Written Testimony of Richard B Belzer

Committee on Environment and Public Works
U. S. Senate

"Oversight Hearing on
Disease Clusters and Environmental Health"

March 29, 2011

Chairman Boxer, Ranking Member Inhofe, and Members of the Committee:

Thank you for the opportunity to testify today on this important subject. I am Richard B. Belzer, president of Regulatory Checkbook, a nonpartisan nonprofit organization based in Virginia. Our mission is to improve the quality of scientific and economic information used for public decision-making. We never take positions on substantive legislation or regulation. I have specific concerns about how well meaning efforts to identify and respond to bona fide disease clusters caused by environmental factors may unwittingly backfire.

MY BACKGROUND

I was raised in Torrance, California, where my parents still reside. I earned Bachelors and Masters degrees in agricultural economics from the University of California at Davis in 1979 and 1980, respectively. In 1982, I earned a Masters in Public Policy from Harvard's John F. Kennedy School of Government, and in 1989 I completed my doctorate from Harvard.

For 10 years, I served as an economist in OMB's Office of Information and Regulatory Affairs. In addition to reviewing draft major regulations, I prepared the final version of OMB 1990 guidance on how to prepare Regulatory Impact Analysis. I contributed

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significantly to OMB's 1995 Principles for Risk Analysis,[1] which remain in effect to this day.[2]

On a number of occasions I reviewed proposed epidemiological surveys to ensure they met applicable statistical quality standards. For example, I personally shepherded through the sometimes Byzantine OIRA clearance process EPA's National Human Exposure Assessment Survey (NHEXAS).[3] At the time, this was the largest and most ambitious EPA effort to obtain statistically valid data on environmental exposure. A search of PubMed shows more than 40 peer-reviewed scholarly papers that have been produced from this data set. I am proud to have helped make this happen.

Besides being an economist I am an experienced risk analyst. In 1988 and 2000, I was elected Treasurer of the Society for Risk Analysis, the premier professional association for environmental risk professionals, and in 2003 I earned the Society's Outstanding Service Award. Service to the professions matters to me. In 2008 and 2010, I was elected Secretary/Treasurer of the Society for Benefit Cost Analysis, a new professional association recently established with significant support from the MacArthur Foundation.

Detecting disease clusters is a very difficult epidemiological and statistical problem. Today, I will show you why several provisions in S. 76, the proposed "Strengthening Protections for Children and Communities From Disease Clusters Act,"[4] have the practical effect of supplanting science with law. I will explain why S. 76 structures the programs it would create in ways that pose a grave risk to the integrity of science. Combined, these elements make it very unlikely that people who actually are part of a disease cluster will be made better off.

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[1] SALLY KATZEN, *Principles for Risk Analysis* (Office of Management and Budget ed., 1995).

[2] SUSAN E. DUDLEY & SHARON L. HAYS, *Updated Principles for Risk Analysis* (Office of Management and Budget and Office of Science Technology Policy ed., 2007).

[3] "Strengthening Protections for Children and Communities From Disease Clusters Act". S. 76. U.S. Senate, 112th Congress, 1st Session. (Boxer and Crapo, 2011).

[4] S. 76.

BROAD GOALS + INDETERMINATE MEASURES OF SUCCESS = FUTURE CONFLICT

The Federal government has ample experience with statutes that have worthy, broadly worded goals. S. 76 is no different. Indeed, its stated goals are so expansive that we can be sure that they will never be achieved. This is clear from just the first of these goals:

> [T]o protect and assist pregnant women, infants, children, and other individuals who have been, are, or could be harmed by, and become part of, a disease cluster;…[5]

No one in America is excluded from this goal.[6] Moreover, there is no way to measure EPA's performance. The Agency will not be able to quantify the outcomes it achieves, so it will have to measure success in terms of outputs. This means "success" will be measured by the numbers of Response Centers and Teams EPA establishes, the numbers of investigations these Teams perform, the number of pages of guidance EPA issues, and potentially the number of meetings EPA holds with stakeholders.

Open-ended goals combined with indeterminate measures of success often result in significant future conflict. We are seeing this now in the case of EPA's efforts to regulate carbon dioxide and other greenhouse gases using the broadly worded language of the Clean Air Act of 1970.[7]

WHAT IS "DISEASE"?

One way to head down a slippery legislative slope is to be ambiguous about the target. S. 76 would provide a statutory definition for a number of important terms, including "disease cluster" and "potential causes of a disease cluster," but notably absent is any definition of "disease." If we are ambiguous about what would be joined together in a "cluster," or vague about what it is that "potential causes" would presumably cause, we will have abandoned all hope of clarity in the endeavor.

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[5] S. 76, Section 4(1).

[6] Indeed, the text does not limit its applicability to U.S. citizens or residents. Everyone on Earth could qualify.

[7] U.S. ENVIRONMENTAL PROTECTION AGENCY, *Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act; Final Rule*, 74 Federal Register 66496 (2009).

Federal law and regulation often use the term "adverse effect" as a synonym for disease. A recent research paper sponsored by the Society for Risk Analysis reported that the term "adverse effect" appears over 300 times in federal laws, but that "the federal statutes themselves give little or no definition or guidance regarding the precise meanings or intended interpretations." Implementing regulations do not add clarity, either:

> Though some statutes purport to define these terms, the definitions are often circular and of little value because they include the term being defined as part of its definition. The statutes generally do not speak to the scientific methods to be used to calculate adverse effects. Agency regulations and judicial interpretations add some clarity, but still leave basic questions of meaning and methodology unaddressed.[8]

The pattern of circularity in Federal law would not be disturbed by S. 76. The term "adverse health effect" is used in a crucial place,[9] but it is not defined. Indeed, as I will point out below, the definition of "potential causes of a disease cluster" cross-references a definition of "environmental pollutants or toxic substances" that relies exclusively on existing statutes with circular or absent definitions of adversity.

In Federal regulatory practice, the practical definition of an "adverse health effect" is remarkably broad. Frank disease is always included, of course, but a wide variety of phenomena at the other end of the spectrum also have been deemed "adverse." Examples include such things as precursors (e.g., hyperplasia), biomarkers of disease (e.g. molecular signatures), biomarkers of exposure (e.g., serum or urine detects of a chemical or its metabolites), and so-called "key events."[10] Exposure below the threshold of an adverse effect (e.g.,

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[8] KELSEY STANSELL & MARK MARVELLI, *'Adverse Effects' and Similar Terms in U.S. Law: A Report Prepared by the Duke Center for Environmental Solutions for the Dose Response Specialty Group of the Society for Risk Analysis (SRA)* p. 3 (Duke University Center for Environmental Solutions 2005).

[9] S. 76, Section 5(7)(H).

[10] EPA defines a "key event" as "an empirically observable precursor step that is itself a necessary element of the mode of action or is a biologically based marker for such an element." The first instance I am aware

below the Reference Dose) cannot have adverse effects, but EPA considers them adverse because an organism exposed below the threshold for adversity may have a diminished capacity to compensate for other, unrelated exposures. Each of EPA's working definitions has scientific content but it is controlled by the explicit or implicit application of substantial policy judgments.[11]

These definitions increasingly extend to phenomena that are quite minor. For example, in the 2008 revision to the National Ambient Air Quality Standards for ozone, EPA deemed short-lived, reversible, single-digit percentage reductions in forced expiratory volume observed in a handful of test subjects to be an adverse effect worthy of prevention through national standards.[12]

Meanwhile, toxicologists and epidemiologists have been unable to come up with a scientific definition of "adverse." Ironically, economics alone among the sciences provides objective scientific definitions for both the adversity and severity of a health effect, but no federal agency uses it.[13]

THE DEFINITION OF "DISEASE CLUSTER"

Chart 1 plots the spatial dispersion of 100 disease cases. The area is divided into 100 equal sized blocks. You may see what appear

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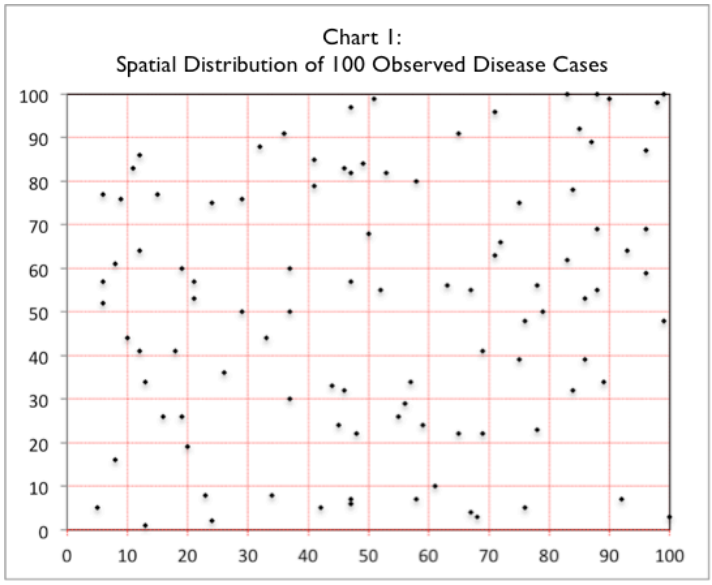
of in which this terminology was used is EPA's 2002 external review draft risk assessment (since rescinded) for perchlorate. See S. 76, Section 5(7)(H).

[11] For example, EPA defines the Reference Dose (RfD) as "[a]n estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used." Each of the underlined terms has no scientific definition, but rather reflect the personal regulatory policy judgments of Agency scientists. See EPA, IRIS Glossary ("Reference Dose") (http://www.epa.gov/iris/help_gloss.htm#r).

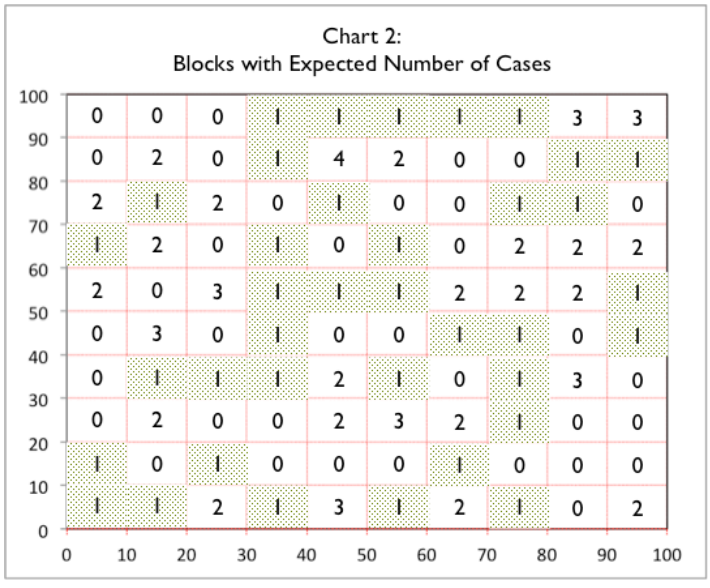
[12] U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF RESEARCH AND DEVELOPMENT NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT, *Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (NCEA-1-05-3), External Review Draft* (U.S. EPA, Office of Research and Development 2002).

[13] An adverse health effect is any health effect that an individual is willing to pay to avoid. The severity of such an effect is the magnitude of the individual's willingness to pay.

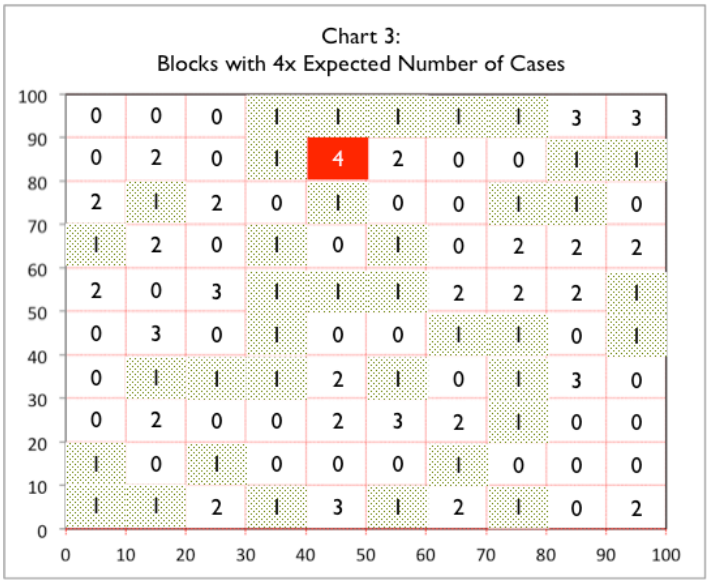
to be disease clusters within certain blocks, and the absence of disease in others. Blocks with a disproportionate number of cases may host a disease cluster.



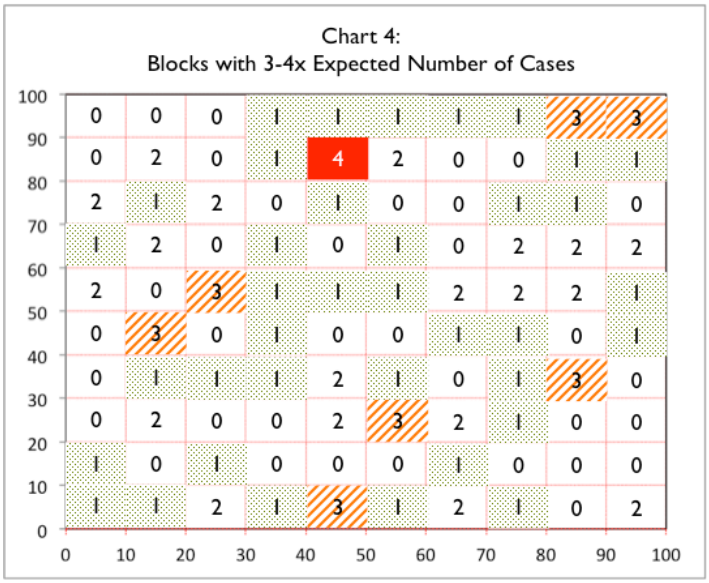
In **Chart 2**, I have replaced the data points with the number of points in each block. Because there are 100 blocks and 100 cases, if there are no disease clusters the expected number of cases in each block is exactly one. I have highlighted these blocks in light green with cross-hatching (for visibility in B&W). For every other block, the number of cases differs from the expected value.



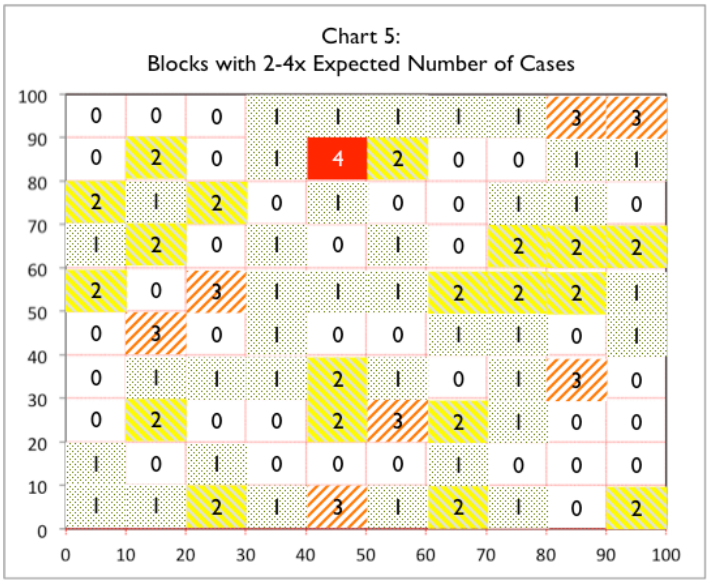
In **Chart 3**, I have highlighted in solid red (black in B&W) one block that contains four times the expected number of cases. It would be logical to look at this particular block as a possible disease cluster.

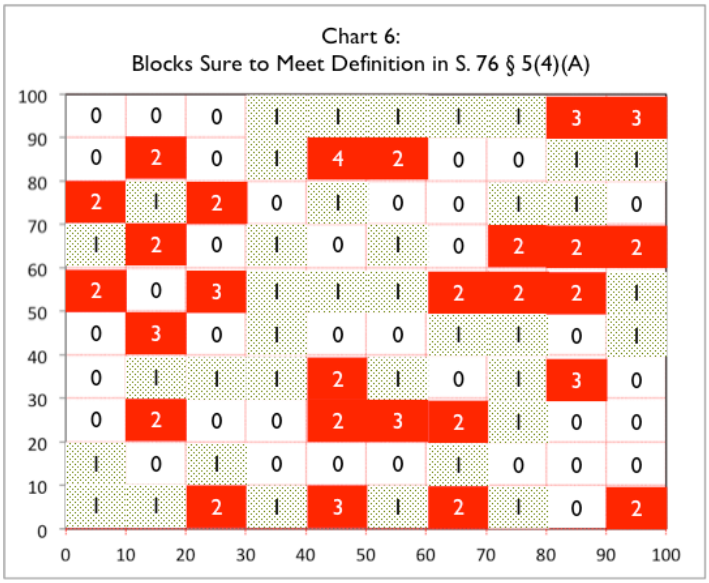


But there are seven additional blocks each with three times the expected number of cases. In **Chart 4**, they are shown in orange (//// diagonal gray stripes in B&W). It also would be logical to consider them as possible disease clusters. Notice that there are two pairs of adjacent blocks, each having 3 times the expected number of cases. It is possible that they represent disease clusters spanning more than one block.



There are 19 more blocks with <u>two</u> times the expected number of cases. In **Chart 5**, I've highlighted them in yellow (\\\\ diagonal gray stripes in B&W). Though perhaps less likely, it is not unreasonable to think that a disease cluster could be found in one or more of them.





Therefore, each of these 27 blocks would be eligible for investigation and regulatory management as a potential disease cluster simply by virtue of geographical proximity. To make this visual, in **Chart 6** I have highlighted them all in solid red (black in B&W).

In sum, 27 of the 100 blocks have greater than the expected number of disease cases. They all meet the first half of the definition of "disease cluster" in S. 76:

> *§ 5(4) DISEASE CLUSTER.—The term ''disease cluster'' means—*
>
> > *(A) the occurrence of a greater-than-expected number of cases of a particular disease within a group of individuals, a geographical area, or a period of time;…*

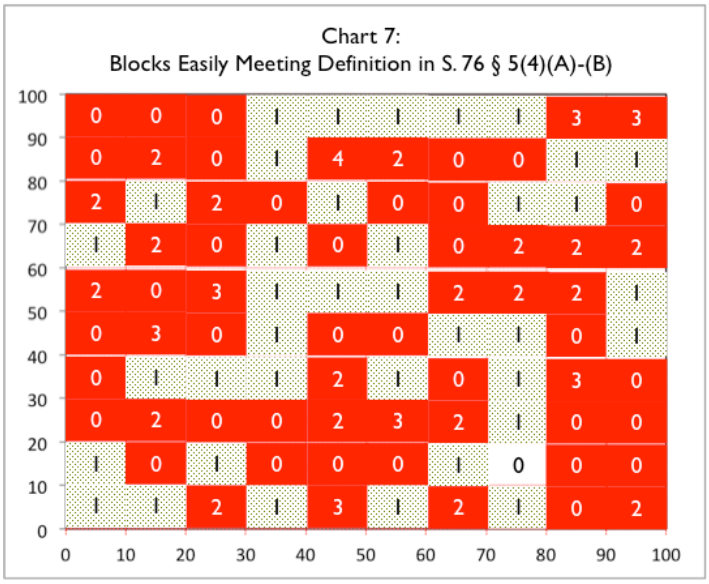
I have not attempted to take into account the extent to which cases would qualify as "disease clusters" under the other two dimensions in the definition: "periods of time" and "groups of individuals." Time can be subdivided, and individuals can be grouped, in a seemingly infinite number of ways. Thus, it is highly likely that many more than the 27 cases I have identified as belonging to potential "disease clusters" would meet the first half of the proposed statutory definition.

The second half of the definition in S. 76 would provide essentially unlimited discretion to the EPA Administrator to deem other relationships as "disease clusters":

> *§5(4) DISEASE CLUSTER.—The term ''disease cluster'' means—*
>
> *…*
>
> *(B) the occurrence of a particular disease in such number of cases, or meeting such other criteria, as the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, may determine.*

To see how this could work in practice, consider the easy situation in which the biomarker of interest is not the presence of something but rather its absence. In that scenario, there are 36 blocks in which the number of "cases" is zero. It would be entirely reasonable for the Administrator to exercise her discretion to deem these cases "disease clusters," too.

In **Chart 7**, I have highlighted in red (black in B&W) all of the blocks that easily meet the full, two-part definition of "disease cluster" in S. 76. Sixty-three of 100 blocks qualify. Under the proposed statutory definition, "disease clusters" could be the norm rather than the exception.



DEFINITION OF "POTENTIAL CAUSE OF A DISEASE CLUSTER"

Disease has many etiologies, some of which may have environmental origin. What proportion does have environmental origin depends on the definition of "environmental." Typically, this term is widely used as a synonym for such things as chemical exposure. However, the environment is much larger than that. It also could be used to encompass disease allegedly associated with climate change, as EPA has done in its 2009 Endangerment Finding. The term also could be used to apply to catastrophic events such as the recent earthquake and tsunami that devastated much of northeast Japan.

S. 76 would establish a definition that is narrow and specific in certain respects, but quite broad in others.[14] The definition is narrow and specific insofar as it is limited to "environmental pollutants and toxic substances," a term defined to include substances regulated under various statutes EPA implements. The definition is broad insofar as it is not limited to these substances, however. It reaches "any other form of environmental pollution or toxic substance that is a known or potential cause of an adverse health effect."[15]

It is difficult to imagine what is not included within this expansive definition.[16] Indeed, alleged health effects from climate change are obviously included by virtue of EPA's Endangerment Finding and the embedded cross reference to the Clean Air Act. But the indirect effects of earthquakes, tsunamis, and presumably meteorite impacts also would be included. Are influenza and foodborne illness covered? They appear to be within "any other form of an environmental pollutant or toxic substance," albeit not one explicitly listed or currently regulated by EPA. What about transportation risks? Probably not, but they could be covered if there were indirect adverse health effects potentially related to environmental pollutants or toxic

[14] U.S. ENVIRONMENTAL PROTECTION AGENCY, *National Ambient Air Quality Standards for Ozone; Final Rule*, 73 Federal Register (2008).

[15] S. 76, Section 5(4).

[16] The proposed definition also defines "sources of … pollutants and substances" by reference to existing environmental statutes. Thus, any entity defined as a "source" under an existing statute or regulation would be presumptively a "source" for a "potential cause of a disease cluster." See

substances.[17] There is empirical evidence suggesting that the annual changeover from Standard to Daylight Savings Time causes a statistically significant short-term increased incidence of acute myocardial infarction (heart attack).[18] Presumably, these health effects could not constitute a "disease cluster," but only because they are the consequence of a legislative act and thus are not within the ambit of an "environmental pollutant or toxic substance."

The insertion of the adjective "potential" before "cause" widens the definition without bound. Strictly speaking, a "potential" cause is present unless it is scientifically or technically infeasible, and as noted above, under some established regulatory definitions of adversity, even technical infeasibility is not necessarily a bar. If exposures below the threshold for an adverse effect are nonetheless adverse because they reduce the margin of safety, there is no such thing as a de minimis effect.

Interestingly, the definition of a "potential causes of a disease cluster" in S. 76 appears to exclude the three most important actual causes of disease: genetics, behavior, and aging. A fair reading of the definition in S. 76 is that none of these dominant factors qualify as "potential causes." Only potential environmental causes matter, and among environmental causes, the ones that matter most are those that are most heavily regulated by EPA.

CONSTRAINING SCIENCE TO FIT A STATUTORY PARADIGM SUBORDINATES SCIENCE TO LAW AND POLITICS

It is strange to define "disease clusters" and their potential causes in ways that have no scientific content. As long as the number of cases is greater than expected, they would be deemed by statute as a "disease cluster." Every chemical present is a "potential cause of a

[17] Were a truck to crash on the Capital Beltway, deaths and injuries from impact would be exempt because they are not health effects. But if the truck spilled hazardous materials that might cause health effects, the exemption is no longer obvious.

[18] S. 76, Section 5(7)(H), emphasis added. The reported incidence ratio (1.05) is greater than the percentage increase in incidence of mortality said to be caused by ozone (0.3% for 10-ppb O_3). See MICHELLE L. BELL, et al., *The Exposure-Response Curve for Ozone and Risk of Mortality and the Adequacy of Current Ozone Regulations*, 114 Environmental Health Perspectives (2006).

disease cluster" regardless of whether exposure occurred, how much exposure occurred, or for how long it occurred. These definitions abandon what we have learned about risk from decades of research. They covert scientific inquiry in the search for knowledge into potentially corrupt political and legal calculations.

The first such calculation would be the preparation by EPA of implementing guidance.[19] By law, those with strong policy views about risk management would have preferential input into the practice of risk assessment.[20] EPA would be required to publish implementing guidance that subordinates science to predetermined policy judgments.[21] No research adhering to these guidelines would meet minimum scientific standards for objectivity, so no responsible scientist would agree to adhere to them.

Another predictable consequence of this statutory structure would be the creation of new, and arguably unlimited, civil liability. Any manufacturer, importer, distributor, retailer, or user of a chemical discovered (or even merely suspected) of being co-located in space or time to a "disease cluster" would be presumptively responsible for any "disease cluster" to which it might be linked, however remotely or spuriously. There is no escape from being a "potential cause of a disease cluster" because the absence of causality can never be proved. And, as noted above, the definition of "disease cluster" is so broad that it is reasonable to expect that, in the limit, every instance of disease would be part of at least one cluster and every source of a Federally regulated pollutant would be a potential cause.

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[19] IMRE JANSZKY & RICKARD LJUNG, *Shifts to and from Daylight Saving Time and Incidence of Myocardial Infarction*, 359 New England Journal of Medicine 1966 (2008).

[20] For example, Section 6(a)(2) would require EPA to ensure that a specific advisory group, the Children's Health Protection Advisory Committee, has "a prominent role on behalf of the Agency in developing and updating guidelines." In practice, this is approximately equal to delegating rulemaking authority to persons who are not officers of the United States Government.

[21] For example, Section 6(b)(4) would require EPA to ensure that its risk assessments were biased "in a health-protective way"—that is, to overstate the strength of association, causality, and the likely magnitude of risk.

POLITICIZED IMPLEMENTATION THROUGH REGIONAL RESPONSE CENTERS AND TEAMS

Any program honestly intending to identify disease clusters has to grapple with what to do with this information once it is obtained. The model that S. 76 would set up consists of myriad Regional Disease Cluster Information and Response Centers and Regional Disease Cluster Information and Response Teams.[22] From the outset, these Centers and Teams would be corrupted by politics, both of the conventional sort and of the internal, bureaucratic variety.[23] They also would be large targets for rentseeking by individuals (serving on Response Teams) and universities (which would house Response Centers and Teams pursuant to EPA grants and cooperative agreements).[24]

Indeed, financial corruption is virtually assured. Just to ensure that their appropriations are sustained, Response Centers and Teams must identify large numbers of disease clusters. If they fail to do so, budget constraints would lead Congress to seriously consider reducing or eliminating their appropriations. By identifying large numbers of disease clusters, however, Response Centers and Teams could build politically resilient constituencies to lobby for sustained funding, and probably to increase it.[25]

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[22] S. 76, Section 6.

[23] S. 76, Section 7.

[24] S. 76, Section 7(a)(2)(A)."The Administrator shall ensure that the Office of Children's Health Protection, in consultation with appropriate advisory committees, such as the Children's Health Protection Advisory Committee, has a prominent role on behalf of the Agency in establishing and operating the Regional Response Centers and the Response Teams."

[25] S. 76 forbids persons with a "direct or indirect conflict of interest" from participating on a Response Team. See Section 7(b)((1)(B). "Conflict of interest" is not defined, however, but it has to exclude those with the greatest financial conflict—persons who actually work for a Response Center or on a Response Team. Moreover, persons who have been identified as belonging to a disease cluster, and their designees and advocates, would be presumed not to have conflicts of interest. However, it is almost certain that a conflict of interest would be discovered for any person directly or indirectly related to, affiliated with, or owning stock in, an entity that is a "potential cause of a disease cluster."

What would the Response Centers and Teams do? Apparently, their activities would be statutorily unbounded. The EPA Administrator would be delegated the authority to decide, and any activities would be permissible so long as they "are consistent with achieving the goals of this Act." As noted above, the goals of S. 76 are unbounded; there is no measurable standard by which the public could conclude that the bill's goals had been met.

One thing the Response Teams will have an incentive to do is encourage the submission of petitions seeking investigation into a potential disease cluster.[26] One of the few areas in which S. 76 denies EPA discretion concerns whether to respond to these petitions. Written responses must be provided within 60 days.[27] For the Response Centers and Teams, the more petitions that are submitted, the greater is the pressure on EPA to deem petitions worthy of investigation, and thus the greater is the apparent demand for their services.

INVITING CAUSATION BY ASSOCIATION, OR LESS

A database of actual disease clusters would be extremely valuable. Unfortunately, the database that S. 76 would direct EPA to establish would not be limited to scientifically validated disease clusters. Rather, it would extend to every legislatively deemed disease cluster and every legislatively deemed potential cause.[28]

The predictable consequence of a database of this design is public misinformation and unwarranted alarm. The public would be encouraged to misinterpret legislative definitions as scientific and to misconstrue association with causation,[29] something that science consistently teaches against. Even the mere suspicion of a relationship between "disease" and a purported "source" appears to be sufficient for memorialization in this database.

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[26] S. 76, Sections 7(a)(2(B) [decribing EPA's funding obligations] and 7(b) [describing who is eligible to participate].

[27] S. 76, Section 7(b)(3)(C). The bill does not provide a procedure for appealing an adverse decision.

[28] S. 76, Section 7(b)(3)(C)(iv).

[29] S. 76, Section 7(b)(6).

IS THERE A GOVERNMENT FAILURE FOR WHICH THIS IS A SOLUTION?

Welfare economics teaches that markets are always imperfect to some degree, and that government intervention may be needed if the magnitude of these imperfections is severe enough and if supplanting market with government allocation results in net social benefits. These principles have been enshrined in Executive branch policy and practice for at least 17 years.[30] An integral part of this policy and practice is the recognition that public institutions (i.e., governments) also are susceptible to imperfection and failure.[31]

Superficially, S. 76 is targeted on a presumptive market failure: individual cases of disease are assumed to be linked to a common environmental source of anthropogenic origin. Looked at more closely, however, S. 76 is targeted on a presumptive government failure. Federal responsibility for disease epidemiology generally is assigned to the Centers for Disease Control and Prevention (CDC), and responsibility for environmental epidemiological research is assigned to the National Institute of Environmental Health Sciences (NIEHS). S. 76 would largely supplant the programs operated by CDC and NIEHS with a new (and much larger) program within EPA, a regulatory agency of enormous scope and scale. At least with respect to disease clusters, S. 76 would make CDC and NIEHS bureaucratically subordinate to EPA, leaving them only minor consultative roles in areas where they have greater scientific and technical expertise.

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. No evidence of failure is provided in the findings section of the bill.[32]

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[30] See S. 76, Section 7(b)(6)(A)(ii)(II)-(IV).

[31] Executive Order 12866 states, "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem" (emphasis added). OMB Circular A-4 says to agencies, "You should show that a government intervention is likely to do more good than harm."

[32] WILLIAM J. CLINTON, *Executive Order 12866--Regulatory Planning and Review*, 58 Federal Register 51735 (1993); OFFICE OF MANAGEMENT AND

RESOURCE ALLOCATION UNDER SCARCITY

In 1848, philosopher Thomas Carlyle ridiculed economics as "the dismal science," a pejorative term that seems to have stood the test of time. Today, economics still has a reputation among some for being dismal, but that's because it insists on identifying and quantifying tradeoffs that many noneconomists prefer to ignore. In a world of scarce resources—that is, the world in which we all live—every decision to commit resources for one purpose requires that they be taken away from the pursuit of another. This is the meaning of the term "opportunity cost": the real "cost" of any expenditure of funds is not mere dollars; rather, it is the value of those things that we must sacrifice in order to obtain the benefits we hope to gain from the expenditure.

Although presumably unintended, S. 76 would address the legitimate issue of disease clusters with a combination of selection bias, statistical bias, and the politicization of science. Selection bias would arise because only environmental causes of disease clusters matter, and among environmental causes only the subset potentially attributable to chemicals matters. We can predict that this selection bias will result in massive resource misallocation. Is cancer an important health effect? Absolutely. What about Alzheimer's Disease? Diabetes? Yes, of course. But under the scheme that S. 76 would establish, learning the etiology of disease clusters only matters if there may be a way to link it to a regulated chemical.

Statistical bias is assured because S. 76 would encourage (if not direct) EPA to bias its risk assessments with specific risk management conclusions. In 1983, when the National Research Council first offered guidance on managing the process of risk assessment in the Federal government, it strongly counseled against this approach:

> We recommend that regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political,

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BUDGET, *Circular A-4: Regulatory Analysis* (2003), at http://www.whitehouse.gov/OMB/circulars/a004/a-4.pdf.

> economic, and technical considerations that influence the design and choice of regulatory strategies.[33]

Over the past 28 years, fidelity to this advice has been sparing. It has long been the practice of EPA staff to infuse risk assessments with policy judgment, and to decline to "explicitly distinguish" where science ends and policy judgment begins.[34]

Finally, science is inherently politicized when its role is limited to the support of pre-determined political purposes. These purposes are self-evident in the findings, the definitions, and the way Response Centers and Teams would be organized and function. That is not to say that the political purposes of the bill are necessarily invalid or inappropriate. The issue here is that science is a method of learning; it has its own philosophy, its own institutionalized practices, conceits, and foibles. But it also enjoys a certain credibility and respect gained from widespread belief that it is apolitical. This would be compromised, if not lost, because of the way S. 76 treats science as an instrument for achieving certain political goals rather than for creating knowledge that informs decision-making.

For EPA, the definition of "disease cluster" is so broad that there is no politically credible way for the Agency to set priorities. Facing a demand that it order the investigation of nearly everything, the Agency would face a stark choice: either designate nearly every claim as a "disease cluster" or focus resources intensively to find true positives. If it does the former, it can make more petitioners superficially happy by acknowledging their distress, but it also can be assured that almost every legislatively deemed "disease cluster" is a false positive of no genuine environmental interest. If it does the latter, however, it is more likely to detect true positives, but be widely

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[33] NATIONAL RESEARCH COUNCIL, Risk Assessment in the Federal Government: Managing the Process p. 7 (National Academies Press. 1983). See, esp., the non sequitur on p.13: "[S]ince EPA is a health and environmental protective agency, EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks."

[34] U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF THE SCIENCE ADVISOR, *An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B-04/001* (2004), at http://www.epa.gov/osainter/pdfs/ratf-final.pdf.

criticized for callously neglecting those whose illnesses are real but whose evidence supporting environmental causation is weak.

For this reason alone, I can predict that if enacted S. 76 would not—indeed, it could not—achieve its stated goals. Sadly, I can also predict that substantial public and private resources will be misallocated based on political rather than scientific concerns. Members of Congress can expect to be deluged with appeals that they intervene on behalf of specific constituents. Many will do so, and because S. 76 is written in a way that maximizes EPA's discretion, the Administrator may be unable to resist the pressure to exercise her discretion in politically sensitive ways.[35]

Aside from politics, the strongest factor in resource allocation decisions under S. 76 would be chance. Although surely it was not intended, S. 76 maximizes the role of chance by making the definition of a "disease cluster" so broad that virtually any phenomenon can fit within its bounds. Meanwhile, the definition of a "potential cause of a disease cluster" is so narrow that it resembles the famous story of the drunkard searching in vain under a lamppost for his keys not because he lost them nearby, but because that's where the light is. In combination, these features of S. 76 make it likely that few of the people it is intended to help would actually benefit from it.

To prove this, I wish to note that the data that I used for my eight charts were actually produced by the random number generator in Microsoft Excel. There are, in fact, no disease clusters in my data. Nonetheless, 27 of 100 blocks have greater than the expected number of cases, thus making them legislatively deemed "disease clusters" under the first prong of the definition. Another 36 of 100 blocks easily could be deemed "disease clusters" under the second prong. With creativity, few of the remaining 37 "cases" in my randomly generated sample of 100 would escape designation as part of a "disease cluster." 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.

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[35] The Administrator would be subject to both conventional political pressure and internal political pressure from the leaders of her Response Teams, who would report directly to the Administrator. See An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B-04/001.

Thank you again for the opportunity to testify today. I am happy to address any questions you might have.

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