For every wild goose chase taken on by government epidemiologists or a Response Team, it would be imprudent for a "potential source of a potential cause"

not to attempt to refute such linkages. That is, they would have little choice but to reallocate scarce resources from productive purposes. Thought it isn't one of the stated purposes in § 3, it is nevertheless likely that investigations would unleash considerable personal injury litigation of inherently dubious merit.

S. 76 likely would destroy the credibility of EPA risk assessment. Perhaps the most important place where S. 76 would lead to egregious public and private resource misallocation is in §§ 6(c)(4) and 7(b)(3)(C)(iii). These provisions, which appear innocuous on their face, would direct EPA to intentionally exaggerate the alleged relationship between a "disease cluster" and a "potential cause," and by extension, to a "potential source of a potential cause." If EPA were directed to produce and disseminate purposefully biased risk assessments for this program, the scientific integrity of all future Agency risk assessment would be suspect.

At the end of my testimony, I mentioned that my database of 100 disease cases was produced by the random number generator in Microsoft Excel®. By definition, random cases of disease cannot be part of a "disease cluster." Thus, the EPA Administrator would be statutorily required to treat at least 63 of my 100 random cases as belonging to one of at least 27 imaginary disease clusters. All resources devoted to identify systemic "causes" for imaginary disease clusters would be wasted. As I testified:

> Untold resources would be devoted trying to tease out environmental linkages that do not exist. The people most harmed by this will be those who really are members of a bona fide disease cluster.

Identifying disease clusters is a scientifically complex task. S. 94 would solve the problem of scientific complexity, but it would do so by removing science from the task.

I appreciate the opportunity to provide this additional information and hope you find it useful. During the March 29 hearing I was asked if I would assist in improving the scientific quality of this bill. I readily agreed to do so, and that offer still stands.

Sincerely,