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The Arithmetic of Arsenic

Cass R. Sunstein

ARTICLES

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ABSTRACT

What does cost-benefit analysis mean, or do, in actual practice? When agencies engage in cost-benefit balancing, what are the interactions among law, science, and economics? This Article attempts to answer that question by exploring, in some detail, the controversy over the EPA's proposed regulation of arsenic in drinking water. The largest finding is that often science can produce only "benefit ranges," and wide ones at that. With reasonable assumptions based on the scientific data before the EPA at the time it made its initial decision, the proposed arsenic regulation can be projected to save as few as 0 lives and as many as 112. With reasonable assumptions, the monetized benefits of the regulation can range from $0 to $560 million. In these circumstances, there is no obviously right decision for government agencies to make. These points have numerous implications for lawyers and courts, suggesting both the ease of bringing legal challenges on grounds specified here and the importance of judicial deference in the face of scientific uncertainty. There are also policy implications. Agencies should be given the authority to issue more targeted, cost-effective regulations. They should also be required to accompany the cost-benefit analysis with an effort to identify the winners and losers, to see if poor people are mostly hurt or mostly helped.

> Americans may disagree on a lot of things, but drinking arsenic isn't one of them . . . . When you turn on the kitchen sink, you ought to be able to drink what comes out, without worrying about being poisoned.[1]

> "What we know is a drop, what we do not know—an ocean." In spite of significant gains in knowledge, we are still moving mainly in the dark when dealing with the quantitative importance of risk factors in chemical carcinogenesis, the mechanisms of action of chemical carcinogens, and hence, their detection and the assessment of their risks to human health. The basic understanding . . . is still missing.[2]

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1. Elizabeth Shogren, *House Votes for Tougher Arsenic Rule; Measure OKs Clinton Water Standard*, CHI. TRIB., July 28, 2001, at 1 (quoting Rep. David Bonior).

2. TOXICOLOGY 178 (Hans Marquardt et al. eds., 1999) (quoting Isaac Newton) (internal references omitted).

> Because the shape of the dose-response curve in the low-dose region cannot be verified by measurement, there is no means to determine which shape is correct. . . . [W]hen modeling the risks associated with lower doses, the dose/risk range in which regulatory agencies and risk assessors are most frequently interested, there is a wide divergence in the risk projected by [different models, all of which fit existing evidence.] . . . In fact . . . the risks predicted by these . . . models produce a 70,000-fold variation in the predicted response.[3]

> Additional epidemiological evaluations are needed to characterize the dose-response relationship for arsenic-associated cancer and noncancer end points, especially at low doses. Such studies are of critical importance for improving the scientific validity of risk assessment.[4]

> Anyone who's read an Agatha Christie mystery knows that arsenic is a poison.[5]

INTRODUCTION

Within the past two decades, cost-benefit analysis (CBA) has become one of the most widely discussed topics in all of regulatory law.[6] Much of the discussion is occurring within the three branches of government. The Office of Management and Budget (OMB) has overseen a series of executive orders calling for cost-benefit balancing,[7] and OMB has attempted to give concrete guidance for agencies to follow.[8] Courts have adopted a series of cost-benefit default principles, authorizing agencies to engage in cost-benefit balancing unless Congress requires otherwise.[9] Congress itself has shown considerable interest in requiring agencies to compile information on the costs and benefits of regulation.[10] At the same time, there has been renewed academic interest in CBA, resulting in explorations of the technique from a remarkable variety of

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3. PHILLIP L. WILLIAMS ET AL., PRINCIPLES OF TOXICOLOGY 456 (2000).

4. SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, ARSENIC IN DRINKING WATER 3 (1999).

5. 147 CONG. REC. H4751 (daily ed. July 27, 2001) (statement of Rep. Anna Eshoo).

6. For an overview, see COST-BENEFIT ANALYSIS: LEGAL, ECONOMIC, AND PHILOSOPHICAL PERSPECTIVES (Matthew D. Adler & Eric A. Posner eds., 2001) [hereinafter COST-BENEFIT ANALYSIS].

7. *See, e.g.*, Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1980); Exec. Order No. 12,498, 50 Fed. Reg. 1036 (Jan. 4, 1985); Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993).

8. *See* OFFICE OF MGMT. AND BUDGET, ECONOMIC ANALYSIS OF FEDERAL REGULATION UNDER EXECUTIVE ORDER 12866 (1996), *available at* http://www.whitehouse.gov/omb/inforeg/riaguide.html. For a useful overview, see Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 CAP. U. L. REV. 21, 29–34 (2001).

9. *See* Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1217 (5th Cir. 1991).

10. *See, e.g.*, Safe Drinking Water Act (SDWA), 42 U.S.C. §§ 300f to 300j-26 (2000).

perspectives.[11]

In all of these contexts, the discussion has tended to be quite abstract. Within the legal culture, there has been little discussion of what CBA specifically entails or of how the technique might be used or improved by agencies.[12] To date, there appears to be no sustained investigation within the legal culture of any regulation in which CBA proved pivotal to the outcome. In this Article, I hope to begin to fill the gap. I do so by exploring one of the most contested early decisions of the Environmental Protection Agency (EPA) under President George W. Bush: the suspension of the EPA regulation of arsenic in drinking water.[13] Much of the contest over that decision has involved a debate about the relevant costs and benefits of the regulation. As we will see, it is possible to draw a range of general lessons from the arsenic controversy.

My principal finding is simple: Sometimes the best that can be done is to specify an exceedingly wide "benefits range," one that does not do a great deal to discipline judgment. Much of this Article will be devoted to establishing this insufficiently appreciated point, with some effort to specify the judgments that must be made both to identify the health benefits and to monetize them. As a result of this finding, it would be wrong to have confidence that the EPA's proposed rule in the Clinton Administration was either right or wrong, based on the evidence before the agency at the time. I also offer three more positive suggestions. First, CBA, even with wide ranges, provides an important improvement over the "intuitive toxicology" of ordinary people, in which general affect helps to determine judgment.[14] This intuitive toxicology can lead people to large blunders in thinking about risk, not excluding the public's excessive reaction to the Bush Administration's decision to suspend the arsenic rule issued by the Clinton Administration.[15] Second, considerable progress could be made by authorizing the EPA both to use market incentives and to target drinking water controls to areas where they would do the most good. Third, the EPA should be required to provide, if feasible, a *distributional* analysis showing exactly who would be helped and hurt by regulation. In its voluminous materials on the effects of the new arsenic rule, for example, the EPA does not say a

11. *See generally* COST-BENEFIT ANALYSIS, *supra* note 6.

12. For a superb discussion of theoretical issues, see Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941 (1999).

13. National Primary Drinking Water Regulations, 66 Fed. Reg. 28,342 (May 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142) (delaying effective date). Note that throughout I will rely on the record compiled by the EPA at the time that it made its decision; subsequent to that decision, new evidence has been found and discussed, giving rise to increased fears about the risks posed by arsenic. *See* SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, ARSENIC IN DRINKING WATER: 2001 UPDATE. In part as a result of this evidence, the EPA has decided to go forward with the Clinton Administration initiative. *See* Katherine Q. Seelye, *EPA to Adopt Clinton Arsenic Standard*, N.Y. TIMES, Nov. 1, 2001, at A18.

14. *See* PAUL SLOVIC, THE PERCEPTION OF RISK 285 (2000).

15. *Id.*

word about whether poor people would bear the sometimes significant costs of the regulation. It would be easier to assess the new rule with a clearer sense of the benefited and burdened classes.

More particularly, I suggest that an understanding of the arsenic controversy offers seven general lessons:

(1) *The illusion of certainty.* CBA can sometimes produce an illusion of certainty.[16] Even when, as in the arsenic case, science has a great deal to offer, the most that the agency can be expected to do may be to specify a range, sometimes a wide range, without assigning probabilities to various points along the spectrum. This suggestion should be taken as an attack not on CBA, but on what might be described as the false promise of CBA: the thought that science and economics, taken together, can produce bottom lines to be mechanically applied by regulatory agencies. "[T]here is wide recognition among experts—but not necessarily in the public opinion—that current approaches to the regulation of most agents remain judgmental."[17]

(2) *The wide benefits range.* With respect to health benefits, plausible assumptions can lead in dramatically different directions. In the case of arsenic, it would be possible to conclude that the annual number of lives saved from the EPA's proposed regulation would be as low as 5 or as high as 112—and that the annual monetized benefits of the proposed standard would be as high as $1.2 billion or as low as $10 million! It is worthwhile to pay special attention to the *dose-response curve,* on which direct information is typically absent. I will make a particular effort to connect the legal and economic issues involved in cost-benefit balancing to the underlying scientific questions.

(3) *The potentially extraordinary power of creative lawyers.* If literate in some basic science and economics, an adroit lawyer, on either side, might mount apparently reasonable challenges to *any* EPA decision about whether and how to regulate arsenic in drinking water. An industry lawyer should be able to urge, not without some force, that any new regulation of arsenic is too severe, because the costs exceed the benefits. An environmental lawyer should be able to urge, not without some force, that nearly any imaginable regulation of arsenic is too lenient, because the benefits of further regulation would exceed the costs. Both challenges would be plausible for a simple reason: It is easy to identify assumptions that would drive the numbers up or down. Hence one of my principal goals is to provide a kind of primer on how informed lawyers can integrate science, economics, and law to challenge regulatory outcomes.

16. This point is also pressed in Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981 (1998).

17. TOXICOLOGY, *supra* note 2, at 1145.

(4) *The need for judicial deference.* In part because of point three, and in light of the scientific and economic complexities, courts should play an exceedingly deferential role in overseeing CBA at the agency level. To say the least, judges are not specialists in the relevant topics, some of which are highly technical, and because good lawyers will be able to raise so many plausible doubts, the best judicial posture is one of deference. In the arsenic case and in many other contexts, agencies must decide in the midst of considerable scientific uncertainty and on the basis of judgments of value on which reasonable people can differ. If agencies have been both open and reasonable, the judicial role is at an end. It follows, for example, that the Clinton Administration's arsenic rule, if it had been finally issued and challenged, should have survived judicial review. It also follows that a less stringent regulation, if it had been chosen by the Bush Administration, should survive judicial review too. The claim for judicial deference, in both cases, is rooted in institutional considerations and above all a sense of the likely problems of intensive judicial review—not in approval of any particular agency decision. Of course courts should invalidate arbitrary or indefensible judgments, but the EPA's approach here was neither arbitrary nor indefensible.

(5) *CBA as indispensable information.* The false precision of CBA is a significant cautionary note, but it should not be taken as a fundamental attack on the method itself, at least if CBA is understood as a way of compiling relevant information. In the arsenic case, an assessment of costs and benefits cannot determine the appropriate regulatory outcome. But even so, the assessment is indispensable to informing the inquiry and to ensuring that discretion is exercised in a way that is transparent rather than opaque. Without some effort to ascertain the effects of regulation, agencies are making a mere stab in the dark. At the very least, an understanding of the data helps show *exactly why the decision about how to regulate arsenic is genuinely difficult*—and why, and where, reasonable people might differ. This is itself a significant gain.

(6) *Targeting.* The Safe Drinking Water Act (SDWA),[18] designed to control pollution in drinking water, has been amended to require cost-benefit balancing, partly to permit the EPA to relax regulatory requirements when the benefits are low and the costs are high.[19] At the same time, however, the SDWA continues to have a high degree of rigidity. The EPA is not authorized to impose regulation selectively or in those areas in which regulation would do the most good; it is required to proceed with a uniform, national regulation.[20] The EPA is also forbidden to create trading programs, which might well make best sense for some pollutants. Statutory amendments would be sensible here, especially under a statute

18. 42 U.S.C. §§ 300f to 300j-26 (2000).
19. *See id.* § 300g-1(b)(3)(C).
20. *See id.* § 300g. *But see id.* § 300g-4 to 300g-5.

dedicated to cost-benefit balancing. Regulatory statutes generally should authorize agencies to target regulations to areas where the benefits exceed the costs and should also allow agencies to use market incentives when appropriate.[21]

(7) *The importance of distributional information.* It would be extremely valuable to assemble information about the *distributional* consequences of regulation. The benefits of some regulations are enjoyed disproportionately by people who are poor and members of minority groups.[22] The burdens of some regulations are imposed disproportionately on exactly the same groups. To assess the arsenic rule, it would be highly desirable to know whether poor people are mostly helped or mostly hurt. Would they bear high costs? Would the regulation operate as a regressive tax? Unfortunately, the EPA has not answered that question, though it would almost certainly be easy for it to do so. Existing executive orders calling for CBA should be amended to require a careful distributional analysis as well.[23]

This Article comes in several parts. Part I offers a general overview of the movement toward cost-benefit balancing, a movement in which the SDWA stands as the most dramatic legislative endorsement. It also gives a brief description of the public outcry over President Bush's decision to suspend the regulation, to fortify the case for CBA. Part II provides a brief outline of the SDWA and of the EPA's rationale in its regulation of arsenic. Part III explores the very different analysis coming from the American Enterprise Institute-Brookings (AEI-Brookings) Joint Center for Regulatory Studies. Part IV—in many ways the heart of the Article—shows how apparently reasonable assumptions lead to a dramatically diverse set of benefit numbers, both monetized and nonmonetized. Part V explores how lawyers and courts might respond to the data. Part VI discusses the role of policymakers and explains that agencies should be permitted to issue targeted regulations and to use economic incentives and that, in keeping with its informational functions, CBA should include a description of the expected winners and losers from regulation.

21. I do not explore here the question whether national standards make sense for drinking water, as opposed to reliance on state regulation. For a pertinent discussion of this question, see Richard L. Revesz, *Federalism and Environmental Regulation: A Public Choice Analysis*, 115 HARV. L. REV. 553, 559–83 (2001).

22. *See* Matthew E. Kahn, *The Beneficiaries of Clean Air Act Regulation*, 24 REG. MAG. NO. 1, at 22 (2001), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=267073.

23. *See supra* note 13. There is a brief reference to "distributive impacts" in Executive Order 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993). *See also* ABT ASSOCS., U.S. ENVTL. PROT. AGENCY, ARSENIC IN DRINKING WATER RULE: ECONOMIC ANALYSIS 8–31 (2000) (analysis developed for EPA discussing need to explore equitable and distributional considerations, including effects on poor and minority communities), *available at* www.epa.gov/safewater/ars/econ_analysis.pdf.

I. INTUITIVE TOXICOLOGY AND THE COST-BENEFIT STATE

A. ARSENIC AND THE PUBLIC

My principal topic will be the contest over the appropriate analysis of existing data relating to arsenic, but it will be useful to begin with a puzzle. In April 2001, the Bush Administration suspended the Clinton Administration's arsenic regulation after calling for further study.[24] There seems to be little question that of all the controversial environmental actions of the Bush Administration's first year, the suspension of the arsenic rule produced the most intense reaction.

A national survey, conducted between April 21 and April 26, 2001, found that fifty-six percent of Americans rejected the Bush decision, whereas only thirty-four percent approved of it—and that majorities of Americans opposed the decision in every region of the nation.[25] At various points, the public outcry combined concern, certainty, and cynicism. "Arsenic Everywhere, and Bush is Not Helping," according to one newspaper.[26] "You may have voted for him, but you didn't vote for this in your water," wrote the *Wall Street Journal*.[27] In an editorial, the *New York Times* demanded that "Americans should expect their drinking water to be at least as safe as that of Japan, Jordan, Namibia and Laos," all of which impose a 10 parts per billion (ppb) standard.[28] A respected journalist asked, "How callous can you get, Mr. Compassionate Conservative?"[29] The public reaction came to a head during the legislative debates on the issue, particularly within the House of Representatives, which voted to reinstate the Clinton rule on the theory that arsenic "is a poison."[30]

Here is the puzzle: With respect to arsenic, the underlying issues are highly technical, and very few people are expert on the risks posed by exposure to low levels of arsenic. What accounts for the public outcry? I believe that the reason is simple: *Arsenic* was involved, and so was *drinking water*.

These two facts made the controversy seem highly accessible, and it was easy to be outraged. Why was the Bush Administration allowing dangerously high levels of arsenic to remain in drinking water? This appeared to be a rhetorical question. By contrast, many environmental problems are both obscure and

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24. *See* National Primary Drinking Water Regulations, 66 Fed. Reg. 16,134 (Mar. 23, 2001) (codified at 40 C.F.R. pts. 9, 141, 142) (delaying arsenic rule); 66 Fed. Reg. 20,579 (Apr. 23, 2001) (ordering subsequent process).

25. *See* Mark Barabak, *Bush Criticized As Fear of Environment Grows*, L.A. TIMES, Apr. 30, 2001, at A1.

26. Erik Olson, *Arsenic Everywhere, and Bush Is Not Helping*, BALT. SUN, May 14, 2001, at 9A.

27. John J. Fialka, *Arsenic and Wild Space: Green Activists from Across Spectrum Unite Against Bush*, WALL ST. J., Apr. 11, 2001, at A20.

28. Robert K. Musil, *Arsenic on Tap*, N.Y. TIMES, Apr. 24, 2001, at A18.

29. Michael Kinsley, *Bush Decision on Arsenic Tough to Swallow*, TIMES UNION, Apr. 16, 2001, at A9.

30. 147 CONG. REC. H4727 (July 27, 2001).

technical, and people do not have an easy or intuitive handle on them. Is carbon dioxide a serious problem? Most people have no idea. But arsenic is well-known, and it is well-known to be a poison, not least because of the exceedingly popular movie, *Arsenic and Old Lace*.[31] An influential environmental group, the Natural Resources Defense Council, exploited exactly this reference with its work on the arsenic problem, under the title, *Arsenic and Old Laws*.[32] The public reaction would have been different if the controversy involved a water contaminant with an obscure name, such as cadmium.

Ordinary people seem to be "intuitive toxicologists," with a set of simple rules for thinking about environmental risks.[33] Among those simple rules is a belief that substances that cause cancer are unsafe and should be banned.[34] That intuitive toxicology does not easily make room for issues of degree. It does not accommodate the judgment that low levels of admittedly carcinogenic substances should sometimes be tolerated because the risks are low and the costs of eliminating them are high. It does not show an understanding of the different imaginable dose-response curves and the possibility of safe thresholds or even benefits from low exposure levels.[35]

As part of intuitive toxicology, people rely on the "affect heuristic," through which rapid, even automatic responses greatly affect judgments about risks.[36] Consider, for example, the remarkable fact that stock prices increase significantly on sunny days, a fact that is hard to explain in terms that do not rely on affect.[37] With respect to risks, affect often operates as a kind of mental shortcut, substituting itself for a more careful inquiry into consequences.[38] Something very much of this sort has happened with the Bush Administration's suspension of the arsenic standard, partly because of skepticism about President Bush, but mostly because of the associations of arsenic. "If there is one thing we all seem to agree on is that we do not want arsenic in our drinking water. It is an extremely potent human carcinogen .... It is this simple: arsenic is a killer."[39] We could easily imagine public outrage over any decision to allow arsenic in drinking water, even if the permissible level were exceedingly low. The outrage would likely be promoted by cascade effects in which people's concern would

31. ARSENIC AND OLD LACE (Warner Bros. 1944).

32. PAUL MUSHAK, NATURAL RES. DEF. COUNCIL, ARSENIC AND OLD LAWS: A SCIENTIFIC AND PUBLIC HEALTH ANALYSIS OF ARSENIC OCCURRENCE IN DRINKING WATER, ITS HEALTH EFFECTS, AND EPA'S OUTDATED ARSENIC TAP WATER STANDARD (2000), *available at* http://www.nrdc.org/water/drinking/arsenic/exesum.asp.

33. *See* SLOVIC, *supra* note 14, at 285–314.

34. *Id.* at 291.

35. *See* Appendix.

36. *See* SLOVIC, *supra* note 14, at 413–27.

37. David A. Hirshleifer & Tyler G. Shumway, *Good Day Sunshine: Stock Returns and the Weather* (2001), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=265674.

38. *See* SLOVIC, *supra* note 14, at 413–27.

39. 147 CONG. REC. H4744 (daily ed. July 27, 2001) (statement of Rep. Waxman).

be heightened by the fact that other people were concerned. Indeed, the Bush Administration's suspension of the arsenic rule seems to have created a cascade effect in which many people objected to the suspension because other (reasonable) people seemed to have objected.[40] In fact one of the most compelling arguments, within both the House of Representatives and the public at large, was that other countries regulated arsenic at the level of stringency proposed in the Clinton Administration.[41] The practices of other countries seemed to operate as a kind of mental shortcut, showing what it is right to do—notwithstanding the reasonable questions that might be asked about the scientific bases for those practices.

There is a deeper point here. The problems in intuitive toxicology and the crudeness of the affect heuristic seem strongly to support the use of CBA,[42] understood not as a way to stop regulation, but to ensure that when government acts, it does so with some understanding of the likely consequences. CBA might well be understood as a way of moving beyond intuitive toxicology toward a form of toxicology that is actually supported by data. This point raises some much larger issues, involving significant trends in the nature of government regulation, to which I now turn.

B. THE EMERGING COST-BENEFIT STATE

More than any other federal statute, the SDWA, as a result of the 1996 amendments, reflects a strong commitment to cost-benefit balancing. The rise of interest in cost-benefit balancing signals a dramatic shift from the initial stages of national risk regulation. Those stages were undergirded by what might be called "1970s environmentalism," which placed a high premium on immediate responses to long-neglected problems, emphasized the existence of problems rather than their magnitude, and was often rooted in moral indignation directed at the behavior of those who created pollution and other risks to safety and health.[43] Important aspects of 1970s environmentalism can be found in the apparently cost-blind national ambient air quality provisions of the Clean Air Act[44] and in statutory provisions requiring that standards be set by reference to "the best available technology" without a requirement of cost-benefit balancing or even an effort to quantify benefits.[45]

It is clear that 1970s environmentalism has done a great deal of good. It has

40. *See* David Hirshleifer, *The Blind Leading the Blind: Social Influence, Fads, and Informational Cascades*, *in* THE NEW ECONOMICS OF HUMAN BEHAVIOR 188 (Mariano Tommasi & Kathyrn Ierulli eds., 1995).

41. *See, e.g.*, 147 CONG. REC. H4743 (July 27, 2001) (statement of Rep. Bonior).

42. *See* Stephen F. Williams, *Squaring the Vicious Circle*, 53 ADMIN. L. REV. 257, 260 (2001).

43. *See* Bruce Ackerman & Richard B. Stewart, *Reforming Environmental Law: The Democratic Case for Market Incentives*, 13 COLUM. J. ENVTL. L. 171, 172–75 (1988).

44. 42 U.S.C. § 7409(b) (2000).

45. *See, e.g.*, 33 U.S.C. § 1311(b)(1)(A) (2000); 42 U.S.C. §§ 7411(a)(1), 7412(d)(2), 7475(a)(4), 7502(c)(1) (2000).

helped to produce dramatic improvements in many domains, above all in the context of air pollution, where ambient air quality has improved for all major pollutants.[46] Indeed, 1970s environmentalism appears, by most accounts, to survive cost-benefit balancing, producing aggregate benefits in the trillions of dollars, well in excess of the aggregate costs.[47] But even though the overall picture is no cause for alarm, a closer look at federal regulatory policy shows a wide range of problems.

Perhaps foremost is the problem of exceptionally poor priority-setting, with substantial resources sometimes going to small problems and with little attention paid to some serious problems.[48] The point has been dramatized by repeated demonstrations that some regulations create significant substitute risks[49]—and that with cheaper, more effective tools, regulation could achieve its basic goals while saving billions of dollars.[50] According to one study, each embodying admittedly rough calculations, better allocations of health expenditures could save 60,000 additional lives each year at no additional cost—and better allocations could maintain the current level of lives saved with $31 billion in annual savings.[51]

In these circumstances, the most attractive parts of the movement for CBA have not been rooted in especially controversial judgments about what government ought to be doing. They have been rooted instead in a more mundane search for pragmatic instruments designed to reduce the problems of poor priority-setting, excessively costly tools, and inattention to the unfortunate side-effects of regulation. By drawing attention to costs and benefits, it should be possible to spur the most obviously desirable regulations, to deter the most obviously undesirable ones, to encourage a broader view of consequences, and to promote a search for least-cost methods of achieving regulatory goals.[52] Notice here that so defended, CBA is not only an obstacle to unjustified regulation; it should be a spur to government as well, showing that regulation should attend to neglected problems. If cost-benefit balancing is supported on these highly pragmatic grounds, the central question is whether that form of

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46. *See* Richard D. Morgenstern & Marc K. Landy, *Economic Analysis: Benefits, Costs, Implications*, *in* ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT 455, 455–56 (Richard D. Morgenstern ed., 1997); Paul R. Portnoy, *Air Pollution Policy*, *in* PUBLIC POLICIES FOR ENVIRONMENTAL PROTECTION 77, 101–05 (Paul R. Portnoy & Robert N. Stavins eds., 2000).

47. *See* Portnoy, *supra* note 46, at 101–05.

48. *See* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 10–11, 18–23 (1993).

49. *See* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Wiener eds., 1995).

50. *See, e.g.*, A. DENNY ELLERMAN ET AL., MARKETS FOR CLEAN AIR: THE U.S. ACID RAIN PROGRAM 253–56 (2000); Robert N. Stavins, *Market-Based Environmental Policies*, *in* PUBLIC POLICIES FOR ENVIRONMENTAL PROTECTION, *supra* note 46, at 31, 35–55.

51. *See* Tammy O. Tengs et al., *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness*, 15 RISK ANALYSIS 369 (1995).

52. For many examples, see ECONOMIC ANALYSES AT EPA, *supra* note 46.

balancing is actually producing what can be taken as policy improvements by people with diverse views about appropriate policy.

On these counts, the record of CBA—at least within the EPA—is generally encouraging.[53] Assessments of costs and benefits has, for example, helped produce more stringent and rapid regulation of lead in gasoline, promoted more stringent regulation of lead in drinking water, led to stronger controls on air pollution at the Grand Canyon and the Navajo Generating Station, and produced a reformulated gasoline rule that promotes stronger controls on air pollutants.[54] In these areas, CBA, far from being only a check on regulation, has indeed spurred government attention to serious problems.

CBA has also led to regulations that accomplish statutory goals at lower cost, or that do not devote limited private and public resources to areas where they are unlikely to do much good. For regulation of sludge, protection of farm workers, water pollution regulation for the Great Lakes, and controls on organic chemicals, CBA helped regulators produce modifications that significantly reduced costs.[55] With respect to asbestos, an analysis of benefits and costs led the EPA to tie the schedule for phasing down (and eventually largely eliminating) asbestos to the costs of substitutes and also to exempt certain products from a flat ban.[56] With respect to lead in gasoline and control of chlorofluorocarbons (destructive of the ozone layer), CBA helped promote the use of economic incentives rather than command-and-control regulation.[57] In this case, economic incentives are much cheaper and make more stringent regulation possible in the first place. For modern government, one of the most serious problems appears to be not agency use of CBA, but frequent noncompliance with executive branch requirements that agencies engage in such analysis.[58]

Of course, CBA is hardly uncontroversial.[59] Insofar as both costs and benefits are measured by the economic criterion of "private willingness to pay," there are many problems. Poor people often have little ability and hence little willingness to pay. Some people will be inadequately informed and hence show unwillingness to pay for benefits that would make their lives go better.[60] Perhaps regulatory agencies should seek not private willingness to pay, but public judgments as expressed in public arenas.[61] Society is not best taken as

53. *See id.*

54. *See* Morgenstern & Landy, *supra* note 46, at 457–58.

55. *See id.* at 458.

56. *See id.*

57. *See* James K. Hammitt, *Stratospheric-Ozone Depletion*, *in* ECONOMIC ANALYSES AT EPA, *supra* note 46, at 131; Albert L. Nichols, *Lead in Gas*, *in* ECONOMIC ANALYSES AT EPA, *supra* note 46, at 49.

58. *See* Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489, 1489–90 (2002).

59. For a general challenge to quantification, see Heinzerling, *supra* note 16.

60. *See* Matthew D. Adler & Eric A. Posner, *Implementing Cost-Benefit Analysis When Preferences Are Distorted*, *in* COST-BENEFIT ANALYSIS, *supra* note 6, at 269, 292–94.

61. Many of these points are pressed in ELIZABETH ANDERSON, VALUE IN ETHICS AND ECONOMICS 204–10 (1993).

some maximizing machine in which aggregate output is all that matters. Sometimes a regulation producing $5 million in benefits but $6 million in costs will be worthwhile, if those who bear the costs (perhaps representing dollar losses alone?) can do so easily, and if those who receive the benefits (perhaps representing lives and illnesses averted?) are especially needy.

In view of these problems, the strongest arguments for cost-benefit balancing are based not only—or even mostly—on neoclassical economics, but also on an understanding of human cognition, on democratic considerations, and on an assessment of the real-world record of such balancing.[62] All of these points are directly relevant to the arsenic controversy. Begin with cognition: Ordinary people have difficulty calculating probabilities, and they tend to rely on rules of thumb, or heuristics, that can lead them to make systematic errors.[63] CBA is a natural corrective here. Because of intense emotional reactions to particular incidents, people often make mistakes in thinking about the seriousness of certain risks.[64] Cost-benefit balancing should help government resist demands for regulation that are rooted in misperceptions of facts. Unless people are asked to seek a full accounting, they are likely to focus on small parts of problems, producing inadequate or even counterproductive solutions.[65] CBA is a way of producing that full accounting.

With respect to democracy, the case for CBA is strengthened by the fact that interest-groups are often able to use these cognitive problems strategically, thus fending off regulation that is desirable or pressing for regulation when the argument on its behalf is fragile.[66] Here CBA, taken as an input into decisions, can protect democratic processes by exposing an account of consequences to public view. With respect to pragmatic considerations, a review of the record suggests that cost-benefit balancing leads to improvements, not on any controversial view of how to value the goods at stake, but simply because such balancing can lead to more stringent regulation of serious problems, less costly ways of achieving regulatory goals, and a reduction in expenditures for problems that are, by any account, relatively minor.[67] All of these points help explain the content of the SDWA, as we shall now see.

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62. I attempt to develop this point in Cass R. Sunstein, *Cognition and Cost-Benefit Analysis*, 29 J. LEGAL STUD. 1059, 1103 (2000). In the same vein, see Allan Gibbard, *Risk and Value*, *in* VALUES AT RISK 94–112 (Douglas MacLean ed., 1986).

63. *See* Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, *in* JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 3, 11 (Daniel Kahneman et al. eds., 1982); *see generally* Roger G. Noll & James E. Krier, *Some Implications of Cognitive Psychology for Risk Regulation*, 19 J. LEGAL STUD. 747 (1990).

64. *See* George F. Loewenstein et al., *Risk As Feelings*, 127 PSYCHOL. BULL. 267, 272–79 (2001).

65. *See* DIETRICH DORNER, THE LOGIC OF FAILURE: RECOGNIZING AND AVOIDING ERROR IN COMPLEX SITUATIONS 186 (1996).

66. *See* Timur Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 724–29 (1999).

67. *See* Morgenstern & Landy, supra note 46, at 457–59.

II. DRINKING WATER: CONGRESS AND THE EPA

A. STATUTORY BACKGROUND

Regulatory statutes typically instruct agencies to require as much as "feasible"[68] or to "protect the public health."[69] Only a few such statutes expressly require agency decisions to turn on cost-benefit balancing.[70] The SDWA is an intriguing hybrid, combining an analysis of public health and feasibility with reference to CBA as well. Indeed, the cost-benefit provisions of the SDWA go as far as any other federal statute in requiring close attention to costs and benefits, and because Congress has been quite interested in imposing more general cost-benefit requirements,[71] the SDWA might well be a harbinger of the future. For this reason alone, the implementation of the statute is worth careful attention.

More particularly, the SDWA asks the EPA to proceed in three steps. First, the EPA is asked to set "maximum contaminant level goals" (MCLG) for water pollutants.[72] The goals must be set "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[73] In practice, this statutory standard will frequently call for a MCLG of zero because many contaminants cannot be shown to have safe thresholds and because the "adequate margin of safety" language will, in these specific circumstances, seem to support a zero MCLG.[74] Second, the EPA is told to specify "a maximum contaminant level [MCL] for such contaminant which is as close to the maximum contaminant level goal as is feasible."[75] The statute defines feasible (not terribly helpfully) to mean "feasible with the use of the best technology, treatment techniques and other means which the [EPA] finds . . . are available."[76] Third, the EPA is required to undertake a risk assessment for pollutants, discussing the level of the danger and the costs of achieving the requisite reduction.[77] The risk assessment is supposed to give an account, for the MCL being considered and for all alternative levels being

68. *See, e.g.*, 29 U.S.C. § 655(b)(5) (2000) ("feasible"); 42 U.S.C. §§ 7521 (a)(3)(A) (2000) ("will be available"), 7412(d)(2) (2000) ("achievable"), 7411(a)(1) (2000) ("has been adequately demonstrated").

69. 42 U.S.C. § 7409(b)(1) (2000).

70. *See, e.g.*, Toxic Substances Control Act, 15 U.S.C. §§ 2601–2692 (2000); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2000).

71. *See* CASS R. SUNSTEIN, FREE MARKETS AND SOCIAL JUSTICE 356–65 (1997).

72. 42 U.S.C. § 300g-1(b)(4)(A) (2000).

73. *Id.*

74. *See* Drinking Water Regulations, 56 Fed. Reg. 26,460 (June 7, 1991) (codified at 40 C.F.R. pts. 141, 142) (establishing a goal of zero for lead); National Primary Drinking Water Regulations, 66 Fed. Reg. 6976 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142) (establishing a goal of zero for arsenic). *But see* Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C. Cir. 2000) (invalidating a chloroform regulation on ground that setting a MCLG of zero was arbitrary and capricious).

75. 42 U.S.C. § 300g-1(b)(4)(B).

76. *Id.* § 300g-1(b)(4)(D).

77. *Id.* § 300g-1(b)(3).

considered, of the "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record";[78] the "[q]uantifiable and nonquantifiable costs";[79] the "incremental costs and benefits associated with each alternative";[80] and "[a]ny increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants."[81]

The risk assessment is no mere disclosure provision. The SDWA expressly permits—but does not require—the EPA to set a MCL at a level other than the feasible level if it determines that the benefits of that level "would not justify the costs of complying with the level."[82] On the basis of that determination, the EPA is permitted to set a maximum level "that maximizes health risk reduction benefits at a cost that is justified by the benefits."[83] Courts are authorized to review the EPA's judgment about whether the benefits of a certain level justify the costs, but only by asking whether that judgment is "arbitrary and capricious."[84]

What does all this mean? The SDWA is quite different from the Toxic Substances Control Act (TSCA), which expressly requires the EPA to base decisions on a simple comparison of costs and benefits.[85] The SDWA is more indirect, even circuitous, in its endorsement of cost-benefit requirements. But the difference between the SDWA and the TSCA is more apparent than real. In regulating contaminants in drinking water, the EPA is required to show that its judgment about cost-benefit balancing is not "arbitrary," and this standard is essentially the same as applied under the TSCA.[86] Perhaps the SDWA gives the EPA somewhat more room for the exercise of discretion. But at most, the difference is one of degree. It is clear that courts are authorized to invalidate an arbitrary or unreasoned assessment on the cost or benefit side or on the question of whether the benefits justify the costs. As we shall see, this point raises many questions for the future.

B. ARSENIC AND THE FEDERAL GOVERNMENT

Arsenic is commonly found in nature as a part of the mineral compound arsenopyrite.[87] As a result of soil and rock erosion, arsenic is released into the

78. *Id.* § 300g-1(b)(3)(C)(i)(I).
79. *Id.* § 300g-1(b)(3)(C)(i)(III).
80. *Id.* § 300g-1(b)(3)(C)(i)(IV).
81. *Id.* § 300g-1(b)(3)(C)(i)(VI).
82. *Id.* § 300g-1(b)(6)(A).
83. *Id.*
84. *Id.* § 300g-1(b)(6)(D).
85. *See* 15 U.S.C. §§ 2601–2692; *see also* Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).
86. *See Corrosion Proof Fittings*, 947 F.2d 1201.
87. *See* Karen Breslin, *Removing Arsenic from Drinking Water*, 106 ENVTL. HEALTH PERSP. A548 (Nov. 1998), *available at* http://ehpnet1.niehs.nih.gov/docs/1998/106-11/innovations-abs.html.

water supply, where it can be found in many regions, including New England, eastern Michigan, and the southwestern United States.[88] It has long been known that arsenic can be toxic,[89] even carcinogenic,[90] and since 1942, the EPA has had in place an arsenic regulation calling for an MCL of 50 ppb.[91] But in the past decades, some evidence has suggested that arsenic may have significant adverse effects at levels well below the 50 ppb standard. The principal evidence comes from epidemiological studies in Chile, Argentina, and above all Taiwan. The evidence from these studies suggests that exposure levels of 300 to 600 ppb cause significant increases of various cancers and other adverse effects.[92] These levels are of course far higher than 50 ppb; but if we extrapolate from the risk at high levels to what might well happen at lower levels, there could be serious reason for concern. I will return to this point shortly.

In 1996, Congress directed the EPA to propose a new standard for arsenic by January 1, 2000.[93] At the same time, Congress told the National Academy of Sciences and the EPA to study the health effects of arsenic in order to assist the rulemaking effort.[94] In 1996, the EPA requested that the National Research Council (NRC) of the National Academy of Sciences conduct an independent review of arsenic toxicity data and recommend changes to the EPA's arsenic criteria.[95] In its 1999 report, the NRC located few studies that examined arsenic effects at low-level concentrations and even fewer studies in agreement.[96] A 1995 Japanese study found cancer mortality near or below expectation among persons exposed to arsenic in drinking water at less than 50 ppb.[97] Domestic research in the same year revealed no association between bladder cancer risk and arsenic exposure, where eighty-one of eighty-eight Utah towns (ninety-two percent) had concentrations below 10 ppb, and only one town exceeded the 50 ppb standard.[98] A 1999 assessment of Utah mortality rates, which the EPA described as "the best U.S. study currently available,"[99] found no increased

88. *Id.*

89. For recent overviews, see Knashawn H. Morales et al., *Risk of Internal Cancers from Arsenic in Drinking Water*, 108 ENVTL. HEALTH PERSP. 655 (July 2000), *at* http://ehpnet1.niehs.nih.gov/docs/2000/108p655-661morales/abstract.html.

90. *See* SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, *supra* note 4, at 83.

91. National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 6977–79 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

92. *See id.* at 7001–03.

93. 42 U.S.C. § 300g-1(b)(12)(iv) (2000).

94. *Id.* § 300g-1(b)(12)(A)(ii).

95. *See* SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, *supra* note 4, at 1–3.

96. *Id.* at 83–130.

97. Toshihide Tsuda, et al., *Ingested Arsenic and Internal Cancer: A Historical Cohort Study Followed for 33 Years*, 141 AM. J. EPIDEMIOLOGY 198, 206 (1995); *see also* SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, *supra* note 4, at 99 (finding results statistically unstable).

98. Michael N. Bates et al., *Case-Control Study of Bladder Cancer and Arsenic in Drinking Water*, 141 AM. J. EPIDEMIOL. 523, 525–26 (1995).

99. National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 7002 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

bladder or lung cancer risks after exposure to arsenic levels of 14 to 166 ppb per liter.[100] More recent studies in Finland and Taiwan, however, linked increased risks of bladder cancer and cerebrovascular disease to groundwater arsenic consumption as low as 0.1 to 50 ppb.[101] The Taiwan study, with its significant population base, seemed especially impressive.[102]

These results could have led the NRC in several different directions. It would not have been entirely astonishing for the NRC to find that the evidence was too inconclusive to support a new rule. Nonetheless, the NRC concluded that the Taiwan studies provided the best available evidence on human health effects of arsenic.[103] The NRC used linear extrapolations from these data to obtain cancer risks at exposure levels below 50 ppb per liter and subsequently recommended that the EPA should significantly lower its current standard.[104] Indeed, the NRC concluded that "considering the data on bladder and lung cancer noted in the studies . . . a similar approach for all cancers could easily result in a combined cancer risk on the order of 1 in 100" from exposure at 50 ppb.[105] The 1 in 100 risk figure is a special source of concern because the EPA is usually attentive to environmental risks at or below 1 in 1 million,[106] and a risk of 1 in 100 seems plainly intolerable.

Critics attacked the NRC's recommendation on the grounds that Taiwanese cooking and health practices put Taiwanese citizens at greater risk for arsenic toxicity than Americans, as demonstrated by the absence of a single report of U.S. arsenic-induced cancer.[107] The Taiwanese population is much poorer than the American population and suffers from a number of dietary and nutritional deficiencies, including a higher intake of arsenic from food and a deficiency in selenium, zinc, and vitamin B12, all of which can reduce the toxicity of arsenic. Animal studies even suggest the possibility that arsenic may be a nutritional requirement, though there is insufficient data to indicate any nutritional role in human health.[108] Despite these criticisms, the EPA relied heavily upon the NRC's scientific conclusions when redeveloping its current MCL.

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100. Denise Riedel Lewis et al., *Drinking Water Arsenic in Utah: A Cohort Mortality Study*, 107 ENVTL. HEALTH PERSP. 359, 362 (1999), *available at* http://ehpnet1.niehs.nih.gov/docs/1999/107p359-365lewis/abstract.html. The EPA discounted these results in its final MCL report based upon the already low cancer rates of the subject population when compared to the entire state.

101. H.Y. Chiou et al., *Arsenic Methylation Capacity, Body Retention, and Null Genotypes of Glutathione S-transferase M1 and T1 Among Current Arsenic-Exposed Residents in Taiwan*, 386 MUTAT. RES. 197, 198 (1997); Päivi Kurttio et al., *Arsenic Concentrations in Well Water and Risk of Bladder and Kidney Cancer in Finland*, 107 ENVTL. HEALTH PERSP. 705 (1999), *available at* http://ehpnet1.niehs.nih.gov/docs/1999/107p705-710kurttio/abstract.html.

102. SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, *supra* note 4, at 17.

103. *Id.* at 7.

104. *Id.* at 8–9.

105. *See* ABT ASSOCIATES, *supra* note 23, at 1-1 (quoting NRC report).

106. *See* ROBERT PERCIVAL ET AL., ENVIRONMENTAL LAW 442 (3d ed. 2000).

107. *See* Sue E. Umshler, *When Arsenic is Safer in Your Cup of Tea Than in Your Local Water Treatment Plant*, 39 NAT. RESOURCES J. 565, 589–92 (1999); *see also* National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 7003–04 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

108. Umshler, *supra* note 107, at 587.

In 2000, the EPA issued a proposed regulation setting an MCLG of 0 ppb, on the ground that no safe level could be identified; an MCL of 3 ppb, on the ground that this was the lowest feasible level; and a regulatory ceiling of 5 ppb, on the ground that the CBA justified this approach but not any more stringent mandate.[109] The EPA also requested comments on regulatory ceilings of 3, 10, and 20 ppb, for which it provided accounts of both benefits and costs. On January 22, 2001, the EPA issued a final rule that essentially embodied the same analysis as the proposal, but with a crucial change to a regulatory ceiling of 10 ppb rather than 5 ppb.[110] The EPA urged that its assessment of costs and benefits for the four different levels of stringency justified the 10 ppb level.[111] The rule was to become effective on March 23, 2001, with a compliance date of January 23, 2006.[112]

1. Costs

The new regulation would have required several thousand water systems—serving about 10 million people—to install new equipment.[113] The overall cost of the 10 ppb standard would have been about \$206 million.[114] This aggregate figure is not entirely informative because the additional payments would vary considerably across the nation. For most households, the annual increase in water bills would be in the range of \$30.[115] Water systems with 500 or fewer customers, however, would face significantly higher costs, ranging up to \$325 per household.[116] These water systems represent a small fraction of the total number of people affected by arsenic, and they tend to involve rural communities.

As it was required to do, the EPA also calculated the costs of alternative levels of regulation. A 20 ppb standard would cost about \$70 million; a 5 ppb standard, \$470 million; and a 3 ppb standard, \$790 million.[117] Here, too, the disaggregated figures are important. The most stringent standard of 3 ppb would cost an average of \$41 per affected household, while the 20 ppb standard would cost about an average of \$24.[118] At the extremes, the 20 ppb standard is actually more expensive (\$351) than the 3 ppb standard (\$317), because of the particular control technologies that would be involved.[119] Consider the following summary:

109. National Primary Drinking Water Regulations, 65 Fed. Reg. 38,888 (proposed June 22, 2000).
110. National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 6981 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).
111. *Id.* at 6979.
112. *Id.* at 6976.
113. *Id.*
114. *Id.* at 7010.
115. *Id.* at 7011.
116. *Id.*
117. *Id.* at 7010.
118. *Id.* at 7011.
119. *Id.*

Table 1
Mean Annual Costs Per Household[120]
(in 1999 dollars)

System Size	3 ppb	5 ppb	10 ppb	20 ppb
Less than 100	317	318.26	326.82	351.15
101-500	166.91	164.02	162.50	166.72
501-1000	74.81	73.11	70.72	68.24
1001-3300	63.76	61.94	58.24	54.36
3301-10,000	42.84	40.18	37.71	34.63
10,001-50,000	38.40	36.07	32.37	29.05
50,001-100,000	31.63	29.45	24.81	22.64
100,001-1,000,000	25.29	23.34	20.52	19.26
More than 1,000,000	7.41	2.79	0.86	0.15
All categories	41.34	36.95	31.85	23.95

The EPA did not offer a population-wide breakdown to show the numbers of people served by the various system sizes and to examine whether the people who would bear the costs could do so easily or with difficulty. One analysis, admittedly from a group with a particular point of view, suggests that eighty-seven percent of people who consume arsenic at a significant level in their tap water (over 1 ppb) are served by systems serving more than 10,000 customers.[121] This data suggests that almost nine out of ten of the people who will have to pay for water technology would face annual increases of less than $30—not entirely trivial perhaps, but certainly not a huge expenditure.

2. Benefits

Within the EPA, the much harder issues involved the benefits of the 10 ppb requirement.[122] The most easily quantified benefits involve prevented cases of bladder and lung cancer; here the epidemiological data, mostly from Taiwan, allowed quantitative estimates to be made.[123] For two reasons, however, even these estimates should be taken with some grains of salt. The first reason is that there are differences between the population of Taiwan and that of the United States.[124] The second reason is that a great deal turns on the nature of the

120. *Id.*

121. MUSHAK, *supra* note 32, at ch. 3.

122. I emphasize that I am dealing here with the evidence at the time of the decision and that subsequent evidence appears to have strengthened the case for stringent regulation. See SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, *supra* note 13.

123. 66 Fed. Reg. at 7001–04.

124. *Id.* at 7003–04.

dose-response curve. If the curve is "linear," meaning that cancer cases do not drop sharply at low exposure levels, many more cancers will be predicted than if the curve is "sublinear," meaning that after exposure declines to a certain level, the number of cancer cases drops off.[125] Lacking any data on the question, the EPA decided to assume that the dose-response curve is linear, noting that "[t]he use of a linear procedure to extrapolate from a higher, observed data range to a lower range beyond observation is a science policy approach that has been in use by Federal agencies for four decades."[126] The EPA added that the policy objectives were "to avoid underestimating risk in order to protect public health and be consistent and clear across risk assessments."[127] From these remarks, it seems clear that the default assumption of linearity is not based on science—which cannot produce a standard default assumption—but on a policy judgment, designed to err on the side of protecting health by ensuring against underestimation of the risks. I will return to this important issue below.[128]

Armed with the assumption of linearity, the EPA thought that estimates were feasible for bladder and lung cancer and calculated bladder and lung cancer risks using the analysis of the NRC.[129] The NRC used the Taiwan data to calculate a 1 to 1.5 per 1000 lifetime risk of male fatal bladder cancer at the current 50 ppb standard; it also examined the Chile and Argentina studies and concluded the rates of cancer were comparable to the Taiwan data.[130] The EPA assessed lung cancer risks, which are known to be two to five times greater than bladder cancer risks, but for many of the health effects from arsenic, the EPA concluded that quantification was impossible.[131]

a. Lives and Health: Quantities. The EPA estimated that the 10 ppb requirement would prevent twenty-one to thirty cancer deaths and sixteen to twenty-six cases of curable cancer.[132] By comparison, a 20 ppb requirement would prevent ten to eleven deaths and nine curable cancers; a 5 ppb requirement, twenty-nine to fifty-four deaths and twenty-two to forty-seven curable cancers; and a 3 ppb

125. *Id.* at 7004.

126. *Id.* In selecting its dose-response model, the EPA examined a 2000 study by Morales which presented ten potential dose-response models based upon interpretations of the original Taiwan data. Morales et al., *supra* note 89. The EPA rejected those models with a comparison population because they resulted in supralinear dose-response relationships (higher than a linear response). 66 Fed. Reg. at 7006. The EPA concluded that there was no basis for this type of relationship because the NRC report had concluded that the dose-response relationship for arsenic at low levels should be either linear or sublinear, with a preference for the latter. *Id.* The EPA chose the linear model based upon the above-mentioned policies. These various points are treated in detail below.

127. 66 Fed. Reg. at 7004.

128. *See* discussion *infra* section IV.A.1.

129. 66 Fed. Reg. at 7006.

130. *Id.*

131. *Id.* at 7006, 7011.

132. *Id.* at 7009.

requirement, thirty-three to seventy-four cancer deaths and twenty-five to sixty-four curable cancers.[133] Consider the following table:

Table 2
Annual Total of Bladder and Lung Cancer Cases Avoided[134]

Arsenic Level (ppb)	Reduced Mortality Cases	Reduced Morbidity Cases	Total Cancer Cases Avoided
3	32.6–74.1	24.6–64.2	57.2–138.3
5	29.1–53.7	22.0–46.5	51.1–100.2
10	21.3–29.8	16.1–25.9	37.4–55.7
20	10.2–11.3	8.5–8.8	19.0–19.8

b. Lives and Health: No Quantities. The EPA also concluded that the 10 ppb standard would produce "important non-quantified benefits .... Chief among these are certain health impacts known to be caused by arsenic, though, while they may be substantial, the extent to which these impacts occur at levels below 50 [ppb] is unknown."[135]

The relevant effects include several kinds of cancer: skin, kidney, liver, prostate, and nasal passages.[136] They also include pulmonary, cardiovascular, immunological, neurological, and endocrine effects.[137] To these health effects, the EPA added that there would be other benefits that would defy quantification. Among these benefits is "the effect on those systems that install treatment technologies that can address multiple contaminants."[138] Some of the technologies that would reduce arsenic levels would also remove "many other contaminants that [the] EPA is in the process of regulating or considering regulating."[139]

c. Converting Quantities to Dollars. To compare the quantified benefits of regulation with the $206 million cost, the EPA was required to engage in several exercises in conversion. With respect to lives saved, the EPA used a value of a statistical life of $6.1 million.[140] That figure was derived by calculating the average of over two dozen studies, conducted mostly in the 1970s and generally designed to show how much an employer had to pay employees to compensate for a statistical risk of death.[141] By multiplying the number of expected mortali-

133. *Id.*
134. *Id.*
135. *Id.* at 7012.
136. *Id.* at 7011.
137. *Id.*
138. *Id.* at 7012.
139. *Id.*
140. *Id.*
141. *Id.*

ties by $6.1 million, the EPA obtained most of the "dollar value" of the arsenic regulation.[142]

As noted, however, many of the cancers caused by arsenic are not fatal. For a nonfatal cancer, the EPA used a figure of $607,000.[143] This figure does not come from measurements of people's willingness to pay to reduce a statistical risk of nonfatal cancer, but instead—and somewhat astonishingly[144]—from shoppers' responses to hypothetical questions about how much they would be willing to pay to reduce a statistical risk of chronic bronchitis.[145] Apparently, the EPA thought that this was the closest available analogue to a nonfatal cancer.

3. Summary of the EPA's Analysis

The EPA's basic analysis is captured in the following table.

Table 3
Estimated Benefits from Reducing Arsenic in Drinking Water[146]
(millions of 1999 dollars)

Arsenic Level (ppb)	Total Quantified Health Benefits, in Millions (Lower and Upper Bounds)	Potential Nonquantified Health Benefits (Applies to All Levels)
3	$213.8–$490.9	Skin cancer, kidney cancer
5	$191.1–$355.6	Cancer of nasal passages, liver cancer
10	$139.6–$197.7	Prostate cancer, cardiovascular effects
20	$66.2–$75.3	Pulmonary, neurological, endocrine effects

The monetized costs of the 10 ppb standard are between $2 million and $60 million higher than the monetized benefits—and the overall benefits are in line with overall costs only at the 20 ppb level.[147] The EPA was well aware of this point. Nonetheless, it concluded that once the nonquantified benefits of the 10 ppb standard were included, the costs would be well justified. The cost per cancer case avoided for the final rule would be between $3.2 million and $4.8

142. *Id.*
143. *Id.*
144. The EPA's decision to this effect is sharply criticized in ARSENIC RULE BENEFITS REVIEW PANEL, ENVTL. PROT. AGENCY, ARSENIC RULE BENEFITS ANALYSIS: AN SAB REVIEW 17 (2001), *available at* www.epa.gov/sab/pdf/ec01008.pdf, suggesting an upper bound of $3.6 million and a lower bound of $607,000; the use of the $3.6 million upper bound would dramatically alter the calculation.
145. 66 Fed. Reg. at 7012.
146. *Id.*
147. *Id.* at 7017.

million—hardly an extraordinary price to pay, and far lower than the $5 million to $12.2 million range produced by a 3 ppb standard.[148]

III. PEER REVIEW? ARSENIC AT AEI-BROOKINGS

The EPA's conclusion was sharply criticized by a widely reported paper from the AEI-Brookings Joint Center for Regulatory Studies.[149] The authors, Jason Burnett and Robert Hahn, concluded that the costs of the rule would exceed the benefits by about $190 million each year and hence that the rule deserved membership in the Joint Center's' "$100 million club," which includes regulations that cost at least $100 million more than they promise to deliver. For two reasons, the Burnett-Hahn study is worth close attention. First, the AEI-Brookings Joint Center is highly respected for its careful work on CBA, and Hahn is an especially able and influential observer of the regulatory process.[150] Second, the disagreements between the EPA and the Joint Center provide a great deal of information about the nature of CBA itself and the likely nature of legal challenges to such analysis by federal agencies. Burnett and Hahn raised no questions about the EPA's finding of a $200 million cost to the arsenic rule. Instead, they made several key adjustments to the EPA's calculation of benefits. The first set of adjustments involved the actual number of cancer cases to be prevented. The second set involved the translation of that figure into a dollar number.

To calculate cancer cases, Burnett and Hahn made two changes. First, they attempted to quantify the "nonquantifiable benefits" by multiplying the EPA's estimate of twenty-eight lives saved by two, for a total of fifty-six.[151] They reasoned that "including 'nonquantifiable risks' would increase the lives-saved estimate by some factor between one and four."[152] This number came from the report of the NRC, which suggests that the risk of death from all kinds of cancer might be eight times the risk of bladder cancers. Recognizing that the EPA's quantified figure represents both bladder and lung cancers, Burnett and Hahn took a multiple of four as producing a "reasonable upper bound" of 112; but they decided to use the fifty-six estimate because it seemed more reasonable.[153]

Second, Burnett and Hahn divided their chosen number of fifty-six by five to reflect their judgment that the risk of arsenic is not linearly related to arsenic concentrations. They explained that "[t]his assumption is not realistic because the human body can metabolize arsenic at low levels, rendering it nontoxic."[154]

148. *Id.* at 7018.

149. *See* JASON K. BURNETT & ROBERT W. HAHN, AMERICAN ENTERPRISE INSTITUTE-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES, EPA'S ARSENIC RULE: THE BENEFITS OF THE STANDARD DO NOT JUSTIFY THE COSTS (2001), *available at* http://aei.brookings.org/admin/pdffiles/reg_analysis_01_02.pdf. Note that I serve on the advisory board of the Joint Center.

150. *See e.g.*, RISKS, COSTS, AND LIVES SAVED (Robert W. Hahn ed., 1997).

151. BURNETT & HAHN, *supra* note 149, at 7.

152. *Id.*

153. *Id.*

154. *Id.* at 5.

(Note that the EPA concluded that recent research has drawn into doubt the claim that the metabolized forms of arsenic are any less toxic.[155]) According to Burnett and Hahn, the upshot is that the new regulation would save about eleven lives annually.[156]

To translate this amount into dollar terms, Burnett and Hahn adjusted the $6.1 million figure downward. They emphasized that cancer follows exposure to arsenic not immediately but only after a latency period ranging from ten to forty years.[157] Burnett and Hahn use a seven percent discount rate on the theory that "future benefits should be discounted just as future costs are."[158] As a result of the adjustment, the value of a statistical life fell to $1.1 million. Sharply disagreeing with the National Research Council's and the EPA's projected risk of 1 in 100, Burnett and Hahn added that "the risk reduction is about 1 in 1 million, which is so small as not to be worth addressing, given the uncertainties in the data and the EPA's limited resources to develop regulations."[159] Burnett and Hahn concluded that no plausible version of the arsenic proposal going beyond the existing 50 ppb standard could be justified on cost-benefit grounds. Here is their overview:

Table 4
AEI-Brookings Joint Center Estimates[160]

	Lives Saved	Benefits	Costs	Net Costs
EPA's Model Without Accounting for Latency	28	$170 million	$210 million	$40 million
EPA's Model Accounting for Latency	28	$50 million	$210 million	$160 million
Our High Estimate	110	$200 million	$210 million	$10 million
Our Best Estimate	11	$23 million	$210 million	$190 million
Our Low Estimate	5.5	$10 million	$210 million	$200 million

155. *See* National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 7000 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142); H. Vasken Aposhian et al., *Occurrence of Monomethylarsonous Acid in Urine of Humans Exposed to Inorganic Arsenic*, 13 CHEMICAL RES. TOXICOLOGY 693, 696 (2000); Jay S. Petrick et al., *Monomethylarsonous Acid (MMAiii) is More Toxic than Arsenite in Chang Liver Human Hepatocytes*, 163 TOXICOLOGY & APPLIED PHARMACOLOGY 203 (2000).

156. BURNETT & HAHN, *supra* note 149, at 7.

157. *Id.* at 6.

158. *Id.*

159. *Id.* at 8.

160. *Id.* at 14.

Burnett and Hahn go further still. They urge that the arsenic regulation is likely to produce a net loss in life rather than a gain. The reason is that expensive regulations have been found to have mortality effects, in part because they make less money available for health care expenditures.[161] According to one estimate, a statistical life is lost for every $15 million expenditure, so that a regulation that costs $15 million per life saved results in no net mortality reduction.[162] If this is correct, a regulation that costs $190 million on net is likely to result in a loss of over ten lives, on balance, every year. This in fact is the Burnett-Hahn conclusion.[163]

It is not clear if the Burnett-Hahn analysis influenced the actions of the Bush Administration, but the arsenic rule was delayed shortly after the election[164] and the EPA asked the National Academy of Sciences to produce an "expedited review" of the options between 3 ppb and 20 ppb. At the same time, the Agency sought new studies on both the cost and benefit sides.[165]

IV. Questions and Doubts

Many questions should be raised about the analysis by both the EPA and Burnett and Hahn. The first set of questions involves the judgment about the likely benefits in terms of mortality and morbidity. The second set involves the translation of those benefits into dollar equivalents.

My goal here is not to take sides on the disagreement between the EPA and Burnett and Hahn. Instead, it is to suggest that the state of scientific knowledge at the time justified only benefit ranges, not specific benefit numbers. This point easily might be taken as a challenge to CBA in general, and it is properly so taken if CBA is justified as a way of giving specific bottom lines to resolve hard cases. But if CBA is justified more modestly, as a way of getting a sense of the potential consequences of various courses of action, nothing I say here should be seen as a challenge to the basic method. Indeed, a virtue of CBA is that it helps to explain why the arsenic question is hard and why competing judgments of value could lead in competing directions. I will say more about all this below.

161. *Id.* at 2.

162. *See* Randall Lutter et al., *The Cost-Per-Life-Saved Cutoff for Safety-Enhancing Regulations*, 37 Econ. Inquiry 599, 605 (1999).

163. Burnett & Hahn, *supra* note 149, at 7.

164. National Primary Drinking Water Regulations, 66 Fed. Reg. 16,134, 16,134 (Mar. 23, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

165. National Primary Drinking Water Regulations, 66 Fed. Reg. 20,579 (Apr. 23, 2001) (codified at 40 C.F.R. pts. 9, 141, 142); Press Release, EPA, EPA Administrator Whitman Establishes Process to Evaluate Arsenic in Drinking Water Standard (Apr. 18, 2001), *available at* http://yosemite.epa.gov/opa/admpress.nsf.

A. LIFE AND HEALTH AGAIN

1. The Dose-Response Curve in General

In calculating health effects, the EPA assumed a linear dose-response curve for arsenic.[166] In so doing, it followed its usual practice, which is to assume a linear, no-threshold model for Class A carcinogens in drinking water. In the EPA's words, this is a "conservative mathematical model for cancer risk assessment" that "is consistent with a no-threshold model of carcinogenesis, i.e., exposure to even a very small amount of the substance is assumed to produce a finite increased risk of cancer."[167] Note that the EPA's Science Advisory Board, which consisted of prominent scientists who issued a report advising the Agency, also recommended linear extrapolation based upon the Taiwan data.[168]

But Burnett and Hahn are correct to urge that this was not an inevitable decision. It is quite possible that the effects of arsenic dwindle at low levels. "There is no strict rule with respect to the shape of the dose-response curve."[169] To summarize what will be a lengthy and somewhat technical discussion: On the basis of what is known about carcinogens generally, the best scientific judgment seems to be that the dose-response curve for arsenic is sublinear. But this is a speculative judgment, not based on direct evidence. In addition, we certainly do not know how sublinear the dose-response curve is, if indeed it is sublinear.

There are many complexities here, for dose-response curves come in many shapes and sizes:

> It has long been recognized that a number of different mathematical models can fit a given set of dose-response data reasonably well, but produce vastly different predictions of risk when extrapolated to doses below the data range. Thus, extrapolated doses corresponding to '*de minimis*' risk levels can differ by several orders of magnitude, depending on the shape of the dose-response curve at low doses.[170]

Often there is no evidence about the relationship between adverse effects and low doses; hence, a great deal of guesswork is involved. An overview suggests that:

> a number of models have been proposed, and there is active debate on which of these is most appropriate. One that is widely used by regulatory agencies

166. National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 6994 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

167. 40 C.F.R. pt. 132, app. C (2001).

168. *See* 66 Fed. Reg. at 7003, 7005.

169. TOXICOLOGY, *supra* note 2, at 1164.

170. Ralph L. Kodell, *U-Shaped Dose-Response Relationships for Mutation and Cancer*, 7 HUMAN AND ECOLOGICAL RISK ASSESSMENT 4, 4 (2001).

> because it is 'conservative' is a linear no-threshold extrapolation. As noted, proof has not been provided for any carcinogen that no threshold exists, and in fact, thresholds have been observed in many studies, particularly with weak carcinogens. The assumption of linearity at low doses is also not well founded. Indeed, even for the less complicated process of chemical mutagenesis *in vivo*, a drop below linearity at low doses has been demonstrated. Therefore, a 'hockey stick'-shaped curve would appear to best fit current data and concepts on carcinogenic mechanisms at low levels of exposure.[171]

There are five basic possibilities.[172]

a. Supralinearity. For some forms of radiation, the curve is actually "supralinear" in the sense that with lower doses, deaths fall at relatively lower rates than a linear curve would predict.[173] If a dose-response curve is supralinear, of course, the death rate will be higher than if it is linear. Agencies do not assume supralinearity, apparently because it is an unusual pattern. No one has urged supralinearity in the context of arsenic.

b. Linearity. It has long been assumed that linear curves are appropriate for "genotoxic" carcinogens; that is, carcinogens that work directly on DNA to produce mutations that give rise to tumors.[174] For a long time arsenic has been assumed not to be genotoxic—a point that draws the EPA's assumption of linearity into some doubt because sublinearity is the ordinary assumption for nongenotoxic carcinogens. But a recent paper suggests that arsenic may be genotoxic after all.[175]

c. Sublinearity. According to a standard text, the typical dose-response curve is "sigmoidal" in shape and thus sublinear at low doses.[176] While there is some dispute about the issue, evidence suggests that this is the shape of the dose-response curve for benzene.[177] As noted, scientists generally assume sublinear-

171. CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 154 (Mary O. Amdur et al. eds., 4th ed. 1991); *see also* D.B. Farrar & K.S. Crump, *Exact Statistical Tests for any Carcinogenic Effect in Animal Bioassays*, 15 FUNDAMENTAL APPLIED TOXICOLOGY 710 (1990); D.G. Hoel et al., *The Impact of Toxicity on Carcinogenicity Studies: Implications for Risk Assessment*, 9 CARCINOGENESIS 2045 (1988); E.M. Laska & M.J. Meisner, *Statistical Methods and Applications of Bioassay*, 27 ANNUAL REV. PHARMACOLOGY & TOXICOLOGY 385 (1987).

172. See Appendix for more detail.

173. JOHN W. GOFMAN, RADIATION-INDUCED CANCER FROM LOW-DOSE EXPOSURE: AN INDEPENDENT ANALYSIS ch. 14 (1990).

174. *See* Kodell, *supra* note 170, at 4.

175. Marc J. Mass et al., *Methylated Trivalent Arsenic Species Are Genotoxic*, 14 CHEMICAL RES. TOXICOLOGY 355, 355 (2001).

176. ENCYCLOPEDIA OF TOXICOLOGY 509 (Philip Wexler ed., 1998).

177. *See* O. Wong & G.K. Raabe, *Cell-Type-Specific Leukemia Analyses in a Combined Cohort of More Than 208,000 Petroleum Workers in the United States and United Kingdom, 1937–1989*, 21 REG. TOXICOLOGY & PHARMACOLOGY. 307, 315 (1995).

ity for substances that are nongenotoxic—that is, that do not work directly on DNA.[178]

d. Thresholds. Sometimes there is a threshold below which exposure produces no adverse effects, as is apparently the case for basal cell carcinoma—exposure to the sun[179]—and also for chloroform.[180] This is the extreme case of sublinearity. It is generally agreed that thresholds exist "for all toxicities other than cancer. . . . Conceptually, a threshold makes sense for most toxic effects."[181] Government agencies tend to treat carcinogens as lacking safe thresholds. Taken purely as a scientific judgment, this is disputed: "It is a fact that most of the identified human carcinogens induce cancer only after exposure to high doses."[182]

e. U-shapes. Some dose-response curves—like the curve for fluoride—actually show desirable effects at low levels, so that what is harmful to health at high doses turns out to produce beneficial effects at low doses.[183] This is true of course for many medicines, like aspirin, antibiotics, and antihistamines. There appears to be increasing reason to believe that u-shapes are common. "In recent years, the concept of hormesis, the phenomenon whereby a toxic substance elicits a beneficial effect at doses below its observed range of toxicity, has been gaining popularity among scientists engaged in toxicology and risk assessment."[184]

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178. I.F.H. Purchase & T.R. Auton, *Thresholds in Chemical Carcinogenesis*, 22 REG. TOXICOLOGY & PHARMACOLOGY 199, 204 (1995).

179. *See* Anne Kricker et al., *A Dose-Response Curve for Sun Exposure and Basal Cell Carcinoma*, 60 INT'L J. CANCER 482 (1995).

180. *See* Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C. Cir. 2000).

181. PRINCIPLES OF TOXICOLOGY 449 (Phillip L. Williams et al. eds., 2000).

182. TOXICOLOGY, *supra* note 2, at 176.

183. Ralph Kodell & Qi Zheng, *U-Shaped Dose-Response Curves for Carcinogenesis*, abstract available at U-Shaped Dose-Response Curves for Carcinogenesis (1999) (unpublished manuscript, on file with the author).

184. *See id.* at 11–12. The author's conclusion is worth quoting:

> For carcinogens that may exhibit U-shaped dose-response curves, traditional linear, low-dose extrapolation truly is conservative in the sense of public-health protection. However, this 'default' procedure cannot be justified simply on the basis of either presumed genotoxicity or additivity to background. If definitive data on low-dose behavior of specific carcinogens should indicate U-shaped behavior, then relaxing the default procedure to accommodate substantially lower-than-linear estimates of risk seems justified, without fear of seriously underestimating risk (EPA 1996). However, it will require strong data, of a nature and quality not customarily available, to warrant a regulatory agency's acceptance of a dose-response relationship that predicts less-than-background risk at low doses. The modeling exercise presented here provides additional support and encouragement for investigators to pursue the gathering of biologically definitive data other than typical tumor incidence data when hormesis is strongly suggested or conjectured.

Id.

2. The Dose-Response Curve in Particular

The possibility of varying shapes suggests many possible projections of the health consequences of exposure to low doses of arsenic. Without having any direct evidence for arsenic in particular, the NRC suggested: "Of the several modes of action that are considered most plausible, a sub-linear dose response curve in the low-dose range is predicted, though linearity cannot be ruled out."[185]

This statement should be taken as exceptionally speculative. It ought not to be read to suggest a reliable scientific judgment about the true dose-response curve, for the NRC offered no evidence that would justify its "prediction" for arsenic. It appears to have been generalizing from the more typical patterns. If a specific judgment is required, this approach is as sensible as any other, but it is not much more than a hunch. Nonetheless, we can reach some more definite conclusions. First: When agencies generally assume linearity, it is not because anything in the science solidly justifies this assumption, but because of a "conservative" approach to uncertain data.[186] This is a policy choice, not a technical one—a point with implications for judicial review, as we shall see. Second: Rather than setting forth a specific number, it seems best to acknowledge the uncertainty about the dose-response curve and hence to identify a range of benefits—capturing a low end and a high end.

The upshot? For arsenic in particular, the high end emerges from a linear curve and therefore would be twenty-eight lives saved annually. The low end is six lives saved annually, which is what emerges from dividing that number by five. That division is essentially arbitrary, so we should not credit the Burnett-Hahn suggestion that it is likely to be accurate.

3. Nonquantified Benefits

What about the nonquantified benefits? Here it would be certainly responsible to say, as did the EPA, that the data do not allow numerical judgments of any kind. But it would also be responsible to attempt to specify an upper and lower bound. Burnett and Hahn estimate the "nonquantified" benefits by multiplying the EPA's expected lives saved by two.[187] But this seems arbitrary. As they note, the National Research Council estimated the risk of all types of cancer as *eight* times greater than the risk from bladder cancer alone. Because the EPA's figure of twenty-eight lives saved came from both bladder and lung cancer, it would have been sensible to posit an upper bound of 112 (arrived at by multiplying twenty-eight by four). The multiplier of four is reasonable because the NRC suggested a risk eight times as high as the risk from bladder cancer, which is to

185. *See*, SUBCOMM. ON ARSENIC IN DRINKING WATER, NAT'L RESEARCH COUNCIL, *supra* note 4, at 7.

186. *But see* Adam M. Finkel, *A Second Opinion on an Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Circle*, 3 N.Y.U. ENVTL. L.J. 295, 341–45 (1995) (providing some evidence that linearity is a scientifically plausible assumption).

187. BURNETT & HAHN, *supra* note 149, at 7.

say approximately four times the risk from bladder cancer and lung cancer. If the lower bound of lives saved (from the analysis of possible sublinearity) is six, the lower bound, from that assumption, would be twenty-four.

4. Problems in Taiwan

I have suggested that there are many reasons to question the Taiwan data, which involved a poorer population with a worse diet, at risk of arsenic exposure from multiple sources other than drinking water. Another criticism of the Taiwan data is that it measures arsenic exposure by overall exposure to village wells and not individual exposure.[188] There is an additional problem. Wells within each village had varying arsenic levels (so that people using certain wells had much higher exposures than others in the same village), but not all village wells were measured, and villagers were assigned a single median concentration (the data also did not account for villagers who moved because it assumed a lifetime exposure to the levels of a subject's present village).[189] Thus the principal data on which the EPA relied did not allow precise extrapolations. The NRC explicitly acknowledged this point: "Some factors, such as poor nutrition and arsenic intake from food, might affect assessment of risk in Taiwan or extrapolation of results in the United States."[190]

On the basis of the EPA's data and with reasonable assumptions,[191] the best conclusion is that the number of lives saved by the regulation would range between 6 and 112. To say the least, that is an exceedingly wide range. If the regulation were expected to cost $6 million, it would seem reasonable to proceed; almost no one denies that a cost per life saved of $1 million is worthwhile. If the regulation were expected to cost $10 billion, it would seem reasonable not to proceed. But what if the cost fell between $6 million and $10 billion? What if the cost were about $200 million, as the EPA estimated? To make progress on that question, it is necessary to discuss the question of monetization.

B. MONETIZING

With respect to money, the principal disagreement between the EPA and Burnett and Hahn involves the appropriate discount rate. For the moment, let us put that issue to one side; I will return to it shortly. As the EPA acknowledges in its "sensitivity analysis," there are good reasons to adjust the EPA's monetized estimate upwards rather than downwards.

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188. *See* National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 7003 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

189. *Id.* at 7003–04.

190. SUBCOMM. ON ARSENIC IN DRINKING WATER, *supra* note 4, at 301.

191. *See supra* Section IV.A.2.

1. Arsenic Versus the Workplace

As I have noted, the EPA's $6.1 million figure comes from workplace risks not involving cancer and generally involving dangers to which workers expose themselves voluntarily—in the sense that they receive compensation in return. In fact many questions might be raised about the workplace risk studies.[192] One problem is the sheer variety of the number in those studies, ranging from $0.7 million to $16.3 million in 1997 dollars. Consider the following table:

Table 5
Value of Life Studies[193]

Study	Method	Value of Statistical Life (VSL) in 1997 Dollars
Kneisner and Leith (1991)	Labor market	0.7 million
Smith and Gilbert (1984)	Labor market	0.8 million
Dillingham (1985)	Labor market	1.1 million
Marin and Psacharopoulos (1982)	Labor market	3.4 million
V.K. Smith (1976)	Labor market	5.7 million
Viscusi (1981)	Labor market	7.9 million
Leigh and Folsom (1984)	Labor market	11.7 million
Leigh (1987)	Labor market	12.6 million
Garen (1988)	Labor market	16.3 million

This wide range of the outcomes raises questions about the reliability of the $6.1 million figure. The EPA updated the relevant numbers for inflation, but it did not otherwise make adjustments. On reasonable assumptions, the EPA appears to have produced a significant undervaluation of the monetary value of the lives at stake. Consider the following points.

a. Income Growth. The EPA acknowledged that the $6.1 million figure reflects no adjustment to account for changes in national real income growth. In principle, the failure to undertake an adjustment seems to be a serious mistake.

192. For several such questions, see Robert H. Frank & Cass R. Sunstein, *Cost-Benefit Analysis and Relative Position*, 68 U. CHI. L. REV. 323 (2001). For a reply, see GREGORY BESHAROV, AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES, THREE QUESTIONS ABOUT THE ECONOMICS OF RELATIVE POSITION: A RESPONSE TO FRANK AND SUNSTEIN, *available at* http://www.aei.brookings.org/publications/working/working_01_08.pdf.

193. *See* U.S. EPA, Guidelines for Preparing Economic Analyses 89 (2000), *available at* http://yosemite1.epa.gov/ee/epa/eed.nsf/pages/guidelines.

Of course people with more money would be willing to pay more, other things being equal, to reduce statistical risks. As the EPA also noted in its sensitivity analysis, the appropriate adjustment would increase the VSL from $6.1 million to $6.7 million.[194]

b. Distinctive Risks. The risk of cancer from drinking water is qualitatively different from the workplace risks that the EPA used to generate its VSL. The risks from drinking water seem peculiarly involuntary and uncontrollable, and a great deal of literature suggests that involuntary and uncontrollable risks produce greater individual concern.[195] It is important not to think that there is a rigid dichotomy between the involuntary-uncontrollable and the voluntary-controllable.[196] This is a continuum without sharp divisions among various points. The underlying issues seem to be whether those exposed to the risk are exposed knowingly and whether it is costly or otherwise difficult for people to avoid the risk. As compared to workplace risks, there can be little doubt that the risk of arsenic from drinking water is worse along the relevant dimensions. For this reason, it makes sense to think that people would be willing to pay a premium to avoid the risks associated with arsenic.

There are some related points. People seem to have a special fear of cancer, and they seem to be willing to pay more to prevent a cancer death than either a sudden unanticipated death or a death from heart disease.[197] The cancer "premium" might be produced by the dreaded nature of cancer; it seems well-established that some risks are particularly dreaded and that dreaded risks produce special social concern, holding the statistical risk constant. Some studies suggest that people are willing to pay twice as much to prevent a cancer death as an instantaneous death.[198]

The EPA was alert to these points. Its own sensitivity analysis suggests the need for an upwards revision of seven percent because of the involuntariness and uncontrollability of the risk.[199] With this revision and the revision for income growth, the value of a statistical life would rise to about $7.2 million.[200] In fact there are reasons to believe that this might be far too low. One study suggests that "the value of avoiding a death from an involuntary, carcinogenic risk should be estimated as four times as large as the value of avoiding an instantaneous workplace fatality."[201] If we take this approach, the value jumps from $6.7 million to $26.8 million.

194. National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 7012 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

195. *See* SLOVIC, *supra* note 14, at 101–02.

196. *See* Cass R. Sunstein, *Bad Deaths*, 14 J. RISK & UNCERTAINTY 259, 260 (1997).

197. *See* George Tolley et al., *State of the Art Health Values*, *in* VALUING HEALTH FOR POLICY: AN ECONOMIC APPROACH 339–40 (George Tolley et al. eds., 1993).

198. *See id.*

199. *See* 66 Fed. Reg. at 7014.

200. *See id.*

201. Revesz, *supra* note 12, at 982.

c. One More Wealth Effect. There is a final point. The studies that produced the $6.1 million figure involved the workplace, and the people involved were poorer than most workers. Because the median salary of all wage earners is twenty-three percent higher than the median salary of most workers involved in the willingness-to-pay studies, a further adjustment seems appropriate, producing a VSL of $33 million.

Now it would be foolish to claim that this figure has a unique claim to accuracy. But with different assumptions, none of them entirely implausible, the value of a statistical life at risk from arsenic can range from $1.1 million to $33 million—and the number of lives saved from 6 to 112. In terms of dollars, that produces a lower bound of $6.6 million, and an upper bound of $3.7 billion!

d. Life-Years as Opposed to Lives. Would the arsenic rule protect young people or old people? The question seems to matter because, in principle, it is better for the government to devote resources toward saving many years rather than simply a few.[202] If the government can prevent a death at seventy-five that would otherwise occur at eighty, surely it should attempt to do so; but if resources are limited, the government would do better to prevent a death at twenty that would otherwise occur at eighty. The point seems to matter here because it appears that the arsenic rule would protect mostly older people, not younger ones. If this is right, it is because of the long latency period. Because arsenic-induced cancer does not occur until decades after exposure, the average age of the victims of arsenic-induced cancer would be relatively high, possibly above retirement age.[203] Nonetheless, the EPA treated each life involved as worth $6.1 million. This number might well be inflated.

e. Nonfatal Cancers. As we have seen, the EPA valued a nonfatal cancer at $607,000 based on shopping mall studies involving answers to hypothetical questions with respect to chronic bronchitis. There are obviously many problems with this approach; chronic bronchitis simply is not nonfatal cancer. In fact another study (also with serious methodological problems) produced a $3.6 million figure for nonfatal cancers.[204] This amount seems quite odd because it suggests that preventing a nonfatal cancer is valued at well over fifty percent of the value of preventing a fatal cancer ($6.1 million using the EPA's estimate). But suppose that this number is taken to be accurate or a reasonable upper bound. If so, the monetized value of reductions in nonfatal cancers from the 10

202. *See* Richard Zeckhauser & Donald Shepard, *Where Now for Saving Lives*, 40 LAW & CONTEMP. PROBS. 5, 11–15 (1976).

203. *See* AM. SOC'Y OF CIVIL ENG'RS, ARSENIC IN DRINKING WATER: AN ANALYSIS OF THE ENVIRONMENTAL PROTECTION AGENCY'S NATIONAL PRIMARY DRINKING WATER REGULATION FOR ARSENIC 66 FED. REG. 6976 (JAN. 22, 2001), at 12 (2001), *available at* http://www.asce.org/pdf/arsenic.pdf.

204. *See* ARSENIC RULE BENEFITS REVIEW PANEL, *supra* note 144, at 17.

ppb standard rises in value to about $93.6 million—a sizeable jump over the $15 million produced by the $607,000 figure.

2. Discounting

It does seem sensible to say that a discount rate should be applied to latent harms. A cancer thirty years from now is not as bad as a cancer tomorrow. Note that this point does not take a stand on the controversial question of whether harms to future generations should be discounted.[205] The only suggestion is that people today would be willing to pay less to prevent a cancer in decades than a cancer in weeks. Now it would be possible to suggest that arsenic regulation is designed to prevent risks, not actual harms, and that the risks, unlike the harms, will occur immediately. The suggestion is correct, but it is not responsive. People would pay more to prevent a risk of harm in a month than a risk of a harm in two decades, and that claim is sufficient to justify discounting here.

But to make an assessment, it is not enough to decide to discount. We also have to decide (a) the appropriate discount rate and (b) the latency period. Burnett and Hahn choose a seven percent figure, which comes from the discount rate for money.[206] But it is not obvious that the *same* discount rate is sensible for latent harms as for money, and there is some reason to think the opposite. If the seven percent figure is correct for money, there are two reasons. First, money can be invested and will grow, and because of that simple fact a dollar today is worth more than a dollar in a year. Second, people have a "pure" time preference for current income. Even apart from investment value, it would be better to have money soon. If willingness to pay is to govern the discount rate, then the calculation of that rate for money should be a function of these two points. To be sure, government selection of the discount rate is usually a simplified version of this analysis and depends on the investment value of money.

Note, however, that the analysis is not the same for risks of harm. It is not possible to "invest" good health, at least not in the same way as dollars. If one is going to get cancer in any event, a cancer-free year cannot be used to produce more of the same. To be sure, most people would rather get cancer thirty years hence than ten years hence—perhaps to ensure more life-years or perhaps because of a pure time preference. And indeed, it would be desirable to shift the analysis from lives to life-years. But there is no reason to think that the time preference for health is identical to the time preference for money. There are many uncertainties here. Some evidence supports a discount rate of two to three percent,[207] which would result, not in a figure of $1.1 million per life saved, but a figure closer to $4.5 million. My principal points are that no evidence shows

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205. See Revesz, *supra* note 12, at 987–1016, for a helpful treatment that separates the two questions.

206. *See* BURNETT & HAHN, *supra* note 149, at 6.

207. *See* Revesz, *supra* note 12, at 992.

that future health benefits should be discounted at the same rate as future monetary costs—and, more speculatively, that there is good reason to think that the discount rate for health benefits should be lower than the discount rate for monetary costs.

What of the latency period? Hahn and Burnett chose thirty years, but this time period seems both long and somewhat arbitrary. If the latency period is chosen to be twenty years rather than thirty, the value per life saved increases still further, approaching $5 million.

Here is my own summary of possible cost-benefit assessments:

Table 6
Cost-Benefit Ranges

	Lives	VSL	Benefits	Costs	Net Benefits
EPA	28 (plus unquantified)	$6.1 million	$170 million (plus unquantified)	$210 million	−$40 million (plus unquantified)
AEI-Brookings "Best Estimate"	11	$1.1 million	$23 million	$210 million	−$187 million
My (Very) High Estimate	112	$33 million	$3.794 billion[208]	$210 million	$3.584 billion
My High Estimate	112	$6.7 million	$789 million[209]	$210 million	$579 million
My Best "Point Estimate"	None; too speculative	$4.5 million	No estimate[210]	$210 million	No estimate
My Low Estimate (based on fundamental acceptance of EPA conclusions)	6	$1.1 million	$13 million	$210 million	−$197 million
My (Very) Low Estimate (based on external criticisms of EPA conclusions)	0	$1.1 million	$0	$210 million	−$210 million

One final point on this table. It might be suggested that some effort should be made to identify a "best estimate" and that analysis would be greatly improved by trying to assign probabilities to the various outcomes, with the "best esti-

208. This number was calculated by multiplying 112 by $33 million, obtaining $3.7 billion, and then adding $3.6 million (the highest reasonable upper bound for nonfatal cancers) multiplied by 26, producing $93.6 million, for the total of $3.794 billion.

209. This number was calculated by multiplying 112 by $6.7 million, obtaining $750 million, and then adding $1.5 million (a more reasonable upper bound for nonfatal cancers) multiplied by 26, producing $39 million, for the total of $789 million.

210. This figure cannot be calculated because there is no estimate of lives saved. To calculate this figure, one would multiply lives saved by about $4.5 million (to accommodate both cancer premium and latency period), multiply nonfatal cancers prevented by about $1.5 million or more, and add those two figures together.

mate" consisting of the most probable one. The goal of this suggestion is correct. When the underlying science and economics allow analysts to come up with a "best estimate" and to assign probabilities to the alternative outcomes, this indeed should be done. In terms of monetizing the relevant values, it seems correct to say that the cancer risk deserves a premium as compared to workplace risks, but also to insist on discounting the monetary value of the risk to take account of the latency period and the fewer life-years saved. Hence, rough estimates of $4.5 million per life saved and $1.5 million per nonfatal cancer prevented seem as reasonable as anything else, even if somewhat arbitrary. At the very least, the EPA's $6.1 million figure appears too high in light of the long latency period, and the AEI-Brookings $1.1 million figure appears too low in light of the high discount rate that it reflects and the various factors suggesting that the workplace studies understate the monetary value of the risk involved here.

But with respect to health benefits, science does not allow best estimates to be provided here. It would be reasonable to suggest that the high estimate of 112 lives saved is unrealistically high and a bit of a scare tactic in light of the problems in the Taiwan data and the probability that the dose-response curve is sublinear. The estimate of zero lives saved is highly improbable. But it does seem to me sensible to move toward concern with life-years saved rather than lives saved, and because of the long latency period, the quantified benefits are most unlikely to be enormously higher than the $210 million price tag.[211] On the other hand, they might well be higher whether or not they are much higher, and for reasons to be elaborated shortly, the "bottom line" numbers need not be dispositive.

C. LESSONS

Does all this suggest that CBA is, in cases of this sort, unhelpful? It would not be hard to imagine an affirmative answer to that question. A skeptic might conclude that because the range of uncertainty is so large, any number at all could be justified and the ultimate decision is essentially political or based on "values." This view is not exactly wrong, but it should not be taken as a convincing challenge to CBA.

An analysis of benefits and costs cannot resolve the ultimate judgment, but it can certainly inform it. Once we understand the potential effects of different arsenic regulations and see where the uncertainties come from, we are in a much better position to know what to do. Of course a decision on that count will be a product of "values"—how could it be otherwise? The point is that the values should be identified as such, so that when the government acts, its

211. This judgment is based on the information before the EPA when it initially decided to issue the new regulation. New data suggest that the monetized benefits may indeed be much higher than the monetized costs. *See* SUBCOMM. ON ARSENIC IN DRINKING WATER, *supra* note 13, at 4.

reasons are transparent and explicable. If what I have said thus far is correct, the choice of a new arsenic rule was a genuinely hard question on the data before the EPA in 2000. Under the best case scenario, the benefits will exceed the costs, though perhaps not by a great deal. Under the worst case scenario, the costs will exceed the benefits. It is a tribute to CBA that we know exactly why the ultimate judgment is hard.

V. CBA IN COURT

We are now in a position to see the multiple possible challenges to any agency decision, that involves cost-benefit balancing. Because such balancing has become a staple of regulatory practice, it is important for lawyers to have some understanding of the underlying ideas and of how agencies might be said to have gone wrong. There are lessons for courts as well, mostly involving the need for deference to agencies.

A. LAWYERS: HOW TO MAKE BENEFITS GO WAY UP OR WAY DOWN

With respect to the regulation of social risks, the legal culture is increasingly required to pay close attention to both science and economics,[212] and here legal understandings remain in a primitive state. If we keep in mind the arithmetic of arsenic, we can see how creative lawyers representing water systems or environmentalists might be able to mount plausible challenges to the EPA's decisions regardless (almost) of the content of those decisions. I do not mean to endorse these challenges, but simply to give a sense of what they might look like. The following list catalogues the potential challenges.

1. The Dose Response Curve

A great deal depends on the dose-response curve, and at low levels the scientific evidence will often be inconclusive. With the assumption of a linear curve, the benefits of regulation will seem far higher than they might otherwise be. But from the scientific point of view, that assumption might be vulnerable. In the case of arsenic, the most striking point is that the independent entities on which the EPA relies actually split on the issue, with the Scientific Advisory Board supporting linearity and the National Research Council tentatively favoring sublinearity. In addition, linearity makes more sense for genotoxic carcinogens, and there is a dispute about whether arsenic is genotoxic. A decision to assume linearity, in the face of scientific uncertainty, is best seen as a (reasonable) policy judgment. Under a statute that calls for a "margin of safety," such a judgment is plainly supportable. It may be that an agency can indulge such a

212. *See, e.g.*, Am. Trucking Ass'ns v. EPA, 175 F.3d 1027 (D.C. Cir. 1999) (discussing the scientific and economic issues involved in regulating particulates and ozone), *rev'd*, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001); Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991) (discussing the economic costs and scientific evidence relating to asbestos regulation).

judgment under a statute that calls for cost-benefit balancing, but certainly not if science clearly points in the other direction.[213] For a lawyer objecting to regulation that seems too stringent, the best claim is that sublinearity is more likely.[214] For a lawyer objecting to regulation that seems inadequate, the best claim is that in the absence of specific data, linearity is the standard default assumption on policy grounds. As a legal matter, the EPA is probably on solid ground in relying on the linearity assumptions if the scientific evidence is unclear.

2. Inadequate Evidence

When regulating a pollutant, the EPA will often have to rely on evidence from other times and areas, and it will be easy to suggest that there are relevant differences between the population at issue and the population from which that evidence derives. In the case of arsenic, the Taiwan data could certainly be challenged as inadequate in light of the absence of data from the United States confirming the basic results.

3. Valuation Problems

If cancer risks are involved, the agency's decision to use its ordinary VSL can be challenged on the ground that good evidence shows a higher VSL for risks that are dreaded and uncontrollable (as cancer risks are likely to be). Lawyers objecting to insufficiently aggressive regulation could use this evidence to suggest that the VSL numbers from workplace studies are simply too low. Lawyers objecting to overaggressive regulation could insist that the only reliable data come from the workplace studies and that any efforts to produce higher numbers are too speculative.[215]

4. Poor Morbidity Data

Agencies frequently lack good data on morbidity risks and therefore use crude substitutes. These are easily subject to challenge. In the arsenic case, an environmental lawyer could urge that the chronic bronchitis numbers are far too low because a case of cancer is very likely to produce higher willingness to pay than a case of chronic bronchitis.[216] For their part, industry lawyers could urge that chronic bronchitis is comparable or perhaps even worse, simply because it is chronic. Perhaps a case of cured cancer, even if it is entirely cured, is not much more serious than a case of any other curable disease, and perhaps a

213. For a holding to this effect, see Chlorine Chemistry Council v. EPA 206 F.3d 1286, 1291 (D.C. Cir. 2000) (ruling that EPA acted arbitrarily and capriciously in overriding scientific evidence that chloroform is a threshold pollutant under the SDWA).

214. *See id.* at 1287–89.

215. *See* SCI. ADVISORY BD., U.S. ENVTL. PROT. AGENCY, VALUING THE BENEFITS OF FATAL CANCER RISK REDUCTION (1999).

216. *See* SUBCOMM. ON ARSENIC IN DRINKING WATER, *supra* note 13, at 33–34.

serious chronic condition such as chronic bronchitis is more serious than a cured cancer. In either case, it would be easy to challenge the actual numbers used for chronic bronchitis as unreliable, because they were generated through responses by shoppers in North Carolina to hypothetical questions. Even if well-designed, that study is not likely to produce reliable numbers.

5. Lives vs. Life-Years

If an agency uses lives rather than life-years, there may be a serious problem, at least if the regulation would protect a large number of children or elderly people. For protection of children, the $6.1 million figure is arguably far too low; for protection of elderly people, that same figure is arguably far too high.[217]

6. Inadequate Quantification of Benefits

For a lawyer on either side, it is not hard to argue that unquantified benefits should be quantified, if this is at all possible.[218] Without quantification, how can agency decisions be evaluated? And once a decision is made to quantify benefits that had formerly been unquantified, agency judgments are subject to challenge because the judgment about how to quantify will be highly speculative. If the agency has not specified a range but has relied on a fairly specific projection, it will be extremely vulnerable.

7. Choice of Discount Rate

The level of monetized benefits will differ dramatically with the chosen discount rate. It would be easy to challenge any agency's decision not to discount a risk that will come to fruition in the future. A monetary loss or a loss to health is worse today than years hence. Once the agency has chosen to discount, any particular discount rate might well be challenged. Economists disagree about the proper approach. If the agency chooses a discount rate for health in the vicinity of the discount rate for money—that is, seven to ten percent—its choice might well be challenged on the ground that no good evidence supports the view that health problems averted should be discounted at the same rate as financial losses averted. But if the agency chooses a discount rate below seven percent, it would not be hard to challenge that choice as essentially arbitrary and unsupported by evidence.

B. AGAINST SCIENCE COURTS

Notwithstanding the availability of countless legal challenges, the basic lesson for courts is simple: Hands off. When courts are reviewing an agency's

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217. It is not clear, however, how to think about willingness to pay in this context. Older people tend to be wealthier, and they might well be willing to pay large amounts to protect relatively few life years.

218. *See* ARSENIC RULE BENEFITS REVIEW PANEL, *supra* note 144, at 19.

judgments about health benefits and how to monetize them, they should give agencies the benefit of every reasonable doubt.

The reasons are threefold. First, the issues are exceedingly complex, and judges are not specialists in the area at hand. Like everyone else, they are prone to error. There is no systematic reason to think that a firm judicial hand will make things better rather than worse. Second, any judicial judgment will perpetuate the status quo and make rulemaking more difficult.[219] Because it is extremely time consuming to make rules and because a clever advocate likely will be able to produce a plausible challenge to whatever an agency does, an aggressive judicial posture will essentially freeze whatever rule is currently in place. In many domains, people have expressed concern with the "ossification" of rulemaking.[220] When a statute calls for cost-benefit balancing, any nondeferential judicial posture will magnify the risk of ossification. Third, many of the underlying decisions involve values, not facts. We have seen that often the choice between a linear and sublinear dose-response curve cannot be based on direct evidence. Any choice has a large policymaking dimension. "[T]here is wide recognition among experts—but not necessarily in the public opinion—that current approaches to the regulation of most agents remain judgmental."[221] In this light, courts should be reluctant to displace the judgments of administrators, who have advantages both as technocrats and public representatives.

This does not mean that agencies should be permitted to do whatever they want. We can easily imagine genuinely arbitrary decisions.[222] But so long as the agency has not done something truly unreasonable, its efforts to quantify and monetize health benefits should be held acceptable.

VI. POLICY ANALYSTS: WHAT SHOULD BE DONE?

A. NO OBVIOUSLY BEST CHOICE

1. Puzzles

On the analysis thus far, it should be clear that there was no obviously best choice for the EPA. Of the options considered, the most dramatic would be the two poles: to retain the existing 50 ppb standard or to select the 3 ppb standard—which the EPA deemed feasible. Neither of these choices would have been ludicrous, and neither should be seen as violative of the SDWA. Notwithstanding the NRC report, it would not be entirely irrational to conclude that the existing data—most of it from Taiwan—simply does not justify further restric-

219. *See* JERRY L. MASHAW & DAVID L. HARFST, THE STRUGGLE FOR AUTO SAFETY 224–26, 245–46 (1990).

220. *See, e.g.*, Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992).

221. TOXICOLOGY, *supra* note 2, at 1145.

222. *See, e.g.*, Chlorine Chemistry Council v. EPA., 206 F.3d 1286 (D.C. Cir. 2000) (holding EPA chloroform rule arbitrary and capricious).

tions, especially in light of studies suggesting no adverse effects from low levels of arsenic in drinking water. And notwithstanding the AEI-Brookings study, it would not be impossible to produce numbers suggesting that the 3 ppb standard might well be justified, at least if the nonquantified benefits are taken into account and pegged at the higher points in the range.

2. Tiebreakers

Could it be possible to resolve the controversy through some general, background considerations? When individuals and governments are not sure what to do, they often invoke "second-order" principles designed to simplify the inquiry in the event of difficulty.[223] There are several possibilities here.

One solution would be to invoke the "precautionary principle," which says that reasonable doubts should be resolved in favor of protecting safety, health, and the environment.[224] The precautionary principle has had a significant influence on both national and international environmental policy.[225] It also seems to track private behavior. People purchase smoke alarms and insurance; perhaps regulation of arsenic can be seen as analogous. In the face of scientific uncertainty, why not make an expenditure that might well turn out to avert serious harm?[226] In a catchphrase: Better safe than sorry.[227]

If this point is meant to suggest that significant investments are worthwhile to prevent speculative harms, it is certainly correct. But everything depends on the size of the investment and the speculative nature of the harm. Taken seriously, one problem with the precautionary principle is that it would lead to huge expenditures, exhausting the relevant budget before the menu of options could be thoroughly consulted. Indeed, the precautionary principle would lead to paralysis because there are risks on all sides of the equation.[228] Recall that many households would be required to spend more than $300 per year for water; EPA Administrator Whitman has expressed a concern that the increased expenditure will lead many people to use small, local wells, which have heavily

223. *See* Cass R. Sunstein & Edna Ullmann-Margalit, *Second-Order Decisions*, *in* BEHAVIORAL LAW AND ECONOMICS 187, 192–203 (Cass R. Sunstein ed., 2000).

224. Ken Geiser, *Establishing a General Duty of Precaution in Environmental Protection Policies in the United States*, *in* PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE xxi, xxiii (Carolyn Raffensperger & Joel Tickner eds., 1999).

225. *See* Julian Morris, *Defining the Precautionary Principle*, *in* RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE 1, 3–7 (Julian Morris ed., 2000)

226. The point may be supported by the fact that people are generally averse to low-probability, high-risk outcomes, and would be willing to pay relatively high amounts so as not to run the relevant risks. *See* Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, *in* CHOICES, VALUES, AND FRAMES 17, 22–25 (Daniel Kahneman ed., 2000).

227. For a critical discussion, see HOWARD MARGOLIS, DEALING WITH RISK: WHY THE PUBLIC AND THE EXPERTS DISAGREE ON ENVIRONMENTAL ISSUES, 75–92 (1996).

228. *See* Indur M. Goklany, *Applying the Precautionary Principle in a Broader Context*, *in* RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE, *supra* note 225, at 190–220.

polluted water.[229] In these circumstances, the precautionary principle suggests that new arsenic regulation is undesirable because it might sacrifice lives. Recall too that expensive regulations can have adverse effects on life and health and hence that the $210 million expenditure for arsenic regulation has, as a worst case scenario, significant adverse health effects, with perhaps as many as thirty to forty lives lost.[230] If this is so, the precautionary principle seems to argue against new regulation. It seems clear that precaution, by itself, can be taken to argue for no regulation, much regulation, and every point in between. On reflection, the idea is insufficiently helpful.[231]

Perhaps a more refined argument is better. For most of the country, the incremental cost of the arsenic regulation is low—less than $30 per year. If the vast majority of people would receive additional protection at a cost that is high in the aggregate ($210 million, for example) but extremely low for each affected family, shouldn't government proceed with regulation, perhaps with exemptions or subsidies for those who would have to pay more? The argument is not implausible, but it proves too much. In many cases, it would be possible to do some good by asking everyone to pay, say, $2 per year. Should the EPA ask every American to pay $2 year, so as to create a $500 million fund to be used to pay for additional reductions in sulfur dioxide emissions? Carbon monoxide emissions? Benzene emissions? Clean-up of lead paint? Anti-tobacco advertising? Childhood immunizations? Relief of poverty? Because the list of possibilities is endless, it is unhelpful to treat small per-family costs as if they were zero or its moral equivalent; we do better to ensure that those funds are used for purposes that would do more good than harm or for the most possible good. This does not mean that a regulation imposing small per-family costs (say, $30 per family for 200 million people) should be treated as identical to a regulation imposing the same aggregate but higher per-family costs (say, $300 per family for 20 million people). High per-family costs do raise particular concerns. But a regulation that badly fails cost-benefit balancing should not be accepted on the ground that each family or person will pay little. (Imagine a program that would require every American to pay $1 per year for little or no return.)

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229. "But we have seen instances, particularly in the West and Midwest, where arsenic is naturally occurring at up to 700 and more parts per billion, where the cost of remediation has forced water companies to close, leaving people with no way to get their water, save dig wells. And then they are getting water that's even worse than what they were getting through the water company." *Evans, Novak, Hunt & Shields* (CNN television broadcast, Apr. 21, 2001) (interview by Robert Novak and Al Hunt with Christine Todd Whitman, EPA Administrator).

230. *See* BURNETT & HAHN, *supra* note 149, at 8, 14 tbl.1. On the general phenomenon, see Cass R. Sunstein, *Health-Health Tradeoffs*, *in* SUNSTEIN, *supra* note 71, at 298–317.

231. For an effort to understand the precautionary principle in a way that takes account of multiple risks, see INDUR M. GOKLANY, THE PRECAUTIONARY PRINCIPLE: A CRITICAL APPRAISAL OF ENVIRONMENTAL RISK ASSESSMENT (2001).

Yet another tiebreaker is possible. Perhaps the EPA should refrain from further regulation on the theory that government should not act unless there is a clear demonstration that it is desirable, all things considered. Perhaps we should adopt a presumption against regulatory controls unless CBA shows that they are justified or unless there are special reasons—perhaps distributional in character—that support them. Perhaps the government should not require costly expenditures here in view of the fact that the same expenditures might be used for other goals, such as crime reduction and automobile safety, where they could do more good.[232]

The problem is that the same kind of argument could have been used against a wide range of environmental regulations even though those regulations have, on balance, been vindicated by history.[233] In the context of air quality regulation, a contemporaneous assessment of costs and benefits would in many cases have given rise to the same kind of uncertainty found here. Note that this is not to suggest that in such cases the costs would have been found to outweigh the benefits. The problem is instead that the most that could have been done was to identify a benefits range leaving a great deal of uncertainty about what to do. If the past is any guide, it suggests that inaction in such circumstances would be a foolish course.

3. Between the Poles?

While no particular approach would be obviously best or obviously unreasonable, the more reasonable approaches would appear to be between the poles. On the existing numbers, the 3 ppb standard is hard to justify. No data support the view that there would be significant health gains from moving from a 10 ppb ceiling to one of 3 ppb.[234] In view of the significant expense of the restriction, 10 ppb seems better. At the same time, the data do suggest that the 50 ppb standard is insufficiently protective. A new regulation might be seen as a kind of insurance policy, one without an enormous price tag. A choice that falls between the 50 and 3 ppb ceiling would seem to be best—especially if it would be possible to relieve the high burdens imposed on some households. Certainly the 10 ppb approach is reasonable.

This last point raises a more general one, overlooked thus far: The EPA's menu of alternatives has been relatively narrow and has lacked much creativity. The EPA discussed four different permissible exposure levels without thinking more imaginatively about how to minimize the costs of arsenic regulation. The blame for this narrow focus lies not with the EPA, but with Congress. I now discuss several other approaches, designed to show more flexibility toward those burdened by drinking water regulation.

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232. *Cf.* BREYER, *supra* note 48, at 59–63 (arguing for better priority-setting).

233. Portnoy, *supra* note 46, at 101–05.

234. Again, I am speaking of the data before the EPA when it made its initial decision to issue the 10 ppb rule.

B. ARSENIC TARGETING AND ARSENIC WAIVING

A possible approach would involve "targeting," that is imposing regulation on water systems when the cost-benefit ratio is especially good. Recall that for much of the country, the cost of compliance with the 10 ppb standard is quite low. On plausible—which is not to say certainly correct—assumptions, the cost-benefit ratio for those systems is adequate to justify the regulation—perhaps even adequate to support a 5 ppb or 3 ppb standard. These points suggest a simple alternative: Impose a targeted rule, with a sliding scale of regulations ensuring that the cost-benefit ratio supports the outcome in each area. When, for example, the annual cost of regulation is less than $50 per household, government might impose a 5 ppb standard; when the annual cost is less than $150, it might impose a 10 ppb standard; when it is less than $350, it might impose a 20 ppb standard.

An approach of this kind would undoubtedly be controversial. Critics would ask: Why should people in some parts of the country be subject to more arsenic in their drinking water than people in other areas? Why should some people have very low levels of arsenic, and other people less low levels? These questions might seem especially difficult to answer if, as seems likely, many of those subject to the more lenient standard would be relatively poor. Why should poor people, and especially poor children, face levels of arsenic found unacceptably dangerous in other parts of the country? But these questions have much more rhetorical force than they deserve. If acceptable levels of risk are a function of both cost and benefit, it makes perfect sense to say that such levels will vary depending on the costs and benefits of controls in different localities. In some areas of the country, it will be worthwhile to "purchase" an additional increment of safety; in other areas, it will not be.

This point seems sufficient to suggest that the EPA should have the authority to impose national standards that are not uniform.[235] But the SDWA forbids any such nonuniform standards. In keeping with its cost-benefit focus, the statute should be amended to allow the EPA greater flexibility.

If the EPA cannot adopt a targeted regulation, could it allow waivers for areas in which the benefits do not justify the costs? Once the data are disaggregated, it seems reasonable to consider the following option: Adopt the 10 ppb regulation for most water systems, when the per-family cost of compliance is low, but offer a variance for water systems when the per-family cost is high. This approach would be quite close to one involving targeted regulation. The SDWA does allow waivers, but only for short periods of time, and hence waivers produce less satisfactory outcomes than does targeting.

C. ARSENIC MARKETS

In contemporary environmental law, some of the most dramatic developments have involved the rise of market instruments for pollution control. These

235. I am not discussing whether national controls can be justified in principle.

instruments take many forms, but among the most popular are "cap and trade" systems, in which the total level of emissions is capped at a certain level and polluters are allowed to trade licenses as long as the cap is respected.[236] A chief advantage of cap-and-trade systems is that they ensure the lowest-cost means of achieving regulatory goals. Those who can eliminate pollution cheaply will do exactly that. Those for whom reductions are expensive will purchase additional permits.

Why not create a system of tradeable emissions rights, involving the right to subject people to arsenic? The idea may well seem macabre. But if so, the reason is likely to be a belief that arsenic is a poison seriously dangerous at any level. This is a form of intuitive toxicology. If we suppose that within the range under discussion (say 3 ppb to 20 ppb) dangerously high exposure levels will not occur, and we suppose that the issue is one of appropriate degrees of safety, we could easily imagine a cap-and-trade system. For example, government could create an overall cap on arsenic and give licenses to subject people to 15 ppb, but also allow trading. As a result, companies that can reduce at low cost will do so, whereas those that can do so at only high cost will stay at 15 ppb or perhaps buy licenses to subject people to higher levels. Because of the familiar "hot spots" problem, government would, under this regime, take steps to ensure that no one is subjected to unacceptably high levels—say, 25 ppb or higher.

As compared with a system of national command-and-control, it is likely that a system of this kind would produce much lower costs. Indeed, a system of tradeable rights would likely spur considerable innovation in arsenic control technology, which would be a significant gain. To evaluate it, we would want to know the aggregate cost of the system and also compare the likely benefits to those that would be enjoyed under the alternatives. It is not unimaginable that a properly designed cap-and-trade system would produce both lower costs and higher benefits than the command-and-control alternative. Note in this regard that the Clinton Administration proposed a 10 ppb ceiling to be applied nationally, but that a cap-and-trade system could ensure that people would have levels well below 10 ppb in much of the country.

As compared with a system of arsenic targeting, the chief advantage of a cap-and-trade system is that it imposes less of an informational demand on the government, allowing the market rather than the EPA to ascertain the costs of arsenic reduction. Under arsenic targeting, the EPA would have to decide, in every area of the country, the real costs of reduction to various points—a difficult determination for which error is inevitable. Under cap and trade, those with low costs will trade their licenses, whereas those with high costs will attempt to acquire more in the way of arsenic rights. Of course the same objections that might be made to arsenic targeting might be made to a system of cap-and-trade. Perhaps poor people will be subject to unusually high arsenic

236. For an excellent discussion, see A. DENNY ELLERMAN ET AL., *supra* note 50.

levels. But if these objections are not convincing there, they are also unconvincing in this context.

Under the SDWA, however, the EPA lacks the authority to implement a trading system for arsenic. This is a serious gap. The statute should be amended to allow the EPA to permit trading if the evidence justifies that step. I emphasize that trading should not be allowed to create what are, under existing science, unacceptable hot spots.

D. ARSENIC REDUCTION SUBSIDIES

It might be suggested that the EPA should impose a stringent regulation of arsenic but that the federal government should subsidize communities for which the annual cost is high. Of course the EPA cannot offer subsidies on its own. But perhaps Congress should do so. In fact, Congress has made federal financial assistance available for water systems, and while the relevant programs contain a degree of discretion, it is certainly possible for financially strapped water systems to receive federal help.[237]

Recall that the total cost of the 10 ppb regulation would be about $210 million each year. To say the least, this would not be a large sum in the federal budget. If the federal government restricted itself to paying the cost of compliance in areas in which the annual per-household cost exceeds $100, its total taxpayer bill would be about $10 million—hardly a large sum to pay.

This would not be a foolish approach to the arsenic problem. In fact, it seems quite reasonable. The major difficulty is that the numbers do not tell us whether this is the best way to spend limited taxpayer dollars. Suppose that the risks that the regulation is reducing are quite small, so that the regulation will save somewhere between 0 and 0.5 lives. Is it really worth spending $10 million to save between 0 and 0.5 lives? Many government programs are designed to decrease risks to life and health; some of those programs attempt to reduce violent crime. Perhaps the $10 million would be better spent on those programs. It would be possible to say that, as a practical matter, any $10 million subsidy is more likely to come from some other, less valuable use and that by using it to protect people against the health hazards of arsenic, we would not really be diverting resources from a more valuable use. Among the universe of imaginable government expenditures, a $10 million subsidy is hardly the worst. But in light of existing data, we cannot be sure that it is the best. The same considerations that justify cost-benefit balancing in the first place suggest that the hard issues cannot be avoided by arguing for an across-the-board 10 ppb standard accompanied by a federal subsidy for those who face a difficult financial burden.

237. National Primary Drinking Water Regulations, 66 Fed. Reg. 6976, 6992 (Jan. 22, 2001) (codified at 40 C.F.R. pts. 9, 141, 142).

E. ARSENIC DISCLOSURE

An alternative possibility would be to rely less on regulation and more on information. In many domains of regulatory policy, government has moved to replace command-and-control regulation with efforts to require companies to disclose their activities and the accompanying risks to the public.[238] In the context at hand, the suggestion would be simple: Require companies to meet some statutory requirement—perhaps 30 ppb—so that people are not exposed to clear harm, but beyond that point, require companies to disclose the level of arsenic in their drinking water, perhaps with information that would put the numbers into some context. Perhaps the disclosure requirement would not apply if companies reached some low level (5 ppb?). We could thus imagine a kind of three-tiered rule with flat mandates, a disclosure requirement for a certain range, and a "floor" below which companies would have no disclosure duties.

For arsenic, this strategy would have both advantages and disadvantages. Because people are not likely to be happy to learn that their drinking water has relatively high levels of arsenic, one advantage of disclosure is that it could spur companies to reduce arsenic levels on their own, without governmental requirements.[239] For companies who chose that route, it is likely that the reductions would not be terribly expensive. Public pressure may produce low-cost reductions in some areas while also allowing companies to maintain certain levels of arsenic if the public in those areas was not so concerned in light of the mix of health benefits and water costs. In this way, disclosure may even produce a kind of "drinking water federalism." Another advantage of disclosure is that it may perform an important educative role by ensuring that people will learn that some carcinogenic substances are not especially dangerous at low levels and also alerting people to the need for tradeoffs (in the form of a higher water bill).

But of course there are pitfalls as well. We have seen that the very idea of arsenic in drinking water seems to cause serious public alarm, in part because of the operation of intuitive toxicology. For a certain percentage of the population, disclosure of arsenic would itself signal reason for concern and perhaps produce excessive fear, even panic. Many people may ask why, exactly, companies are disclosing this fact and whether disclosure means that they are, in some sense, being poisoned. The point suggests that sometimes disclosure will not really inform people because their background beliefs will lead them to read the information badly. The question remains whether it is possible to give some contextual information so that people have an accurate sense of what the disclosure actually means. In this context, we should probably be unsure whether the contextual information would really help.

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238. *See generally* Bradley Karkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?*, 89 GEO. L.J. 257 (2001); Cass R. Sunstein, *Informational Regulation and Informational Standing:* Akins *and Beyond*, 147 U. PA. L. REV. 613 (1999).

239. *See* Karkainen, *supra* note 238, at 295.

As a legal matter, the issue is simple because the EPA has no authority to use information disclosure as a substitute for regulation. In the particular context of the SDWA, Congress's choice for regulatory mandates may even make sense. But in the future, it would be useful to allow agencies to experiment in this vein to see if disclosure will, in some cases, do more good than alternative approaches.

F. THE MISSING QUESTION: DISTRIBUTIONAL ISSUES

There is one significant gap in the discussion thus far: A full account of the *distributional* effects of different arsenic regulations. To have an adequate sense of whether and how to proceed, it would be most valuable to match the assessment of the range of costs of the rule with an account of the income and wealth of those who will be subject to those costs. If, for example, those who would bear $300 or more in increased annual costs are also disproportionately poor, there is good reason for government to hesitate before imposing the regulation. It is easy to imagine a situation in which water quality regulation is "regressive" in the sense that its costs come down especially hard on poor people. That is not a decisive objection to the regulation, but it is certainly an important point to consider.

It would be easy to imagine the following sort of rejoinder: Shouldn't poor people have water that is as safe as that of wealthy people? Why should poor people, including poor children, have water quality inferior to that enjoyed by wealthy people? The simplest answer is that safety is a matter of degree, and if safer water quality is very expensive, then poor people are better off without it than with it. Cars should certainly be safe, but wealthy people are more likely than poor people to buy Volvos. It would not be a good idea for the government to force poor people to buy Volvos, and the reason is that if you are poor, you might reasonably use what money you have on something other than adding an additional margin of safety to your car. Perhaps you will use that money on food, or medical care, or shelter. The same is true for water quality. If the consequence of decreasing (small) risks is to decrease significantly family income for poor people, then it is perfectly legitimate for the government to refuse to act. Of course it is possible that the benefits of environmental regulation will be enjoyed disproportionately by poor people and that they will bear disproportionately few of the costs.

The more general suggestion is that whenever an agency is producing a regulatory impact analysis, it should consider a distributional analysis as well. It is important to know who will bear both the benefits and the burdens of regulation. A recent study shows, for example, that the benefits of pollution control in California have gone disproportionately to poor people and minority group members.[240] It would be extremely desirable to assemble similar information for drinking water regulation.

240. *See* Kahn, *supra* note 22, at 23–25.

CONCLUSION

My aim in this Article has been to cast light on the actual practice of CBA by considering the EPA's most highly publicized decision under the federal statute that most explicitly calls for that form of analysis. The basic message is that even when there is a considerable amount of scientific data, it is possible that CBA will identify only a range of reasonable choices, and often a wide range at that. With plausible assumptions, the nonmonetized health benefits of new controls on arsenic in drinking water can be made to seem very small or very large. Once the health benefits are monetized, the range becomes larger still, making it extremely difficult to compare costs against benefits.

It would be possible to take this demonstration as an attack on CBA on the ground that a specification of benefits and costs tells us little that we did not already know.[241] If CBA is justified as a way of actually producing decisions in hard cases, CBA has indeed been criticized by the analysis here. But this would be the wrong lesson. As a substitute for intuitive toxicology and for the crudeness of the affect heuristic, an effort to trace both costs and benefits can inform inquiry making decisions less of a stab in the dark. This is indeed a substantial gain. Once the range is specified, a judgment of value, and not of fact, will be involved in the ultimate decision whether or not to proceed. But the judgment of value will be easier to identify once we understand what we understand and what we do not know. A real virtue of CBA is that it helps to explain exactly why the choice of regulation in the case of arsenic is genuinely difficult. In this way CBA is a large improvement over the "intuitive toxicology" seen in the public reaction to the decision of the Bush Administration.

I have also attempted to provide a kind of lawyer's primer on the law of CBA, showing how future cases might be litigated. There is no question that courts will eventually be asked to assess the kinds of questions raised in this Article.[242] Lawyers can drive predicted benefits up or down by manipulating the dose-response curve, by raising epidemiological questions, by challenging the discount rate, by asking about the voluntariness and controllability of the risk, and by quantifying difficult-to-quantify risks. We could easily imagine a dozen kinds of opinions invalidating a 10 ppb standard as too stringent; we could easily imagine the same number of opinions invalidating that standard as too lenient. Indeed, we could easily imagine an emerging set of doctrines in which courts produce a kind of common law of CBA. In view of the complexity of the underlying questions, many diverse views would undoubtedly be expressed by federal courts. I have urged that things would be simplified, and generally better, if courts maintained a posture of deference, rejecting agency views only

241. This is one reading of Heinzerling, *supra* note 16.

242. *See, e.g.*, Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991) (asking the court to evaluate a number of issues explored here, including the appropriate discount rate and both arbitrary and nonarbitrary ways to balance costs and benefits).

in cases in which those views are patently unreasonable. There is indeed an emerging common law of cost-benefit analysis,[243] but thus far it is being generated by agencies rather than courts. This is entirely proper.

I have also discussed the underlying policy issues. The EPA could make many reasonable decisions here, and in the range below 50 ppb and above 5 ppb, there is no obviously correct choice. But my principal claims have involved broadening the agencies' view screen. First, agencies should have the flexibility to produce variable standards targeting regulation to areas where it would survive cost-benefit balancing and also adopting economic incentives to ensure low-cost solutions. Second, agencies should be required to identify the winners and losers produced by regulation—to show when poor people or wealthy people are disproportionate losers or gainers. A distributional analysis should not be taken as conclusive, but it will help to inform the analysis. An effort to increase agency flexibility and also to identify both winners and losers would be natural steps not toward placing regulatory judgments in an arithmetic straightjacket, but toward ensuring that when government acts, it does so in a way that is informed by a full account of the consequences.

APPENDIX

Dose-Response Curves

To evaluate risks associated with toxic substances and to undertake cost-benefit analysis, it is often important to have a sense of the dose-response curve. For arsenic, clear evidence is absent. This appendix offers a sense of the possibilities.

The dose-response curve can have a variety of shapes, including linear, where response increases proportionally with dose. Figure (A)(1) displays the linear relationship between dietary dose of organophosphate insecticide dioxathion and inhibition of the enzyme cholinesterase in rats.

Figure (A)(2) demonstrates another linear relationship, this one between subcutaneous administration of carcinogenic hydrocarbon dibenzanthracene and tumor incidence in mice.

Chemicals such as benzene, radon, and formaldehyde exhibit sublinear dose-response relationships, where elicited responses are less than proportional. Figure (B)(1) displays a sublinear relationship for primary pulmonary (lung) tumors in rats following exposure to plutonium dioxide.

Figure (B)(2) exhibits a sublinear dose-response relationship between the number of female rat liver foci (a precursor to cancer) and the log dose of phenobarbital expressed as picomole per kilogram.

Some chemicals produce no adverse effects below a certain level, resulting in a threshold curve. Threshold-model agents include dioxins and chrysotile asbes-

243. *See* COST-BENEFIT ANALYSIS, *supra* note 6, at 310–11.

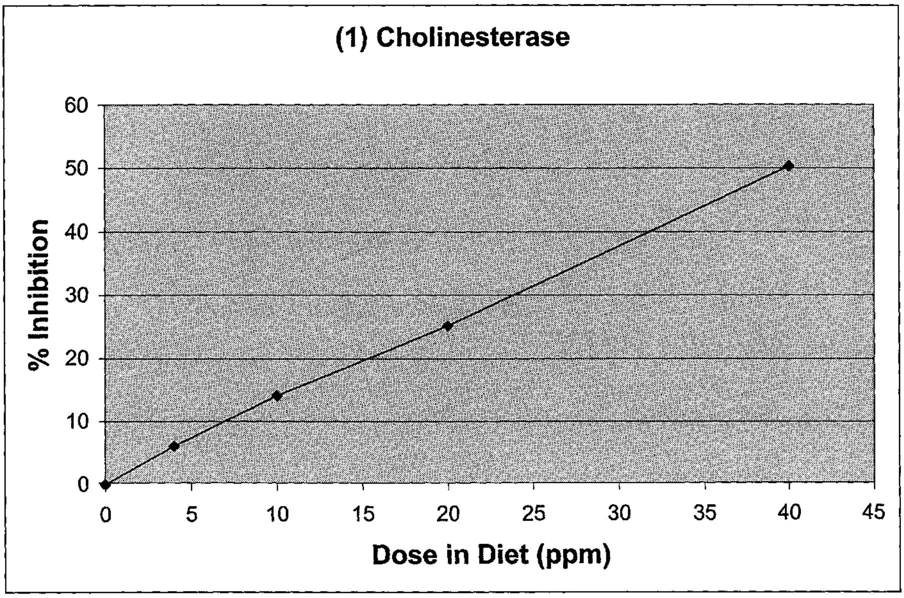
tos; in addition, nongenotoxic carcinogens are generally assumed to have threshold doses. Figure (C)(1) demonstrates a threshold for the carcinogenic hydrocarbon benzpyrene causing sarcomas in mice.

Dose-response relationships exceeding proportionality, such as vinyl chloride, are supralinear. Figure (D)(1) demonstrates a supralinear curve for the inhibition of carboxylesterase enzyme activities in rats as a function of insecticide dioxathion dose.

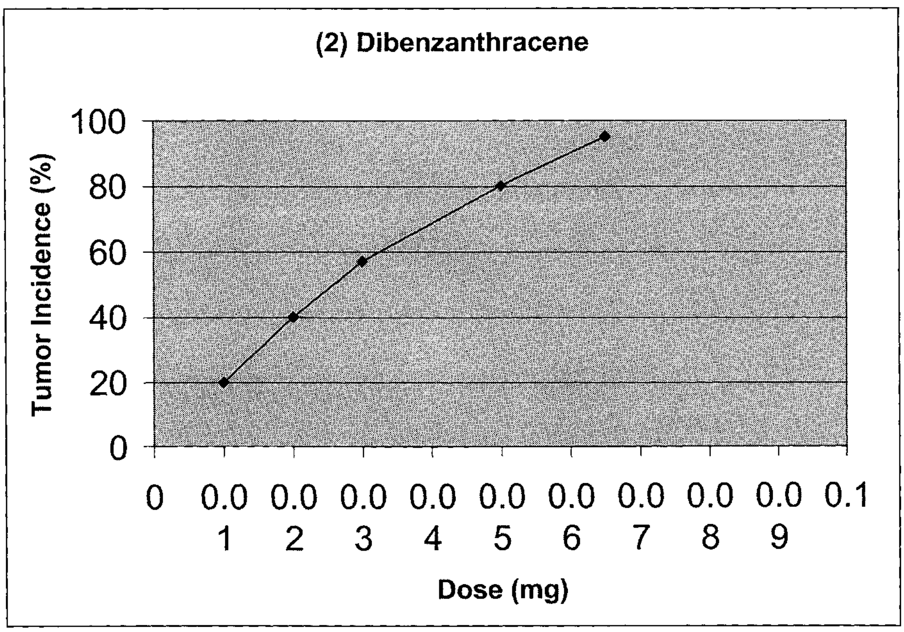
The slight concave-upward pattern in Figure (D)(2) demonstrates a weaker supralinear relationship between exposure to radiation via an atomic bomb and cancer deaths per 10,000 people.

Hermatic chemicals such as essential nutrients and vitamins exhibit beneficial effects at low doses, coupled with toxic effects at high doses, resulting in a u-shaped curve. The dose-response relationship of fluoride, which exerts positive effects at lower doses but is toxic at high doses, is outlined in Figure (E)(1).

(A) LINEAR RELATIONSHIPS

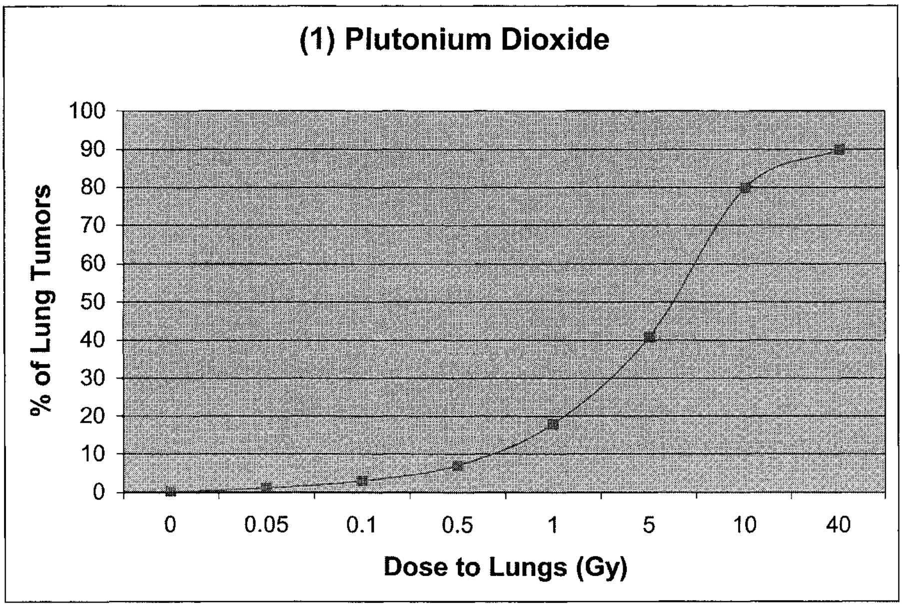


S.D. Murphy & K.L. Cheever, *Effects of Feeding Insecticides: Inhibition of Carboxylesterase and Cholinesterase Activities in Rats*, 17 ARCHIVES ENVTL. HEALTH, 749 (1968), *reprinted in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 19, fig.2-2 (Mary O. Amdur et. al. eds., Pergamon Press 5th ed. 1996).

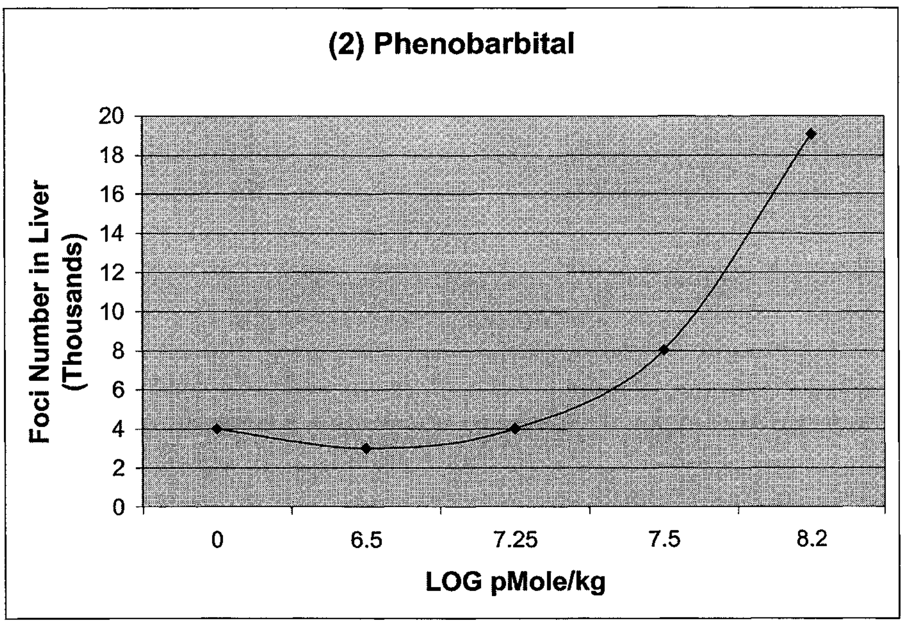


Casarett and Doull's Toxicology: The Basic Science of Poisons 23, fig.2-6 (Mary O. Amdur et. al. eds., Pergamon Press 5th ed. 1996), modified from W.R. Bryan & M.B. Shimkin, *Quantitative Analysis of Dose-Response Data Obtained with Three Carcinogenic Hydrocarbons in Strain C3H Male Mice*, 3 J. NAT'L CANCER INST. 503 (1943).

(B) SUBLINEAR RELATIONSHIPS

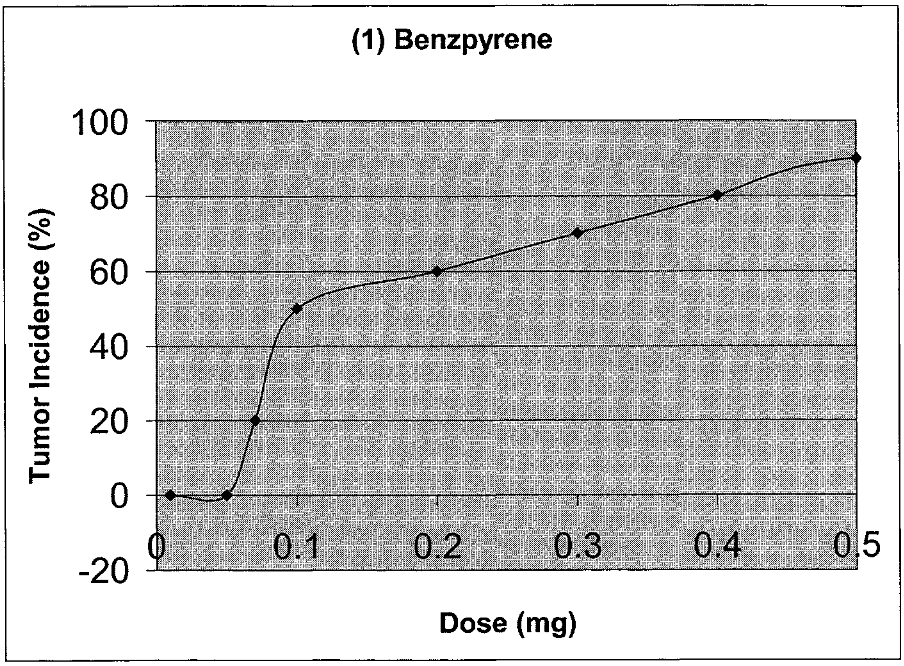


C.L. Sanders & D.L. Lundgren, *Pulmonary Carcinogenesis in the F344 and Wistar Rat After Inhalation of Plutonium Dioxide*, 144 RADIATION RES. 206, 212 (1995).



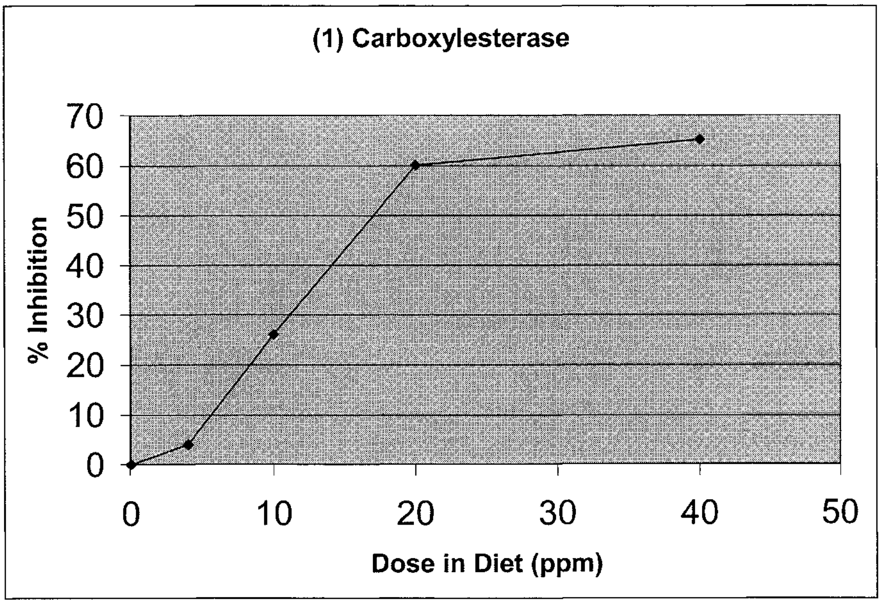
Kirk T. Kitchin et al., *Dose-Response Relationship in Multistage Carcinogenesis: Promoters*, 102 ENVTL. HEALTH PERSP. 255, 257 (1994).

(C) THRESHOLD RELATIONSHIPS

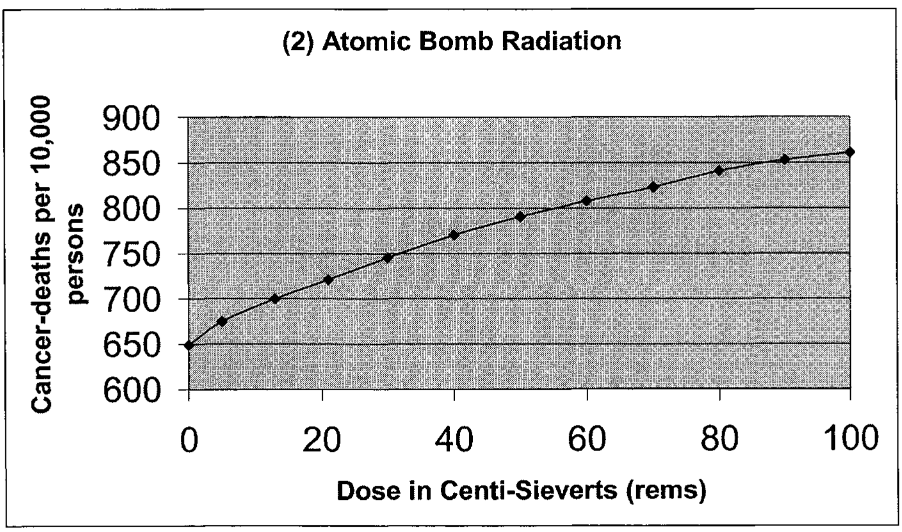


CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 23, fig.2-6 (Mary O. Amdur et. al. eds., Pergamon Press 5th ed. 1996), modified from W.R. Bryan & M.B. Shimkin, *Quantitative Analysis of Dose-Response Data Obtained with Three Carcinogenic Hydrocarbons in Strain C3H Male Mice*, 3 J. NAT'L CANCER INST. 503 (1943).

(D) SUPRALINEAR RELATIONSHIPS

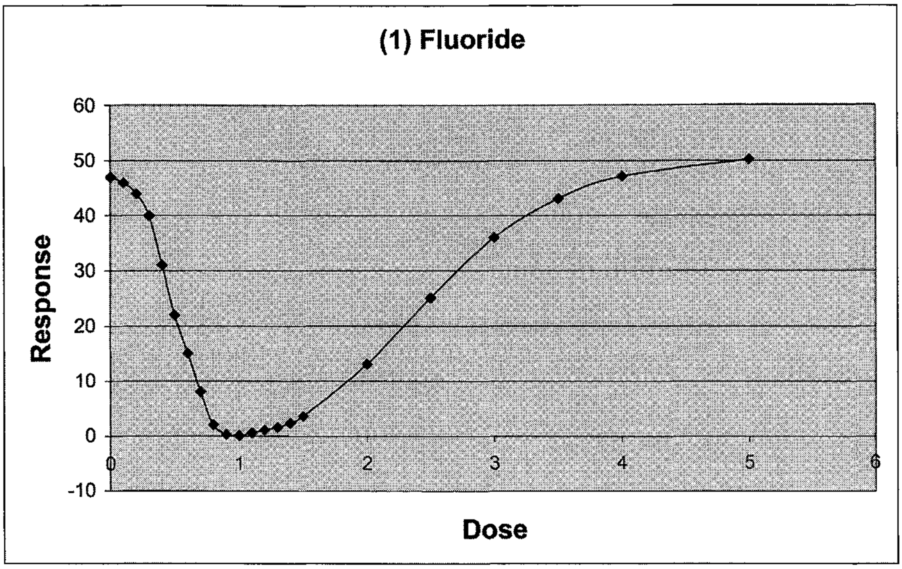


S.D. Murphy & K.L. Cheever, *Effects of Feeding Insecticides: Inhibition of Carboxylesterase and Cholinesterase Activities in Rats*, 17 ARCHIVES ENVTL. HEALTH, 749 (1968), *reprinted in* CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS 19, fig.2-2 (Mary O. Amdur et. al. eds., Pergamon Press 5th ed. 1996).



JOHN W. GOFMAN, RADIATION-INDUCED CANCER FROM LOW-DOSE EXPOSURE: AN INDEPENDENT ANALYSIS, fig.14A, 14F (1990), *available at* http://www.ratical.org/radiation/CNR/RIC/chp14F.html#fig14e.

(E) U-SHAPED RELATIONSHIPS



Gordon A. Fox, *EVR 2001: Risk and Toxicity* 9–10, fig.2 (2000), *at* http://chuma.cas.usf.edu/~gfox/EVR2001/risk_and_toxicity.pdf (last visited Sept. 4, 2002).