
FALSE CERTAINTY: JUDICIAL FORCING OF THE QUANTIFICATION OF RISK

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Risk, which is by definition only the possibility of harm, is speculative and amorphous. To transform risk into something more concrete and measurable, courts reviewing risk determinations by agencies or individuals in certain contexts will insist that the parties quantify this risk. However, the quantification of risk does not fulfill its promise; beneath the veneer of objectivity and certainty is a messy and subjective process. Instead of ensuring that agencies adhere to their legislative mandates, quantifying risk may force agencies to contradict precautionary directives. Moreover, the quantification of risk leaves room for political and self-interested maneuvering by obscuring the role of policy in agency decision making. The quantification of risk becomes a proxy for reasonableness and a rhetorical reinforcement against the accusation of judicial overreach and extrajudicial action.

This Article analyzes the judicial forcing of the quantification of risk in two contexts: first, the review of agency action, and second, the determination of whether probabilistic injury satisfies the injury-in-fact standing requirement. By juxtaposing these two contexts, the Article illuminates the work expected of the quantification of risk and the flaws in the process. It then turns to proposals for improving the judicial review of risk determinations.

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I. INTRODUCTION

The speculative nature of risk, which is by definition only the chance or the possibility of harm, makes it ill suited for adjudication by federal courts. Nevertheless,

federal courts confront risk often, notably in the disparate contexts of (a) reviewing agency action, and (b) assessing whether a party's alleged increased risk of harm constitutes sufficient injury in fact to establish standing to sue.¹ In both of these areas, courts must negotiate the nature of risk with the judicial enterprise, managing the uncertainty of risk with the boundaries of judicial review. Risk determinations, critical to the modern regulatory state, and ubiquitous in challenges to regulation, must coexist with the Article III requirement that courts can only hear cases or controversies involving actual or imminent injury,² and with the need for courts to balance deference with a searching review in their review of administrative action.³

It is for this reason that courts find the quantification of risk to be appealing. For the purposes of this Article, the quantification of risk happens in two ways. First, an agency charged with passing regulation to protect the public health and safety will initially assess the risk posed by a substance, activity, or event to the public, and this assessment will be communicated in numbers. When a regulation based on such an assessment is challenged in court, the court must determine the extent to which it will delve into the preliminary risk assessment. Second, a federal court confronted with a plaintiff claiming that he or she is at greater risk because of an agency decision must determine at what point the plaintiff's risk passes the point of mere speculation and suffices to become injury in fact. In this scenario, a court may ask the plaintiff to quantify his or her risk before allowing the case to proceed.

The act of quantifying risk transforms the concept from speculative and amorphous to definable and assessable. Moreover, quantification carries the implication of objectivity and can be easily communicated to the public.

Beneath the veneer of objectivity and certainty covering quantification, however, is a messy and subjective process. This process involves complex policy determinations, political conflict, and the negotiation of scientific uncertainty. The perceived benefits of the quantification of risk are therefore worth scrutinizing. These perceived benefits include the ability to objectively measure risk, the availability of an instrument to bridge the expertise gap faced by a generalist judiciary, a method to clearly communicate risk to the public, and a way to keep the judiciary within its proper constitutional role.

Unfortunately, however, the quantification of risk does not fulfill its promise. To the contrary, it actually undercuts the purposes of judicial review. Instead of ensuring that agencies adhere to their legislative mandates, quantifying risk may force agencies to contradict precautionary directives by waiting for proof of harm before regulating.⁴

1. See, e.g., *Natural Res. Def. Council v. EPA*, 658 F.3d 200, 201 (2d Cir. 2011) (reviewing "EPA's decision not to apply [a specific] safety factor for certain risk assessments"); *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin. (Pub. Citizen II)*, 513 F.3d 234, 237 (D.C. Cir. 2008) (determining whether the plaintiff's estimate of the difference in the risk of injury was sufficient to show injury in fact).

2. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (holding that Article III standing requires an injury in fact which is "concrete and particularized" as well as "actual or imminent" (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990))).

3. See, e.g., *Ethyl Corp. v. EPA*, 541 F.2d 1, 34 (D.C. Cir. 1976) (noting that while the Clean Air Act requires a "highly deferential" standard of review of agency actions that presumes agency action valid, the court must not "rubber-stamp the agency decision as correct").

4. See, e.g., *Indus. Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607, 691-92 (1980) (Marshall, J.,

And instead of promoting legitimacy, the quantification of risk leaves room for political and self-interested maneuvering by obscuring the role of policy in agency decision making. Courts are cursorily reviewing, and giving their imprimatur, to agency science that comprises both scientific and policy decisions.⁵ Moreover, forcing parties to quantify increased risk to assess the existence of injury in fact actually forces courts, by making a determination on the acceptable amount of increased risk, to act legislatively—exactly the position courts were trying to avoid.

This Article juxtaposes these two contexts for the first time, discussing the judicial forcing of the quantification of risk in both the review of agency action and the determination of whether probabilistic injury satisfies the injury-in-fact standing requirement. In regards to the former, courts often defer to agency treatment of quantitative risk assessment, which has been the dominant method used by federal agencies to determine the necessity for health and safety regulation for over three decades.⁶ Its dominance was, in fact, triggered by judicial opinion.⁷ The degree of deference given by courts to these quantitative risk assessments encourages agency reliance on quantification and can have an inhibitory effect on regulation.⁸

And, as to the Article III requirements, courts grapple with the question of whether probabilistic harm, or harm based on increased risk itself, can ever satisfy injury in fact. Certain courts, when confronted with this inquiry, mandate that the party

dissenting) (noting that Occupational Health and Safety Act requires the Secretary of Labor to set standards to protect against “health hazards of ‘unprecedented complexity’ [resulting] from chemicals whose toxic effects ‘are only now being discovered’” (quoting S. REP. NO. 91-1282, at 5178 (1970))).

5. See Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1661 (1995) (suggesting that judicial review exacerbates “the misrepresentation of policy issues as science”).

6. See Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European “Fashion” Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 505 n.57 (2008) (“Over the last two decades, [now almost three decades] quantitative risk assessment has emerged as the dominant paradigm in the United States for including science in regulatory decisionmaking as the best way to manage threats to public health and the environment.” (alteration in original) (quoting Gail Charnley & E. Donald Elliott, *Risk Versus Precaution: Environmental Law and Public Health Protection*, 32 ENVTL. L. REP. 10363, 10363–64 (2002)); cf. Thomas O. McGarity, *The Story of the Benzene Case: Judicially Imposed Regulatory Reform Through Risk Assessment*, in ENVIRONMENTAL LAW STORIES 141, 169 (Richard J. Lazarus & Oliver A. Houck eds., 2005) (concluding that quantitative risk assessments will continue to be part of setting agency health and environmental standards considered by courts). See *infra* Part II.A.2.a for a discussion of courts’ deference to agency risk assessments.

7. See McGarity, *supra* note 6, at 165–67 (relating how the imposition of quantitative risk assessment by the Benzene Case affected two federal agencies).

8. E.g., U.S. GEN. ACCOUNTING OFFICE, CHEMICAL RISK ASSESSMENT: SELECTED FEDERAL AGENCIES’ PROCEDURES, ASSUMPTIONS, AND POLICIES 186 (2001) [hereinafter 2001 GAO REPORT] (stating that “the agency only publishes two or three proposed or final rules per year”); see also Wendy E. Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63, 118–19 (2003) (noting that the *Benzene Case* had the effect of increasing the “amount of evidence required for the agency to justify a standard,” and that “[t]his increase in the agency’s burden of proof ensured that fewer standards would be promulgated”). In *Natural Resources Defense Council v. EPA*, the court criticized the EPA for foot-dragging in promulgating standards for benzene emissions and ordered that final standards be published by 1990. 705 F. Supp. 698, 702–03 (D.D.C. 1989). In the book *In Search of Safety*, the authors describe how the EPA was basically paralyzed on the issue during the 1980s due to internal debates over what constituted “significant risk” and the cost-effectiveness of standards. JOHN D. GRAHAM ET AL., *IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK* 91–108 (1988).

alleging such injury quantify her risk.⁹

Judicial forcing of the quantification of risk is doing the same work in each context, and by drawing out these similarities, this Article exposes the flaws in this methodology. The seeming objectivity and simplified nature of quantification allow the court to fulfill its function without appearing to overstep its authority. The quantification of risk becomes a proxy for reasonableness and a rhetorical reinforcement against the accusation of judicial overreach and extrajudicial action.

What, however, should change? The fact remains that courts must review regulation based on risk assessment and assess claims based on the possibility of future harm, and the quantification of risk is an invaluable tool in these determinations. But, in the context of the judicial review of agency action, there are certain signals that indicate the need for a court to look more closely at an agency's treatment of a quantitative risk assessment. These signals include intra-agency discord and convoluted statutory interpretation. Moreover, the creation of an independent advisory board formed for the purpose of reviewing agency risk determinations would be a beneficial development.¹⁰

And, when a court assesses the adequacy of a party's injury in fact for standing purposes, the better rule is not to require quantification. Instead, a court that accepts increased risk as a basis for injury in fact should allow a party able to show a particularized, credible harm to present its case to the court.¹¹ Other mechanisms exist to weed out frivolous cases. This is not the purpose of the injury-in-fact doctrine.¹²

Section II of this Article describes these two scenarios in which courts grapple with, and require, the quantification of risk—the judicial review of agency action and the assessment of increased risk as a basis for injury in fact. This Section discusses the history and practice of quantitative risk assessment in agency decision making, and the tradition of judicial deference to these assessments. Here, the Article addresses the role of policy determinations within quantitative risk assessments and the tendency of such determinations to be masked by scientific rhetoric. Next, this Section looks at the increased-risk-of-harm doctrine and discusses its treatment by various courts, and in various contexts, as a basis for injury in fact.

Section III of this Article turns to the perceived benefits to judicial review of quantifying risk, which include creating a seemingly objective measure to assess risk, bridging the expertise gap between agency officials and the judiciary, clearly communicating risk determinations to the public, and assisting the court to remain within its adjudicative role. This Section then addresses the detriments of quantifying risk. These detriments include the possibility of contradicting a congressional intent to

9. See, e.g., *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin. (Pub. Citizen II)*, 513 F.3d 234, 237–38 (D.C. Cir. 2008) (noting that the imminence requirement for standing “requires ‘a very strict understanding of what increases in risk and overall risk levels’ will support injury in fact” (quoting *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin. (Pub. Citizen I)*, 489 F.3d 1279, 1296 (D.C. Cir. 2007))).

10. See STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 59–72 (1993) (describing the characteristics of a “small, centralized administrative group, charged with a rationalizing mission” to monitor agency risk assessments).

11. E.g., *Baur v. Veneman*, 352 F.3d 625, 636–41 (2d Cir. 2003). A “widely shared” harm can still be particularized. *Id.* at 635 (citing *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 24 (1998)).

12. *Id.* at 641–42.

protect the public health and safety by authorizing agencies to regulate based on the possibility of future harm, of concretizing policy determinations and uncertain calculations into unalterable law, of making plaintiffs prove their case on the merits during what should be an Article III threshold determination, of supporting the misdirection of resources, and of confusing the public by providing a false sense of certainty. Part III.C also looks at the purposes of judicial review, and demonstrates how the forcing of the quantification of risk undercuts these purposes.

Section IV makes certain suggestions for improving judicial review of risk. It discusses the proposal for an advisory board envisioned by Justice (then-Professor) Stephen Breyer two decades ago,¹³ and in the absence of such a board, notes the signals that a court can seek to indicate the need for a closer look at agency treatment of quantitative risk assessments. It also advocates that in the context of Article III standing, a plaintiff's ability to show that she suffers a credible risk of harm should be enough to satisfy the injury-in-fact requirement.

II. JUDICIAL QUANTIFICATION OF RISK

This Section describes two scenarios in which the quantification of risk plays a large part in judicial decision making. First, courts are often called upon to assess the reasonableness of agency determinations that are based, at least partially, on quantitative risk assessments. This Section explains the general structure of these quantitative risk assessments, and looks at some general trends in the judicial review thereof. Second, certain courts that allow an allegation of an increased risk of harm to satisfy the Article III standing requirements require that such increase in risk be quantified.

This Section does not suggest that these are the only situations in which courts are confronted with the quantification of risk. For example, plaintiffs in private disputes such as medical malpractice or breach of contract cases may quantify their alleged increased risk to describe their harm, and the quantification of risk may be a useful indicator of the robustness of the suit. In the two scenarios addressed here, however, the quantification of risk becomes a proxy for the reasonableness of agency action and a rhetorical reinforcement against the accusation of judicial overreach and extrajudicial action.

A. *Judicial Review of Quantitative Risk Assessments*

To fulfill a statutory mandate to protect the public from harm, federal agency officials are responsible for assessing the risks posed by substances, events, or activities to the public's health and safety.¹⁴ "Risk assessment" is therefore both a colloquialism and a term of art. First, "the term *risk assessment*, in its broadest sense, encompasses any attempt, whether quantitative or qualitative, to evaluate and weigh the

13. BREYER, *supra* note 10, at 59–72.

14. *Cf.* Alon Rosenthal et al., *Legislating Acceptable Cancer Risk From Exposure to Toxic Chemicals*, 19 *ECOLOGICAL L.Q.* 269, 273–74 (1992) (explaining that risk assessment, though typically not required by statute, is used to inform administrative decisions).

likelihood of a particular hazard occurring,”¹⁵ and second, the term is used to refer to a specific four-step process used by federal agencies for the purpose of estimating the probability of harm from a toxic or carcinogenic substance, an activity, or an event.¹⁶ This Article uses the term quantitative risk assessment (QRA) to refer to the latter usage of the term.

1. Quantitative Risk Assessment

a. *The Practice and Policy of Quantitative Risk Assessment*

QRA developed from techniques used by the Food and Drug Administration (FDA) in the 1940s and 1950s to assess the safety of food additives, and it was codified for regulatory purposes in the 1980s with a 1983 report by the National Research Council on risk assessment, known as the *Red Book*.¹⁷ The four steps of quantitative risk assessment are (1) hazard identification, (2) dose-response evaluation, (3) exposure assessment, and (4) risk characterization.¹⁸ Each step is as it sounds—hazard identification determines “whether an ‘agent’ (for example, an industrial chemical, a natural product in the environment, or a particular lifestyle)” may increase the likelihood that a person may develop disease; dose-response evaluation assesses how the probability of developing disease changes with various exposures to, or doses of, the agent; exposure assessment explores the amount of exposure people may have to an agent; and risk characterization combines the numbers “to yield an overall estimate of risk . . . expressed numerically as the incremental lifetime risk of [disease] due to a particular agent at a particular level of exposure.”¹⁹ Although easy to describe, none of the steps is as straightforward as its name implies, as is discussed below.²⁰

The QRA is appealing to federal agencies charged with protecting the public health and safety for several reasons. First, it enables agencies to translate general statutory mandates into specific action plans. For example, the Clean Air Act mandates that the Environmental Protection Agency (EPA) must list and regulate “emissions of which, in [its estimation], cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.”²¹ To move forward, the EPA translates directives such as these into quantitative goals, and in doing so determines the meaning of “endanger public health or welfare.”²² Second, QRA provides measurements that can be compared to each other, and can thus aid in regulatory

15. Mary Jane Angelo, *Harnessing the Power of Science in Environmental Law: Why We Should, Why We Don't, and How We Can*, 86 TEX. L. REV. 1527, 1542 (2008).

16. HOLLY D. DOREMUS ET AL., ENVIRONMENTAL POLICY LAW 395 (3d ed. 2008).

17. COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter RED BOOK]; Angelo, *supra* note 15, at 1541 n.75, 1542–43; DOREMUS ET AL., *supra* note 16, at 395.

18. Rosenthal et al., *supra* note 14, at 278.

19. *Id.*

20. *See id.* at 279 (noting that “risk estimates . . . can be quite difficult to quantify with precision”).

21. 42 U.S.C. § 7408(a)(1)(A) (2006).

22. *Id.*; *see also* Wagner, *supra* note 5, at 1618 (explaining that the translation of unreasonable risk into a quantitative goal is often “resolved with a single, express policy choice”).

prioritization.²³ And third, QRA provides a simple, seemingly objective explanation for an agency's regulatory choices for the purposes of both judicial review and public consumption.²⁴

Quantitative risk assessment, however, is not an exclusively scientific enterprise. Instead, it involves policy judgments at each step. These policy judgments are necessary because the risk assessment inquiry is infused with uncertainty that stems from gaps in our scientific knowledge and questions about desirable policy outcomes. “[D]espite appearances to the contrary, contemporary science is incapable of completely resolving the level at which a chemical will pose some specified, quantitative risk to humans.”²⁵ The National Research Council's *Red Book*, published in 1983, identified more than fifty science-policy decisions involved in risk assessment.²⁶

For example, there are two ways in which hazards to humans are identified. The first is through the science of epidemiology, which is the statistical study of human populations and “attempts to establish associations between human exposure to a suspected [harm] causing agent and the frequency of [disease] in the human population.”²⁷ In the case of cancer, however, this is difficult²⁸—cancer has a long latency period, it is difficult to document initial exposure to a suspected carcinogen, and individuals tend to have complicated backgrounds that may make the source of any cancer unclear.²⁹ The second method in hazard identification is animal studies, which has its own difficulties. These studies are limited in size because of financial constraints, and any effects on the animals must be translated to effects on humans, both in regards to physiological difference and size discrepancy.³⁰

23. See Rosenthal et al., *supra* note 14, at 272 (stating that “EPA risk assessments influence how the agency allocates its resources”).

24. See *id.* at 273–74 (stating that agencies started using risk assessment, not because of a legislative mandate, but “in the spirit of using good science to inform administrative decisions,” and that courts have supported such a development, going so far as to overturn administrative decisions if they “[lack] an adequate foundation in risk assessment”).

25. Wagner, *supra* note 5, at 1619. This statement applies with equal force today and to activities and events in addition to substances. Consider, for example, the effects of hydraulic fracturing on local water supplies and the earth. See Henry Fountain, *Add Quakes to Rumbblings Over Gas Rush*, N.Y. TIMES, Dec. 12, 2011, at D1 (discussing the difficulties of quantifying the increased risk of earthquakes from fracking).

26. RED BOOK, *supra* note 17, at 29–33.

27. Rosenthal et al., *supra* note 14, at 279; accord DANIEL A. FARBER ET AL., CASES AND MATERIALS ON ENVIRONMENTAL LAW 68 (2010) (confirming that epidemiology is the statistical study of human populations and can be used to measure disease in the general population).

28. Cancer holds an exceptional place in the national imagination and in public fear, and this is reflected statutorily and in agency policy. In 2010, a quarter of all American deaths were caused by cancer. SIDDHARTHA MUKHERJEE, *THE EMPEROR OF ALL MALADIES: A BIOGRAPHY OF CANCER* xv (2010). During their lifetimes, one in three women, and one in two men will develop cancer. *Id.* The word “cancer” evokes more than the disease itself, and more than the many diseases that the term encompasses. It is a “shape-shifting entity imbued with such penetrating metaphorical, medical, scientific, and political potency that cancer is often described as the defining plague of our generation.” *Id.* at xvii.

29. FARBER ET AL., *supra* note 27, at 68.; see, e.g., Siddhartha Mukherjee, *Patrolling Cancer's Borderlands*, N.Y. TIMES, July 17, 2011, at SR8 (describing, in part, the difficulty of establishing a possible link between cell phone use and brain cancer).

30. FARBER ET AL., *supra* note 27, at 68.

Thus, policy judgments must be made to carry out both epidemiological studies and animal studies, from what population to use and what animal to study, to how to filter the statistical results and translate animal results to humans.³¹ The same need for policy judgments infiltrates dose-response evaluation, the second step of QRA, including what kinds of tumors in animals to count (all, or just malignant) and the dosage appropriate for each species.³²

Exposure assessment, the third step of QRA, “determines just how much exposure to a [disease-causing agent] people actually confront.”³³ This step involves the assessment of how much exposure is seen in a population, as well as the maximum individual risk (MIR).³⁴ Both of these calculations involve uncertainty and policy judgments. For example, to estimate the MIR, an agency may use the maximally exposed individual (MEI), the “person expected to receive the greatest lifetime exposure from a particular source.”³⁵ However, the use of the MEI is a conservative policy judgment, and critics say that its use leads to overregulation.³⁶

Each agency dealing with risk uses default assumptions to grapple with the uncertainties faced in risk assessment. Default assumptions are used to reduce the amount of policy determinations made in each individual situation, or at least to standardize these determinations, but of course, the default assumptions themselves entail policy judgments.³⁷ For example, the EPA and the FDA use default assumptions about how much water people drink daily, how much food they eat, and how much air they breathe.³⁸

These default assumptions are not standardized across agencies. Interagency inconsistencies have been repeatedly documented, and criticized, by governmental entities since the 1970s.³⁹ For example, two agencies may rely on different assumptions regarding population exposure, and on different methods of extrapolating the high

31. See Wagner, *supra* note 5, at 1622 (explaining that “[t]o reach a final quantitative standard, policy considerations must fill in the gaps that science cannot inform” (footnote omitted)). Such “gaps in knowledge” are called “trans-science”—“questions which can be asked of science and yet which cannot be answered by science.” *Id.* at 1619 (emphasis omitted) (quoting Alvin M. Weinberg, *Science and Trans-Science*, 10 *MINERVA* 209, 209 (1972)).

32. Rosenthal et al., *supra* note 14, at 287.

33. *Id.* at 290.

34. *Id.*

35. *Id.* at 290–91.

36. *Id.* at 291.

37. See Robert G. Hetes, *Science, Risk, and Risk Assessment and Their Role(s) Supporting Environmental Risk Management*, 37 *ENVTL. L.* 1007, 1014 (2007) (noting that the EPA uses default assumptions “to address inherent uncertainties and data gaps” among other techniques to limit policy questions to “analytically manageable problems”).

38. Rosenthal et al., *supra* note 14, at 292–93. The FDA has a protocol for determining safe levels of chemicals in Gulf seafood based on estimates of national seafood consumption and body weights. These standards have been challenged by the Natural Resources Defense Council for grossly underestimating actual seafood consumption and human body weights in certain parts of the country. Press Release, Natural Res. Def. Council, FDA Underestimates Gulf Coast Residents’ Exposure to Carcinogens in Seafood (Dec. 8, 2010).

39. See Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 *COLUM. L. REV.* 1260, 1314–21 (2006) (discussing federal regulatory disagreement on issues such as peer review standards and cancer guidelines).

doses of agents that animals receive in controlled experiments to the lower doses that humans may receive.⁴⁰ The EPA generally uses conservative assumptions, erring on the side of protecting public health when faced with scientific uncertainty.⁴¹ A 1993 interagency survey of carcinogenic risk assessment conducted by the Presidential/Congressional Commission found that “practices in these areas vary among Federal agencies and even among regulatory programs within the EPA.”⁴² This was confirmed in 2001 by a GAO report titled *Chemical Risk Assessment: Selected Federal Agencies’ Procedures, Assumptions, and Policies*.⁴³

The final step of QRA, risk characterization, is based on the steps and the assumptions that came before it. Ideally, risk characterizations should explain the uncertainties contained within, and the assumptions used throughout the risk assessment practice.⁴⁴ This is not always the case, however. “[I]n spite of its appearance of precision, QRA is fraught with gaps in knowledge that are filled with guesses and assumptions.”⁴⁵ The appearance that risk assessment is wholly scientific masks its endemic policy determinations. Whether this masking is intentional or not, the appearance of scientific certainty is appealing to courts engaged in the judicial review of agency risk assessments.⁴⁶

b. The Rise of Quantitative Risk Assessment in Agency Decision Making

Although it is ubiquitous now, the primacy of quantitative risk assessment as the dominant risk assessment methodology was the subject of some controversy through the 1970s and early 1980s. Its triumph reflects some of the main needs of the federal government in forming and maintaining health and safety regulation—quantitative risk assessment elides both scientific uncertainty and the use of individual discretion in

40. *Id.* at 1321–22.

41. Hetes, *supra* note 37, at 1016.

42. Bagley & Revesz, *supra* note 39, at 1321 (quoting Lorenz R. Rhomberg, *A Survey of Methods for Chemical Health Risk Assessment Among Federal Regulatory Agencies*, 3 HUM. & ECOLOGICAL RISK ASSESSMENT 1029, 1030 (1997) (internal quotation marks omitted)).

43. 2001 GAO REPORT, *supra* note 8, at 46; *see also* Bagley & Revesz, *supra* note 39, at 1321 (noting that the EPA, FDA, Occupational Health and Safety Administration, and Consumer Product Safety Commission use different methods and approaches in their overlapping regulatory activities). The 2001 GAO REPORT concluded:

Although there were more similarities than differences in the general risk assessment procedures of [EPA, FDA, and OSHA], there were also some notable differences in the agencies’ specific approaches, methods, and assumptions. These differences can significantly affect the results and conclusions drawn from the assessments. Therefore, risk estimates prepared by different agencies, or by different program offices within those agencies, may not be directly comparable, even if the same chemical agent is the subject of the risk assessment.

2001 GAO REPORT, *supra* note 8, at 46.

44. *Step 4 – Risk Characterization*, U.S. EPA, <http://epa.gov/riskassessment/risk-characterization.htm> (last updated July 31, 2012).

45. Rosenthal et al., *supra* note 14, at 295.

46. *See* Wagner, *supra* note 5, at 1631–44 (discussing the difference between an “[u]nintentional [science] [c]harade,” in which an agency’s use of “hypertechnical risk assessment guidelines and complex computer models” incidentally marginalizes other policy considerations, and an “intentional charade,” in which “bureaucrats consciously disguise policy choices as science”).

decision-making processes. Both of these qualities are enormously appealing to policymakers seeking widespread support for a system to manage risk. A brief look at the struggle that took place over cancer policy four decades ago illuminates some of the oversimplifications and flaws on which contemporary risk assessment is based.

After struggling with the regulation of toxic substances in the environment and the workplace because of “huge gaps in scientific knowledge,” both the EPA and Occupational Health and Safety Administration (OSHA) worked towards the development of formal “cancer principles” during the late 1970s.⁴⁷ Both agencies looked to an extremely influential 1970 Report to the Surgeon General that suggested a policy of zero tolerance for exposure to carcinogens.⁴⁸ Each agency, however, developed a markedly different approach to the regulation of carcinogens: the EPA outlined a “case-by-case ‘weight of the evidence’ approach to addressing the carcinogenic risks posed by chemical substances,” while OSHA crafted a Generic Carcinogen Policy that aimed to “prescribe in advance the regulatory consequences of various findings concerning the carcinogenicity of workplace chemicals.”⁴⁹

The EPA’s approach to carcinogens entailed a detailed assessment of each chemical’s effect on the environment and on health, and allowed for repeated discussions of the propriety of the use of certain scientific information, whereas OSHA’s approach streamlined this process: “once a substance fell into the category of regulated chemicals, the only relevant issue was the feasibility of attaining the level that OSHA prescribed.”⁵⁰ OSHA’s approach seemed to be gaining primacy even though it was extremely unpopular with regulated entities.⁵¹ The Consumer Product Safety Commission (CPSC) began using an approach modeled after OSHA’s, and OSHA published its final policy in 1980.⁵²

In *Industrial Union Department v. American Petroleum Institute* (Benzene),⁵³ a famous 1980 decision, OSHA’s approach was struck down by the United States Supreme Court.⁵⁴ This case involved a 1977 standard promulgated by OSHA that reduced the amount of benzene allowable in the workplace from ten parts per million to one part per million.⁵⁵ In a divided opinion striking down the standard, Justice Stevens’s plurality opinion held that “the burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health

47. McGarity, *supra* note 6, at 146.

48. *Id.* at 147.

49. *Id.* at 148–49 (quoting OFFICE OF THE SCI. ADVISOR, U.S. EPA, INTERIM PROCEDURES AND GUIDELINES FOR HEALTH RISK AND ECONOMIC IMPACT ASSESSMENTS OF SUSPECTED CARCINOGENS (1976)).

50. *Id.* at 150.

51. *See id.* at 151 (describing the effort by some industries to attack the general carcinogen approach to regulation).

52. *Id.* at 151.

53. 448 U.S. 607 (1980). Throughout this Article, I will refer to *Industrial Union Department v. American Petroleum Institute* as the Benzene case as it is commonly known throughout legal scholarship. I will, however, continue to cite the case using the title as it appears in the *United States Reports*.

54. *Indus. Union Dep’t*, 448 U.S. at 662.

55. *Id.* at 617–23.

impairment,”⁵⁶ which, according to Justice Stevens, OSHA had not done.⁵⁷ Although not requiring the agency to use quantitative risk assessment, and making it clear that OSHA need not “support its finding that a significant risk exists with anything approaching scientific certainty,”⁵⁸ the Court “strongly implied that quantitative risk assessment offered the agency a safe harbor against future challenges.”⁵⁹

Thomas McGarity wrote that the “*Benzene* decision effectively resolved the science-policy battle in favor of the proponents of quantitative risk assessment.”⁶⁰ The case legitimized and encouraged the use of QRA by agencies. The National Research Council issued a study on agency use of risk assessment in 1981, followed by an Office of Science and Technology Policy review of carcinogenic risk assessment in 1985.⁶¹ Moreover, during the early 1980s, the administrator of the EPA, William Ruckelshaus, was a big booster of the technique.⁶²

The prevalence of, and support for, QRA can be explained partly by its rigid structure and apparently objective nature. It divides hard questions into simple steps, which can then be addressed scientifically. This provides agencies with justifications for their risk-management decisions and support to defend their determinations when challenged, either administratively or in court. Risk assessment is “easy to understand and appears to be a relatively straightforward method to provide clear answers to technical questions. However, although relatively easy to explain and to understand, it is rife with difficulties, prone to error, and yields often uncertain results.”⁶³

2. The Judicial Review of Quantitative Risk Assessments

a. *The Principle of Deference*

A judicial challenge to a quantitative risk assessment often takes place as one component of a broader challenge to agency action. And “[a]lthough the challenged decision is likely one of policy, the hallmark of these lawsuits is the challenger’s obsession with the scientific underpinnings of the agency’s decision.”⁶⁴ Unless

56. *Id.* at 653. Justice Powell wrote separately, concluding that the standard should be struck down because OSHA was required to do a cost-benefit analysis before regulating. *Id.* at 664 (Powell, J., concurring). Justice Rehnquist also wrote separately, arguing that the OSHA standard violated the nondelegation doctrine. *Id.* at 671 (Rehnquist, J., concurring). In 1981, the Court held, in an opinion joined by Justice Stevens, that OSHA was not required to do a cost-benefit calculation before regulating, thereby rejecting Justice Powell’s position. *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 509 (1981).

57. *Indus. Union Dep’t*, 448 U.S. at 653.

58. *Id.* at 656.

59. McGarity, *supra* note 6, at 164.

60. *Id.* at 165. *See also* Angelo, *supra* note 15, at 1544 (stating that the Benzene case “signal[ed] that some form of quantitative risk assessment was required as a prerequisite to deciding whether a risk was large enough to merit regulation”).

61. Angelo, *supra* note 15, at 1544–45 (citing COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT’L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 33 (1994); RED BOOK, *supra* note 17).

62. *Id.* at 1545.

63. *Id.* at 1558.

64. Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 749 (2011) (describing challengers’ “textbook

otherwise statutorily prescribed, a scenario addressed below, the judicial review of QRAs is governed by section 10 of the Administrative Procedure Act (APA),⁶⁵ which provides that a court may overturn agency action only if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”⁶⁶ This is a highly deferential standard, and courts must presume that the agency action is correct.⁶⁷

If the court is reviewing agency interpretation of a statute, review can be constrained by the scheme set out in *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*⁶⁸ or other degrees of judicially created deference.⁶⁹ *Chevron* deference provides that a court reviewing an agency interpretation of a statute, when that interpretation is made in the exercise of authority “to make rules carrying the force of law,”⁷⁰ must ask first “whether Congress has directly spoken to the precise question at issue,” and, if it has not, “whether the agency’s answer is based on a permissible construction of the statute.”⁷¹ Agency interpretations not found to require *Chevron* deference may nevertheless be entitled to significant deference, especially when the regulatory scheme is complex and the agency has superior expertise in the field.⁷²

Deferential review is also driven by policy. The policy choices inherent in translating congressional directives to a regulatory structure are explicitly delegated by the legislature to agencies.⁷³ The judiciary’s role is to oversee the boundaries of this activity—to ensure that administrative decision making is made within agency authority and that the decision is reasonable.⁷⁴ Beyond that, however, a court walks the line of judicial policymaking, thus overstepping its own authority.⁷⁵

Deference, however, is not synonymous with a rubber stamp. The judiciary recognizes that oversight requires more than a cursory review of agency policy; “[r]ather, the reviewing court must assure itself that the agency decision was ‘based on

approach” of arguing that a particular outcome was the result of “bad science”—performing the wrong test or using a flawed methodology—and that reaching a different outcome will require merely a better scientific design and not a change in policy).

65. Pub. L. No. 404, § 10, 60 Stat. 237, 243–44 (1946) (codified as amended at 5 U.S.C. § 706 (2006)).

66. 5 U.S.C. § 706(2)(A). If the agency action was the result of formal adjudicative process, the court uses a “substantial evidence” standard in its review. *Id.* § 706(2)(E).

67. *See, e.g., Miami-Dade Cnty. v. EPA*, 529 F.3d 1049, 1058 (11th Cir. 2008) (stating that a final action by the EPA is subject to a highly deferential standard of judicial review under the APA); *Ethyl Corp. v. EPA*, 541 F.2d 1, 33–37 (D.C. Cir. 1976) (explaining the high level of deference given to agencies by courts).

68. 467 U.S. 837 (1984).

69. *See United States v. Mead Corp.*, 533 U.S. 218, 234–35 (2001) (holding that a court may give an agency some deference in interpretation “whatever its form,” even though such interpretation is not entitled to *Chevron* deference).

70. *Id.* at 226–27.

71. *Chevron*, 467 U.S. at 842–43. Lisa Schultz Bressman notes that “[a]lthough the relationship between the *Chevron* inquiry and the [APA’s] arbitrary and capricious test has confused courts, the effect of each is much the same. Agency interpretations, like all agency policy decisions, must comport with the reasoned decisionmaking requirement.” Lisa Schultz Bressman, *Chevron’s Mistake*, 58 DUKE L.J. 549, 585 (2009). *See also Meazell, supra* note 64, at 739 n.26 (noting scientific uncertainty may play a role in a court’s review of agency action because the agency’s interpretation of a statute may implicate its area of expertise).

72. *Mead*, 533 U.S. at 234–35.

73. *Chevron*, 467 U.S. at 865–66.

74. *Id.* at 866.

75. *Id.* at 865–66.

a consideration of the relevant factors.’ Moreover, it must engage in a ‘substantial inquiry’ into the facts, one that is ‘searching and careful.’”⁷⁶ Courts maintain a higher level of deference when reviewing scientific or highly technical determinations, out of respect for the agency’s superior expertise and to maintain the appropriate role of the courts in forming policy.⁷⁷ This higher level of deference also applies when the agency determination involves an area of scientific uncertainty.⁷⁸ Nevertheless, the court must ensure that the record shows that the agency has considered all of the relevant evidence before it, and agency decision making must still be “rational.”⁷⁹

Courts, therefore, essentially undertake a two-step process when reviewing agency determinations. First, a court examines the administrative record and determines whether the agency took all of the relevant information into account, or whether it inexplicably ignored something potentially pertinent.⁸⁰ For example, in *Miami-Dade County v. EPA*, the Sierra Club argued that Miami-Dade County had not looked at the effects of a certain category of contaminants in disposal wells, but the court determined that the agency had, in fact, adequately studied these contaminants.⁸¹

Second, a court determines whether the agency’s decision, based on the information before it, was made rationally.⁸² For example, in *Natural Resources Defense Council v. EPA*,⁸³ the Second Circuit held that the EPA had acted arbitrarily and capriciously by not providing an explanation for its failure to use an elevated children’s safety factor, as it was statutorily mandated to do, in its risk assessment of a certain chemical.⁸⁴ To assess each of these factors, courts must look closely at the agency’s stated reasons for its action, without, however, substituting their own judgment for that of the agency.⁸⁵

It is clear why an adequate statement of reasons is a necessary component of

76. *Ethyl Corp. v. EPA*, 541 F.2d 1, 34–35 (D.C. Cir. 1976) (quoting *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 416 (1971)).

77. *See, e.g.*, *City of Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003) (stating that an extreme degree of deference to the agency is required when the court is evaluating scientific data within the technical expertise of the agency). *But see* Meazell, *supra* note 64, at 772–73 (arguing that courts do not always exercise “super deference” to agencies and pointing out examples in which courts have analyzed the underlying science of a policy).

78. *See Ethyl Corp.*, 541 F.2d at 28 (stating that rigorous step-by-step proof of cause and effect is not required when the evidence is hard to come by, due to the developing nature of scientific knowledge).

79. *Natural Res. Def. Council v. EPA*, 658 F.3d 200, 215 (2d Cir. 2011) (quoting *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

80. *See Miami-Dade Cnty. v. EPA*, 529 F.3d 1049, 1064 (11th Cir. 2008) (noting that an agency rule is arbitrary and capricious by law if, among other things, the agency “failed to consider an important aspect of the problem” (quoting *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43)).

81. *Miami-Dade Cnty.*, 529 F.3d at 1066–67.

82. *See, e.g.*, *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 840 (1984) (explaining that the court’s analysis turns on whether the agency employed a “reasonable construction” of the statutory language).

83. 658 F.3d 200 (2d Cir. 2011).

84. *Natural Res. Def. Council*, 658 F.3d at 218.

85. *See, e.g.*, *League of Wilderness Defenders-Blue Mountains Defenders Biodiversity Project v. U.S. Forest Serv.*, 549 F.3d 1211, 1215 (9th Cir. 2008) (noting the narrowness of judicial review under the arbitrary and capricious standard and stating that an agency decision will only be overturned if a “clear error of judgment” is apparent (quoting *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989))).

agency decision making. Beyond encouraging rational action from the agency, the statement of reasons allows interested parties to assess the challenged determination without the need to engage in the potentially prohibitive review of the record. In addition, a sufficient statement of reasons provides a court engaging in judicial review access to agency decision making. A court may not, and in any event, could not, replicate the agency's decision-making process by assessing the entire factual record.⁸⁶

b. Specific Statutory Judicial Review Provisions

The previous discussion of deference assumed that review is governed by section 706 of the APA. Certain statutes, however, contain specific review provisions, which further restrict a court's discretion in its review of agency decision making. One such statute is the Occupational Health and Safety Act of 1970 (OSH Act).⁸⁷ When OSHA promulgates a new standard, the Secretary must "include a statement of the reasons for such action."⁸⁸ The OSH Act also provides that "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole," a more stringent standard than the arbitrary and capricious standard.⁸⁹ Courts have interpreted this provision to apply to factual evidence as opposed to policy judgments.⁹⁰

It is difficult, however, for courts to separate factual determinations from legislative policy judgments when reviewing ultimate agency determinations. When reviewing OSHA's standard regulating employee exposure to ethyleneimine, which the agency had found to be a potential human carcinogen, the Third Circuit noted that "[t]his case is a good illustration of the difficulty of attempting to measure a legislative policy decision against a factual yardstick" because extrapolating animal study data to effects on humans is a determination that involves both factual assessments and policy judgments.⁹¹ "[T]he extrapolation of that determination from animals to humans is not really a factual matter."⁹² Other circuits have grappled with the difficulty of separating factual findings from legislative policy judgments in the context of the OSH Act as well.⁹³

86. *See Dry Color Mfrs. Ass'n, Inc. v. Dep't of Labor*, 486 F.2d 98, 106 (3d Cir. 1973) (requiring agencies to justify actions with sufficient reasoning—and not mere conclusory statements—so courts can avoid an after-the-fact review of a voluminous factual record in search of a rationalization that may not reflect the agency's actual reasoning at the time the regulation was issued).

87. 29 U.S.C. § 655 (2006).

88. *Id.* § 655(e).

89. *Id.* § 655(f).

90. *See, e.g., Synthetic Organic Chem. Mfrs. Ass'n v. Brennan*, 503 F.2d 1155, 1158 (3d Cir. 1974).

91. *Id.* at 1158–59.

92. *Id.* at 1159.

93. *See, e.g., AFL-CIO v. OSHA*, 965 F.2d 962, 970 (11th Cir. 1992) (stating that the substantial evidence test applies to both policy decisions and factual determinations even though policy decisions are not as easily refuted or verified); *Pub. Citizen Health Research Grp. v. Tyson*, 796 F.2d 1479, 1485 (D.C. Cir. 1986) (describing the problem reviewing courts have applying the substantial evidence test to OSHA's hybrid rulemaking, which combines formal and informal aspects of decision making); *United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1206–07 (D.C. Cir. 1981) (describing the peculiar problem courts have applying the substantial evidence test to OSHA regulations which are rooted in inferences and complex data).

Because of the impossibility of cleanly distinguishing factual and policy judgments, courts have interpreted the OSH Act to allow for judicial review of both, although only facts are subject to the “substantial evidence” test.⁹⁴

[B]ecause judicial review of legislative-like decisions inevitably runs the risk of becoming arbitrary supervision and revision of the Secretary’s efforts to effectuate the legislative purposes in an area where various responses might each be legitimate in the sight of Congress, [a court should] remand only those provisions of [a] standard which le[ave] “nagging questions . . . as to the reason and rationale for the Secretary’s particular choices.”⁹⁵

And to negotiate the OSH Act’s restraints on judicial review while also ensuring that the promulgated standards fit appropriately within the purview of OSHA, the Third Circuit has developed a five-step inquiry. The court looks to

- (1) determine whether the Secretary’s notice of proposed rulemaking adequately informs interested persons of the action taken;
- (2) determine whether the Secretary’s promulgation adequately sets forth reasons for his action;
- (3) determine whether the statement of reasons reflects consideration of factors relevant under the statute;
- (4) determine whether presently available alternatives were at least considered; and
- (5) determine whether substantial evidence in the record as a whole supports the Secretary’s determination, if it is based in whole or in part on factual matters subject to evidentiary development.⁹⁶

This test imposes a seemingly objective inquiry over the necessarily subjective review of an agency decision that is most likely based on both facts and policy determinations. Each step nominally allows the judiciary to assess the record before it to ensure that the agency has acted properly, while not encroaching on the agency’s authority.

Other statutes contain judicial review provisions as well, although some of these mirror the APA’s language. For example, the Clean Air Act provides that a court may reverse an agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”⁹⁷ The Federal Food, Drug, and Cosmetic Act (FFDCA) “contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions,” which prescribe which court (district court or court of appeals) will hear appeals from agency action.⁹⁸

94. See, e.g., *Pub. Citizen Health Research Grp. v. Dep’t of Labor*, 557 F.3d 165, 175 (3d Cir. 2009) (stating the court would not disrupt OSHA’s policy determinations as long as the Agency’s decisions were “reasonably drawn” from the record); *Am. Iron & Steel Inst. v. OSHA*, 577 F.2d 825, 831 (3d Cir. 1978) (noting that the court would apply the “substantial evidence” test only on factual matters and not on “non-factual, legislative-like policy decisions”).

95. *Pub. Citizen Health Research Grp.*, 557 F.3d at 175 (omission in original) (second, third, and fourth alteration in original) (quoting *Am. Iron & Steel Inst.*, 577 F.2d at 834).

96. *Id.* at 176–77 (quoting *Am. Iron & Steel Inst.*, 577 F.2d at 830–31).

97. 42 U.S.C. § 7607(d)(9)(A) (2006).

98. *In re Natural Res. Def. Council*, 645 F.3d 400, 404 (D.C. Cir. 2011) (quoting *Cutler v. Hayes*, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987)).

c. The Principle of Deference and Quantitative Risk Assessment

Under the judicial review provisions of both the APA and specific statutes, courts are instructed to defer to agency decision making, but are also signaled to do a searching review of the record to ensure rational decision making.⁹⁹ The review of a quantitative risk assessment fits easily into this scheme. The presence of a QRA in the decision-making process of an agency provides answers to the questions that courts ask of agencies to ensure that the agency has not acted arbitrarily or capriciously. QRAs are both highly technical and exactly structured.¹⁰⁰ They thus provide a seemingly accessible answer to the question of whether an agency considered all of the relevant information. Moreover, the apparently logical nature of the conclusion reached through a QRA—the last step, characterization of risk, is reached by means of the other three steps—negates any accusation of arbitrariness.¹⁰¹ By deferring to an agency's use of QRA, the court is able to show that it respects both the agency's superior technical expertise, as well as the agency's resolution of uncertainty. The court therefore remains within its appropriate role and properly negotiates the balance between deference and searching review.¹⁰²

For these reasons, courts often affirm agency action regarding QRAs,¹⁰³ even when they overturn other aspects of an agency determination.¹⁰⁴ This is true whether the agency accepts and uses the outcome of the QRA, or whether the agency chooses to reject the QRA.¹⁰⁵

d. The Failure to Defer

There are, of course, situations where courts do not defer to agency decision making, both in regards to risk assessments and to ultimate regulatory determinations. In these cases, courts are usually responding to one or more of several clear signals that the agency decision making was inappropriate. These signals include the agency's noncompliance with a strong statutory command, documented intra-agency disagreement, and an allegation that the agency is acting outside of its jurisdictional

99. See 5 U.S.C. § 706 (2006) (instructing courts to overrule agency decisions when they are arbitrary and capricious, unconstitutional, or exceed statutory authority).

100. See *supra* Part II.A.1.a for a discussion of the QRA process.

101. See *supra* note 19 and accompanying text for an explanation of the last step in a QRA.

102. See *supra* Part II.A.2.a for a discussion of the deference courts will give to agencies using QRA.

103. See, e.g., *Miami-Dade Cnty. v. EPA*, 529 F.3d 1049, 1071 (11th Cir. 2008) (deferring to the judgment of the EPA because the regulation was sufficiently supported by the administrative record and was not arbitrary and capricious); *Kennecott Greens Creek Mining Co. v. Mine Safety and Health Admin.*, 476 F.3d 946, 952–53 (D.C. Cir. 2007) (affirming an agency regulation due to the exhaustive risk assessment analysis that was conducted).

104. See, e.g., *Natural Res. Def. Council v. EPA*, 658 F.3d 200, 219–20 (2d Cir. 2011) (overturning the Agency's use of a lowered safety factor for children and infants in one risk assessment because of lack of adequate explanation, but upholding the Agency's other risk assessments); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 528 (D.C. Cir. 2009) (upholding the EPA's decision not to rely on a risk assessment, while overturning other aspects of the EPA's determinations).

105. See, e.g., *Am. Farm Bureau*, 559 F.3d at 528 (denying petition seeking review of the EPA's decision not to rely on a specific risk assessment); *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 373 (D.C. Cir. 2002) (deferring to the EPA's adequately explained decision to ignore risk assessment).

authority.¹⁰⁶

For example, in *American Farm Bureau Federation v. EPA*,¹⁰⁷ several organized groups, including environmental advocates and industry, challenged the EPA's revised National Ambient Air Quality Standards for a certain type of air pollution.¹⁰⁸ The court held that some of the challenged standards were "contrary to law and unsupported by adequately reasoned decisionmaking," and remanded them to the agency.¹⁰⁹ In doing so, the court looked to a disagreement that had taken place between the EPA and the Clean Air Scientific Advisory Committee (CASAC), an independent scientific review board appointed by the EPA's Administrator, and to the fact that the EPA had, over time, changed its position on the standards.¹¹⁰

When the EPA rejects recommendations made by CASAC, it is statutorily required to explain why, and the court concluded that the agency had not done so in *American Farm Bureau*.¹¹¹ The court also found that the EPA did not adequately explain why it no longer relied on short-term studies, as it had a decade earlier.¹¹² These disagreements, between the EPA and an independent advisory board, and between the EPA and an earlier version of itself, signaled to the court that there was the possibility that the promulgated standards rested on shaky ground.¹¹³ The EPA's failure to explain these disagreements to the court's satisfaction confirmed this suspicion.¹¹⁴

In *Natural Resources Defense Council*, the court vacated and remanded part of an EPA order that assessed the risk of a carcinogenic pesticide.¹¹⁵ The court found that the EPA had not adequately explained why it used a threefold safety factor instead of a tenfold safety factor, as was mandated by statute.¹¹⁶ This failure to explain was arbitrary and capricious.¹¹⁷ The EPA had failed to comply with a clear statutory

106. See *Am. Farm Bureau*, 559 F.3d at 519 (explaining the factors the court will look at in determining whether to defer to agency decision making).

107. 559 F.3d 512 (D.C. Cir. 2009)

108. *Id.* at 517–19 (listing the American Lung Association, Environmental Defense, National Parks Conservation Association, individual states, state agencies, National Pork Producers Council, National Cattlemen's Beef Association, and Agricultural Retailers Association as petitioners).

109. *Id.* at 515.

110. *Id.* at 521.

111. *Id.*

112. *Id.* at 522.

113. *Id.* at 528.

114. The court remanded the standards for reconsideration. It did not vacate the standards because "the EPA's failure to adequately explain itself is in principle a curable defect." *Id.* at 528; see also *Pub. Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D. D.C. 1987) (finding the Secretary of Health and Human Services' rejection of the FDA's recommendation that interstate sales of raw milk be banned arbitrary and capricious).

115. *Natural Res. Def. Council v. EPA*, 658 F.3d 200, 201 (2d Cir. 2011).

116. *Id.* at 218. The Food Quality Protection Act (FQPA), Pub.L. No. 104–170, 110 Stat. 1489 (1996), requires the EPA to use a tenfold margin of safety "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." *Natural Res. Def. Council*, 658 F.3d at 203 (quoting 21 U.S.C. § 346a(b)(2)(C)(ii)). A different margin of safety may be used by the EPA "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.* at 203–04 (emphasis omitted). In *Natural Resources Defense Council*, the petitioners alleged, and the court agreed, that the EPA had not explained why the lesser margin used would be safe for infants and children. *Id.* at 217–18.

117. *Natural Res. Def. Council*, 658 F.3d at 218.

directive, and the court therefore overturned the EPA's use of its risk assessment.¹¹⁸

Similarly, in *Les v. Reilly*¹¹⁹ and *Public Citizen v. Young*,¹²⁰ two courts of appeals refused to allow the FDA or the EPA to read an implicit de minimis exception into the "Delaney Clause," the provision of the FFDCA that prohibits all food and color additives found to induce cancer.¹²¹ In *Young*, the District of Columbia Circuit reluctantly held that the FDA had erred in reading a de minimis policy into the Delaney Clause.¹²² The court found that the agency had correctly characterized the risks posed by the dyes as trivial and that "if the statute were to permit a de minimis exception, this would appear to be a case for its application."¹²³ The court also explained the importance of the de minimis exception in statutory interpretation, writing that "[c]ourts (and agencies) are not, of course, helpless slaves to literalism."¹²⁴

Here, however, the court held that it could not agree that the Delaney Clause allowed for a de minimis interpretation.¹²⁵ It based its decision on legislative history, the fact that the strictness of the Clause could be explained by the public's fear of cancer, and the lack of intrinsic value in color additives.¹²⁶ In 1992, the Ninth Circuit extended the District of Columbia Circuit's interpretation to food additives in *Reilly* and overturned EPA regulations allowing pesticides with a trivial carcinogenic risk to be used as food additives.¹²⁷

The District of Columbia and Ninth Circuits' refusals to defer to the EPA and FDA's interpretations of the FFDCA were not a foregone conclusion. There was, arguably, room for the courts of appeals to have interpreted the Delaney Clause as permitting a de minimis exception.¹²⁸ There are several statutory exceptions to the Delaney Clause,¹²⁹ and there have been several recent judicial decisions encouraging

118. *Id.* at 219.

119. 968 F.2d 985 (9th Cir. 1992).

120. 831 F.2d 1108 (D.C. Cir. 1987).

121. *Reilly*, 968 F.2d at 990; *Young*, 831 F.2d at 1122.

122. *Young*, 831 F.2d at 1122.

123. *Id.* at 1112. The lifetime cancer risk for Orange No. 17 was calculated at one in nineteen billion, and the lifetime cancer risk for Red No. 19 as one in nine million. *Id.* at 1111.

124. *Id.* at 1112. The purposes served by the doctrine included the conservation of agency resources, the avoidance of absurd or futile results, and the avoidance of results that are "directly contrary to the primary legislative goal." *Id.* at 1112-13 (emphasis omitted). For example, if no de minimis exception to the Delaney Clause were made, a manufacturer may use a substance in a color additive that, although not carcinogenic, may carry more risk to humans than the banned carcinogen. *Id.* at 1117-18.

125. *Id.* at 1123.

126. *Id.* at 1113-17.

127. *Les v. Reilly*, 968 F.2d 985, 990 (9th Cir. 1992).

128. See Margaret Gilhooley, *Plain Meaning, Absurd Results and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267, 298-99 (1988) (arguing that Congress's lack of concern with very low levels of residue permit reading a de minimis exception into the Delaney Clause, and that the Clause would still have an important function despite the acceptance of a triviality exception).

129. These exceptions include the "DES exception" and the saccharin exception. 21 U.S.C. § 360b (2006). In 1962, Congress amended the Delaney Clause to make it inapplicable to DES, a synthetic estrogen that aids in livestock growth. *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 979 (D.C. Cir. 1974) (citing 21 U.S.C. § 360b(d)(1)(H)). And in 1977, while the FDA was preparing to withdraw the approval of saccharin based on the Delaney Clause, Congress added a provision to the FFDCA postponing any restriction on saccharin for two years, which was reenacted four times through 2001. See Richard A. Merrill, *FDA's*

discretion in defining “food additive.”¹³⁰ Moreover, the courts recognized the criticism that a rigid interpretation of the Delaney Clause could lead to more harm than good (when, for example, manufacturers substituted newer and not-yet-tested, or potentially toxic, substances for carcinogenic substances).¹³¹ In addition, the District of Columbia Circuit itself had previously established what almost amounted to a presumption in favor of construing statutes to have de minimis clauses.¹³² Nevertheless, the courts of appeals found themselves constrained to overturn agency action because they interpreted the Delaney Clause to be a strong and clear statutory command.

There are, of course, cases where courts fail to defer to agency action in the area of risk assessment in the absence of any of the signals described above. The most famous of these cases is the Benzene case, which is noteworthy for its particularly interventionist and nondeferential approach to the judicial review of agency action. In the Benzene case, the Court invalidated a standard set by OSHA on the chemical benzene, and in doing so, the plurality disagreed with OSHA’s interpretation of its guiding statute,¹³³ and argued with the Agency’s interpretation of the scientific data it had collected.¹³⁴ Here, there was neither a “clear” statutory command to which the

Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?, 5 YALE J. ON REG. 1, 30 (1988) (explaining the vehement opposition to saccharin bans which led to postponement of any restrictions on the additive). Doubts as to saccharin’s carcinogenicity began to arise in the 1990s. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 1163 (3d ed. 2007). In 2000, the National Toxicology Program released a list of potential human carcinogens, and saccharin had been removed. *Id.* Also in 2000, Congress repealed the warning requirements for saccharin. Consolidated Appropriations—FY 2001, Pub. L. No. 106-554, § 517, 114 Stat. 2763 (2000) (repealing subsection (c) and (d) of section 4 of the Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451 (1977)).

130. See *Scott v. FDA*, 728 F.2d 322, 324 (6th Cir. 1984) (affirming the FDA’s approval of a color additive containing a carcinogenic constituent); *Monsanto Co. v. Kennedy*, 613 F.2d 947, 953–54 (D.C. Cir. 1979) (explaining that the FDA had a “greater measure of discretion in applying the statutory definitions of ‘food additive’ than [it] appears to have thought,” and that “there is latitude inherent in the statutory scheme to avoid literal application of the statutory definition of ‘food additive’ in those de minimis situations that, in the informed judgment of the Commissioner, clearly present no health or safety concerns”).

131. See *Reilly*, 968 F.2d at 990 (discussing a recent study suggesting that “some pesticides might be barred by rigid enforcement of the Delaney clause while others, with greater cancer-causing risk, may be permitted through the flow-through provisions because they do not concentrate in processed foods”); Cass R. Sunstein, *On the Costs and Benefits of Aggressive Judicial Review of Agency Action*, 1989 DUKE L.J. 522, 526 (1989) (arguing that “the courts’ literal approach to the Delaney Clause has increased regulatory irrationality by imposing serious costs and in fact bringing about fewer rather than more improvements in safety and health”).

132. *Pub. Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987) (stating that the rigid language of the Delaney Clause does not necessarily provide an exemption for small but measurable risks).

133. See *Indus. Union Dep’t v. Am. Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality opinion) (stating that before regulating, OSHA must find that “the workplaces in question are not safe,” but noting that “‘safe’ is not the equivalent of ‘risk-free’”).

134. See *id.* at 634–35 (stating that OSHA mistakenly rejected industry contentions in evaluating the data). The Court did not actually engage with the scientific determinations made, but rather argued that OSHA had selectively relied on certain evidence. *Id.* The Court took care to explain that although its “review of these cases has involved a more detailed explanation of the record than is customary,” it did not make “factual determinations of [its] own, nor . . . rejected any factual findings made by the Secretary.” *Id.* at 658–59. It remains, however, that OSHA had determined that a reduction of the benzene level to the lowest feasible limit was necessary, and the Court, based on its determination that the studies did not show a risk at 10ppm,

Court could point (the OSH Act was ambiguous on the question presented), nor was there intra-agency disagreement.¹³⁵ The Court's lack of deference to the Agency has received much criticism,¹³⁶ as has the plurality's misguided attempt to buttress its conclusions with justifications based on risk assessment. For example, some commentators suggest that because Justice Stevens "neglected to mention the extent of exposure to the risk-producing activity, one of the most elementary concepts of risk assessment,"¹³⁷ "[t]he opinion effectively equated uncertain risk with insignificant risk,"¹³⁸ and also note the burden shifting undertaken by the plurality may have been based on an imperfect reading of the APA.¹³⁹

B. The Quantification of Increased Risk of Harm for the Purpose of Article III Standing

Agencies attempt to quantify risk for the purpose of crafting regulation that is protective of public health and safety while not stifling economic growth.¹⁴⁰ Courts rely on, and defer to, this quantification because it provides a seemingly objective indicator of the agency's consideration of relevant factors and reasoned determination.¹⁴¹ The quantification of risk also allows courts to feel comfortable adjudicating issues beyond their expertise and to remain comfortably within their sphere of authority. A QRA is a measurable, coherent, and structured analysis that demonstrates to a court that an agency is doing its job.¹⁴²

These qualities—objectivity, expertise bridging, and authority reinforcement—transform risk from amorphous and subjective to measurable and objective. It is for this reason that certain courts require that risk be quantified in other contexts, notably when allowing the increased risk of harm to satisfy Article III standing.

To satisfy the Article III standing requirements, a plaintiff in federal court must show (1) that she has suffered injury in fact, which must be concrete and particularized, and actual or imminent; (2) traceability—that she can trace her alleged injury to the targeted harm; and (3) redressability—that her injury will be redressed by the remedy

disagreed with this finding. *Id.* at 634.

135. See *id.* at 616–25 (detailing the Agency's findings and noting no disagreement within the Agency).

136. See McGarity, *supra* note 6, at 165 (noting that a deferential approach emphasizing the Occupational Safety and Health Act of 1970 § 6(b)(5), 29 U.S.C. § 655(b)(5), as OSHA had done, "would have avoided the embarrassment of a judicially created and incoherently defined concept of 'significant risk'"); Meazell, *supra* note 64, at 762–63 (listing numerous critiques of the Benzene case).

137. McGarity, *supra* note 6, at 164; see also GRAHAM ET AL., *supra* note 8, at 113 (arguing that "[t]he ambiguity of 'significant risk' in the plurality opinion may reflect the twin evils of ignorance and opportunism").

138. Howard A. Latin, *The Feasibility of Occupational Health Standards: An Essay on Legal Decisionmaking Under Uncertainty*, 78 NW. U. L. REV. 583, 589 (1983) (emphases omitted).

139. *Id.* at 590 (explaining that the APA imposes the burden of proof on the proponent of a rule unless it is otherwise provided by statute, and questioning whether the OSH Act implicitly shifts the burden).

140. See, e.g., *Indus. Union Dep't*, 448 U.S. at 611 (stating that the purpose of OSH Act was to provide the most stringent regulation "that is technologically and economically possible").

141. See *supra* Part II.A.1.a for a discussion of the purposes and processes of QRA.

142. See *supra* Part II.A.1.a for a discussion of the purposes and processes of QRA.

sought.¹⁴³ These are threshold requirements. Whether or not the person prevails is a different matter from whether that person can bring a suit in federal court.¹⁴⁴

Injury in fact is usually, and most straightforwardly, met by showing actual harm. A person is hurt, and that person brings suit against the person or entity that hurt him to fix his injury. However, one need not wait for the potentially irreversible harm to take place before bringing suit.¹⁴⁵ The Seventh Circuit has explained that “[i]njury need not be certain. Any pre-enforcement suit entails some element of chance: perhaps the plaintiff will desist before the law is applied, perhaps the law will be repealed, or perhaps the law won’t be enforced as written. But pre-enforcement challenges nonetheless are within Article III.”¹⁴⁶

If the plaintiff does not allege actual injury, she can either allege future harm or probabilistic injury. Future harm is exactly that—harm that will occur in the future, and it only satisfies the injury-in-fact requirement if it is “certainly impending.”¹⁴⁷ Probabilistic injury is based on the idea that a plaintiff is at an increased risk of harm due to the defendant’s actions, and that this increased risk constitutes a harm in and of itself.¹⁴⁸ In reality, these two categories of harm run together, although courts will consider the magnitude of the harm in light of its probability of occurring in the probabilistic injury context.¹⁴⁹ In other words, the worse the injury, the less likely it need be to suffice for injury in fact.¹⁵⁰ In one probabilistic injury case, the plaintiffs alleged that the forest in which they recreated was at an increased risk of a catastrophic wildfire because of governmental policy.¹⁵¹ The District of Columbia Circuit held that this allegation satisfied the standing requirements, finding that “[t]he more drastic the injury that government action makes more likely, the lesser the increment in probability necessary to establish standing.”¹⁵² Cases involving medical claims may also be brought based on probabilistic injury.¹⁵³

143. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992).

144. *Amnesty Int’l USA v. Clapper (Amnesty Int’l I)*, 638 F.3d 118, 131 (2d Cir. 2011), cert. granted sub nom. *Clapper v. Amnesty Int’l USA*, 132 S. Ct. 2431 (May 21, 2012) (No. 11–1025).

145. Cf. *Ayers v. Twp. of Jackson*, 525 A.2d 287, 297–98 (N.J. 1987) (stating that if a plaintiff waits until the harm has actually taken place before bringing suit, she may run into a statute of limitations problem).

146. *Brandt v. Vill. of Winnetka*, 612 F.3d 647, 649 (7th Cir. 2010) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 140–48 (1967)).

147. Cassandra Sturkie & Suzanne Logan, *Further Developments in the D.C. Circuit’s Article III Standing Analysis: Are Environmental Cases Safe From the Court’s Deepening Skepticism of Increased-Risk-of-Harm Claims?*, 38 ENVTL. L. REP. 10460, 10461 (2008) (emphasis omitted) (citing *Lujan*, 504 U.S. at 564 n.2).

148. See Claire Finkelstein, *Is Risk a Harm?*, 151 U. PA. L. REV. 963, 967 (2003) (arguing that “exposing someone to a risk of harm itself harms him”). Finkelstein explains that “exposure to risk is a setback to a legitimate interest,” which is the definition of harm, and finds evidence that in certain cases the legal system supports this notion. *Id.* at 972, 975–90. Finkelstein looks specifically at the tort system and the criminal law context. *Id.*

149. E.g., *Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003).

150. *Id.*

151. *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1232 (D.C. Cir. 1996).

152. *Id.* at 1234; see also *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002) (holding that the petitioners had standing to challenge the construction of a fuel producing facility based on the possibility that the construction of the facility would cause the air they breathed to contain more pollutants).

153. See *Sutton v. St. Jude Med. S.C., Inc.* 419 F.3d 568 (6th Cir. 2005) (holding that plaintiffs

Probabilistic injury suits are a source of anxiety for courts, however. There is the possibility that

[o]pening the courthouse to these kinds of increased-risk claims would drain the “actual or imminent” requirement of meaning in cases involving consumer challenges to an agency’s regulation (or lack of regulation); would expand the “proper—and properly limited”—constitutional role of the Judicial Branch beyond deciding actual cases or controversies; and would entail the Judiciary exercising some part of the Executive’s responsibility to take care that the law be faithfully executed.¹⁵⁴

It is as a result of these concerns that the District of Columbia Circuit requires plaintiffs to quantify their increased risk as a prerequisite to obtaining standing.¹⁵⁵ Other courts, however, do not require quantification.¹⁵⁶ This Part discusses the differing approaches of two Circuits, the Second and the District of Columbia, and the ways that courts have negotiated increased-risk claims in two contexts—that of claims for medical-monitoring expenses because of an increased risk of harm and that of claims for credit-monitoring expenses because of an increased risk of identity theft.

1. The Second Circuit and Increased-Risk-of-Harm Claims

The Second Circuit has recognized increased risk of harm as a basis for Article III standing in several contexts, including in food and drug safety,¹⁵⁷ fraudulent tax advice,¹⁵⁸ and government surveillance.¹⁵⁹ The court does not require that plaintiffs quantify their risk, although it states that “probabilistic injuries constitute injuries in fact only when they reach a certain threshold of likelihood.”¹⁶⁰

demonstrating an increased risk of harm as a result of the use of a new medical device as compared to traditional surgery have pleaded sufficient facts to confer standing); *Baur*, 352 F.3d at 641 (“The relevant ‘injury’ for standing purposes may be exposure to a sufficiently serious risk of medical harm—not the anticipated medical harm itself—thus only the exposure must be imminent, not the actual onset of disease.”).

154. *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin. (Pub. Citizen II)*, 489 F.3d 1279, 1295 (D.C. Cir. 2007).

155. *E.g., Mountain States*, 92 F.3d at 1238.

156. See *infra* Part II.B.1 for a discussion of the Second Circuit’s view on the quantification of risk.

157. See *Baur*, 352 F.3d at 640–41 (holding that the plaintiff alleged a sufficiently credible risk of harm in a claim involving exposure to meat products from downed livestock).

158. *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264–65 (2d Cir. 2006). The court elaborated:

An injury-in-fact may simply be the fear or anxiety of future harm. For example, exposure to toxic or harmful substances has been held sufficient to satisfy the Article III injury-in-fact requirement even without physical symptoms of injury caused by the exposure, and even though exposure alone may not provide sufficient ground for a claim under state tort law.

Id.

159. See *Amnesty Int’l USA v. Clapper (Amnesty Int’l I)*, 638 F.3d 118, 134 (2d Cir. 2011) (holding that the plaintiff had standing to challenge the constitutionality of an amendment to the Foreign Intelligence Surveillance Act), *cert. granted sub nom.* *Clapper v. Amnesty Int’l USA*, 132 S. Ct. 2431 (May 21, 2012) (No. 11–1025); *cf. Caudle v. Towers, Perrin, Forster & Crosby, Inc.*, 580 F. Supp. 2d 273, 279–80 (S.D.N.Y. 2008) (allowing increased risk of harm to satisfy the injury-in-fact requirement in case based on the threat of future identity theft); *Shariff v. Goord*, 235 F.R.D. 563, 570 (W.D.N.Y. 2006) (allowing increased risk of harm to satisfy the injury-in-fact requirement in case based on the defendant’s failure to secure the plaintiff prisoner’s wheelchair properly when he was being transported).

160. *Amnesty Int’l I*, 638 F.3d at 133.

In *Baur v. Veneman*,¹⁶¹ which is the Second Circuit's "principal 'probabilistic injury' case,"¹⁶² the court overturned the district court's denial of standing to the plaintiff, Michael Baur.¹⁶³ Baur had sued the United States Department of Agriculture (USDA) to reverse its policy allowing downed cattle into the food supply.¹⁶⁴ Downed cattle are cattle that are too sick to stand or walk before slaughter, and at the time, USDA policy allowed such animals into the food supply after inspection.¹⁶⁵ Baur claimed standing based on his status as a consumer of meat who was at increased risk of harm of contracting mad cow disease because of the Department of Agriculture's policy.¹⁶⁶ The district court held that Baur's claim was too hypothetical and speculative to serve as the basis for Article III standing, as mad cow disease had not, as yet, been detected in the United States.¹⁶⁷

The Second Circuit vacated and remanded, holding that "enhanced risk of disease transmission may qualify as injury-in-fact in consumer food and drug safety suits," and that Baur had "alleged a sufficiently credible risk of harm" in the present case to satisfy the Article III requirements.¹⁶⁸ The court held that, as in environmental cases, "the potential harm from exposure to dangerous food products or drugs 'is by nature probabilistic,' yet an unreasonable exposure to risk may itself cause cognizable injury," and that the purpose of the statutes under which Baur sued, the Federal Meat Inspection Act and the FFDCFA, was to protect consumers from the very type of injury that Baur alleged.¹⁶⁹

These two factors—the fact that the potential harm was by nature probabilistic, and the fit between the injury alleged and the statutory scheme—have been subsequently noted as the factors for which a court should look when determining an increased-risk-of-harm standing question.¹⁷⁰ Notably, however, the court made no attempt to quantify the increase in risk faced by Baur, nor does it require quantification in later probabilistic injury cases.¹⁷¹

161. 352 F.3d 625 (2d Cir. 2003).

162. *Amnesty Int'l USA v. Clapper (Amnesty Int'l II)*, 667 F.3d 163, 198 (2d Cir. 2011) (Livingston, J., dissenting in the denial of rehearing en banc).

163. *Baur*, 352 F.3d at 628.

164. *Id.* at 627–28.

165. *Id.*

166. *Id.* at 628–29.

167. *Id.* at 628.

168. *Id.*

169. *Id.* at 634–35 (quoting *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 160 (4th Cir. 2000)). Here the court assumes that risk itself is a cognizable harm, which is, of course, not entirely uncontroversial. See Finkelstein, *supra* note 148, at 976 (discussing the position traditionally taken by courts that harm from risk is not legally cognizable). The Federal Meat Inspection Act and the FFDCFA protect against exposure to the disease that Baur feared, not the general increased risk thereof. See *Baur*, 352 F.3d at 634 (stating that to have standing a plaintiff must not only allege a general increased risk of harm, but also "exposure to potentially harmful products").

170. *Amnesty Int'l USA v. Clapper (Amnesty Int'l II)*, 667 F.3d 163, 194–96 (2d Cir. 2011) (Livingston, J., dissenting in the denial of rehearing en banc) (criticizing the majority for ignoring these important factors and expanding the categories of probabilistic injuries that merit standing).

171. *Baur*, 352 F.3d at 634–35.

In *Denney v. Deutsche Bank AG*,¹⁷² the court granted standing to “future-risk plaintiffs,” who had relied on fraudulent tax advice but had not been audited at the time of the case.¹⁷³ The court granted standing because, in part, it was possible that the future-risk plaintiffs could be audited under an exception to the statute of limitations.¹⁷⁴ Although an audit—the link to the tax penalties which were the ultimate harm feared—was not “certainly impending,”¹⁷⁵ the plaintiffs were subject to an increased risk that this chain of events would take place.¹⁷⁶

And in *Amnesty International USA v. Clapper (Amnesty International I)*,¹⁷⁷ decided in 2011, the court found that the plaintiffs’ fear of future injury was “in anticipation of future government action that is reasonably likely to occur.”¹⁷⁸ To assess this likelihood, the court looked to whether the government conduct was authorized by a present governmental policy or statute, which it was, and whether the plaintiffs had “good reason” to believe that their actions would fall within the scope of the statute, which they did.¹⁷⁹ Nor did the dissent from the denial of rehearing en banc, which criticized the opinion’s treatment of probabilistic injury, call for a quantification of the plaintiffs’ increased risk of harm due to the statute.¹⁸⁰ Instead, it focused on the fact that the conduct targeted by the plaintiffs was only feared, not impending.¹⁸¹

In all of these cases, the ultimate injury feared by the plaintiffs was uncertain. In *Baur* and *Amnesty International I*, even the exposure to the harm-causing agent (mad cow disease and government surveillance, respectively) was uncertain. Nevertheless, the imminence of the exposure—not that of the injury—was permitted to satisfy the requirements of injury in fact.¹⁸² And, in none of these cases did the court seek quantification of this increased risk.

2. The District of Columbia Circuit and Increased-Risk-of-Harm Claims

The District of Columbia Circuit takes a stricter approach to increased-risk-of-harm claims. When a petitioner seeks review of governmental action in the District of Columbia Circuit, he must “support ‘by affidavit or other evidence’ each of the three

172. 443 F.3d 253 (2d Cir. 2006).

173. *Denney*, 443 F.3d at 264–66 (internal quotation mark omitted).

174. *Id.* (reasoning that future-risk plaintiffs had suffered injury in fact because they had acted based on fraudulent tax advice, including costs plaintiffs incurred to rectify their mistakes).

175. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 567 n.3 (1992) (citing the requirement that the harm be “certainly impending” to satisfy the Article III injury-in-fact requirement).

176. *See Denney*, 443 F.3d at 265 (finding that although some members of the class had not been audited at the time of the suit, there was still a risk that they may be assessed a penalty as a result of the fraudulent tax advice).

177. 638 F.3d 118 (2d Cir. 2011).

178. *Amnesty Int’l I*, 638 F.3d at 140 (holding various attorneys, journalists, and labor, legal, media, and human rights organizations had standing to challenge the constitutionality of a section of the Foreign Intelligence Surveillance Act of 1978 that authorizes electronic surveillance of noncitizens).

179. *Id.* at 138–39.

180. *See Amnesty Int’l USA v. Clapper (Amnesty Int’l II)*, 667 F.3d 163, 198 (2d Cir. 2011) (Livingston, J., dissenting in the denial of rehearing en banc) (stating only that the determination of when injury in fact has been established is “elastic,” but that it had not been established by the plaintiffs).

181. *Id.* at 199.

182. *Amnesty Int’l I*, 638 F.3d at 140; *Baur v. Veneman*, 352 F.3d 625, 641 (2d Cir. 2003).

elements of Article III standing.”¹⁸³ Under narrow circumstances, the court has allowed increased-risk-of-harm claims to satisfy the injury-in-fact requirement.¹⁸⁴ A petitioner must show both “(i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account,” with “a very strict understanding of what increases in risk and overall risk levels can count as ‘substantial.’”¹⁸⁵

The court is wary of increased-risk-of-harm claims because of the possibility that allowing such claims could

drain the “actual or imminent” requirement of meaning in cases involving consumer challenges to an agency’s regulation (or lack of regulation); would expand the proper—and properly limited—constitutional role of the Judicial Branch beyond deciding actual cases or controversies; and would entail the Judiciary exercising some part of the Executive’s responsibility to take care that the law be faithfully executed.¹⁸⁶

Nonetheless, the court has not categorically precluded such claims.¹⁸⁷ Instead, it requires that the increase in risk be quantified.¹⁸⁸

In *Public Citizen, Inc. v. National Highway Traffic Safety Administration (Public Citizen I)*,¹⁸⁹ several organizations challenged a safety standard promulgated by the National Highway Traffic Safety Administration (NHTSA) regarding a warning system to be placed in new cars to alert drivers when tires were underinflated.¹⁹⁰ Public Citizen, which challenged the standard as not sufficiently protective, claimed that it had associational standing because its members were at increased risk of harm: “some of Public Citizen’s ‘members allegedly will suffer car accidents in the future that

183. Sturkie & Logan, *supra* note 147, at 10461 (quoting *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002) (internal quotation marks omitted)).

184. See, e.g., *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1235 (D.C. Cir. 1996) (holding that when plaintiffs can show that they will be injured as a result of increased risk, they have established injury in fact for purposes of establishing standing).

185. *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin. (Pub. Citizen II)*, 513 F.3d 234, 238 (D.C. Cir. 2008) (emphasis added).

186. *Id.* at 237 (quoting *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin. (Pub. Citizen I)*, 489 F.3d 1279, 1295 (D.C. Cir. 2007)).

187. At least one Judge on the Circuit—then Judge, now Senior Judge David B. Sentelle—believes that such claims should be categorically denied, writing in 2008 that there is an

ill fit between judicial power and that sort of future event and possible harm. The wide-ranging, near-merits discussion at the standing threshold is the sort of thing that congressional committees and executive agencies exist to explore. The judicial process is constitutionally designed for cases or controversies involving actual or imminent harm to identified persons—that is, the persons who have standing. If we do not soon abandon this idea of probabilistic harm, we will find ourselves looking more and more like legislatures rather than courts.

Pub. Citizen II, 513 F.3d at 242 (Sentelle, J., concurring).

188. See *id.* at 240 (majority opinion) (finding that Public Citizen’s failure to quantify the increase in the number of accidents fatal to their ability to establish standing).

189. 489 F.3d 1279, 1295 (D.C. Cir. 2007).

190. *Pub. Citizen II*, 513 F.3d at 236. In 2000, Congress passed the Transportation Recall Enhancement, Accountability, and Documentation Act (TREAD Act) to address vehicle accidents caused by tire blowouts. Pub.L. No. 106-414, 114 Stat. 1800 (2000). The Act required the NHTSA to promulgate a regulation requiring new vehicles to warn operators when tires were significantly underinflated. *Id.* § 13, 114 Stat. at 1806.

otherwise would be prevented' if NHTSA were to adopt Public Citizen's proposals."¹⁹¹

The court concluded that it did not have enough information to determine whether there was both a substantially increased risk of harm from the safety standard and whether the "ultimate risk of harm" from the standard was substantial, and it adjourned the case for supplemental briefing.¹⁹² Public Citizen submitted briefs that quantified the increase in risk of death, injury, or property damage that its members would face if the NHTSA adopted its safety standard instead of that proposed by Public Citizen.¹⁹³

After briefing, the court dismissed Public Citizen's petition in *Public Citizen, Inc. v. National Highway Traffic Safety Administration (Public Citizen II)*,¹⁹⁴ finding that the organization had failed to establish standing.¹⁹⁵ The court did not, however, find that the increase in risk was too small; instead, the court found that the petitioner's methods of measurement were inadequate.¹⁹⁶ Public Citizen challenged three aspects of the safety standard. First, it challenged the failure of the warning system to work with replacement tires; its statistician quantified the difference in risk of injury between a system that worked with replacement tires, and one that did not, like NHTSA's.¹⁹⁷ Public Citizen did not, however, have its statistician compare the increase in risk of injury with a system that did not work with replacement tires, like NHTSA's, with the increase in risk if the same system was in place, but a list of the tires that the system *did* work with was published.¹⁹⁸ This latter alternative had been proposed by Public Citizen at an earlier point in the litigation,¹⁹⁹ and the court commented that "Public Citizen obviously is not injured for purposes of standing if Standard 138 poses no greater risk of injury than one of Public Citizen's proposed alternatives."²⁰⁰

Second, Public Citizen challenged the twenty-minute lag time between the underinflation of tires and the activation of a warning light.²⁰¹ The court found Public Citizen's attempt to quantify increased risk in this context to be "simplistic and unreliable," and agreed with Public Citizen that "any increased risk of injury from the 20-minute lag time as compared to a one-minute lag time is 'more difficult to quantify' than the risk related to its other claims."²⁰² And third, Public Citizen challenged the warning light's trigger at twenty-five percent underinflation.²⁰³ The court, however, found the organization's calculations to be flawed and unreliable.²⁰⁴ Finding none of Public Citizen's calculations of increased risk to be acceptable, the court dismissed the

191. *Pub. Citizen II*, 513 F.3d at 237 (quoting *Pub. Citizen I*, 489 F.3d at 1291).

192. *Id.* at 238 (quoting *Pub. Citizen I*, 489 F.3d at 1297).

193. *Id.*

194. 513 F.3d 234 (D.C. Cir. 2008).

195. *Pub. Citizen II*, 513 F.3d at 241.

196. *Id.* at 238–41.

197. *Id.* at 238–39.

198. *Id.* at 240.

199. *Id.* at 238.

200. *Id.* at 239.

201. *Id.* at 238–40.

202. *Id.* at 239–40 (quoting Brief for Petitioner at 16).

203. *Id.* at 240–41.

204. *Id.* at 239–41.

petition.²⁰⁵

In this case, the court signaled its distaste for the probabilistic injury doctrine as a basis for Article III standing:

If we were deciding this case based solely on the Supreme Court's precedents, we would agree with the separate opinion [disapproving the concept of probabilistic injury as a basis for standing]. As we read our [earlier] decisions . . . , however, "this Court has not closed the door to all increased-risk-of-harm cases."²⁰⁶

The court also indicated its dislike of the concept by agreeing with petitioner regarding the difficulty of quantification, yet requiring quantification.²⁰⁷

Public Citizen II, as the District of Columbia Circuit's most recent probabilistic injury case, shows the court's "increasingly negative view of probabilistic injury."²⁰⁸ Moreover, the court has mandated the quantification of increased risk²⁰⁹ and "has made abundantly clear that it expects to see quantitative risk assessments in appropriate cases,"²¹⁰ but has itself expressed ambivalence about the adequacy of this method in the assessment of whether probabilistic injury constitutes injury in fact.²¹¹

3. Medical-Monitoring Cases

Courts have also grappled with "whether an increased risk of harm requiring current medical monitoring is a sufficient injury in fact to confer standing."²¹² Such a case is the quintessential probabilistic injury case because the remedy sought—medical monitoring—is meant to address the risk of harm, which has been increased by an action of the defendant, *not* the anticipated harm itself.²¹³ Medical monitoring is intended as an early diagnostic tool for plaintiffs who are not yet sick, but who face an increased risk of future harm.²¹⁴

It is important to note two things about these cases at the outset of the discussion. First, in these cases, exposure is certain. Plaintiffs in these cases have been exposed to a harm-causing substance or activity, such as faulty medical care or devices, adulterated drugs, or toxic substances, although their ultimate injury is uncertain. This is unlike

205. *Id.* at 241.

206. *Id.* (quoting *Public Citizen I*, 489 F.3d at 1295).

207. *Id.* at 240–41.

208. Sturkie & Logan, *supra* note 147, at 10461; *see also* Va. State Corp. Comm'n v. Fed. Energy Regulatory Comm'n, 468 F.3d 845, 848 (D.C. Cir. 2006) ("Reliance on standing in the form of probabilistic injury—here, an increase in the probability the investors will inaccurately evaluate Dominion's financial position—requires a showing of a 'substantial probability' of the alleged injury The word 'substantial' of course poses questions of degree, questions far from fully resolved." (quoting *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002))). The D.C. Circuit's holding in *Virginia State Corp.* was a predecessor to its broad rejection of probabilistic injury in *Public Citizen II*. Sturkie & Logan, *supra* note 147, at 10463.

209. *See, e.g., Va. State Corp.*, 468 F.3d at 848 (indicating "increased risk or probability cannot suffice" to establish standing).

210. Sturkie & Logan, *supra* note 147, at 10471.

211. *Pub. Citizen II*, 513 F.3d at 240–41.

212. *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 571 (6th Cir. 2005).

213. *Cf. Ayers v. Twp. of Jackson*, 525 A.2d 287, 308 (N.J. 1987) (rejecting the plaintiffs' claims for damages due to the overly speculative enhanced risk of injury).

214. *Id.*

cases such as *Baur*, where the petitioner challenged USDA policy.²¹⁵ Although *Baur* was certainly exposed to the faulty governmental policy that he challenged, his exposure to the food-borne pathogen he feared, as well as his potential contraction of disease, were both uncertain. It is also unlike *Public Citizen*, where Public Citizen alleged that its members were at increased risk of harm because of NHTSA's safety standard.²¹⁶ Whether the organization's members would actually be exposed to the feared risk, the underinflation of tires without the activation of a warning light, as well as their ultimate injury, were both uncertain.

Second, medical monitoring is the remedy to an underlying tort,²¹⁷ and this type of claim is located in federal court in the context of a diversity action.²¹⁸ These claims can only be brought in certain jurisdictions because not all states recognize actions for medical monitoring if a present, physical injury cannot be shown.²¹⁹

It is also important to mention that in tort cases there is a difference between a claim for damages for the enhanced risk of future illness, and a claim seeking the remedy of medical monitoring.²²⁰ An enhanced risk claim "seeks a damage award, not because of any expenditure of funds, but because plaintiffs contend that the . . . injury to their health and life expectancy should be presently compensable, even though no evidence of disease is manifest."²²¹ Courts are reluctant to recognize enhanced-risk claims based on unquantified injury, and many require that future injury be "reasonably certain."²²² In contrast, a claim for medical monitoring expenses is different than a claim for enhanced risk, as "[i]t seeks to recover the cost of periodic medical examinations intended to monitor plaintiffs' health and facilitate early diagnosis and treatment of disease caused by plaintiffs' exposure to toxic chemicals."²²³

215. See *supra* notes 161–71 and accompanying text for a discussion of *Baur*.

216. See *supra* notes 189–211 and accompanying text for a discussion of the *Public Citizen* opinions.

217. *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 572 (6th Cir. 2005) (stating that "medical monitoring is more properly considered one of a number of possible remedies to an underlying tort, rather than a separately actionable tort").

218. *Id.* at 569.

219. See *id.* at 572 n.3 ("[P]laintiffs in a cause of action for medical monitoring costs do not have to prove a present, physical injury in Colorado, the District of Columbia, Kansas, Kentucky, New York, Pennsylvania, Utah, Washington, and Guam. Physical injury must be shown in Delaware, Virginia, West Virginia, and the Virgin Islands." (citing *In re Teletronics Pacing Sys., Inc.*, 168 F.R.D. 203, 215–16 (S.D. Ohio 1996))).

220. See *Ayers v. Twp. of Jackson*, 525 A.2d 287, 304 (N.J. 1987) (noting that while an enhanced risk and medical surveillance claim were based upon the same expert testimony, the two claims sought redress for the violation of two separate interests).

221. *Id.*

222. *Id.* at 306.

223. *Id.* at 308. In *Ayers*, residents brought a nuisance action against their town after toxic pollutants from a landfill contaminated their water. *Id.* at 291. A jury found for plaintiffs and awarded the cost of future medical surveillance, among other awards. *Id.* The New Jersey Supreme Court affirmed the award for medical monitoring based on enhanced risk. *Id.* at 312. The court also affirmed the trial court's dismissal before trial of a claim for damages based on the unquantified enhanced risk of disease. *Id.* at 308. In dismissing the enhanced-risk claim while affirming the award for medical monitoring, the court negotiated the difficult terrain of accommodating toxic-exposure claims within the common-law tort system. *Id.* at 298–302. The court noted that state statutes of limitation and difficulties in proving negligence and causation are "obstacle[s] to judicial resolution of mass exposure tort claims." *Id.* at 300.

In *Sutton v. St. Jude Medical S.C., Inc.*,²²⁴ the plaintiff, Michael Sutton, sued the manufacturers of a cardiac device on behalf of himself and a class of people who had been implanted with this device during cardiac surgery.²²⁵ Sutton, and the class of people for whom he sued, had not yet suffered injury from the allegedly defective device, and they sought medical monitoring for future harm.²²⁶ The district court dismissed the Sutton class complaint for lack of standing, finding that “Sutton failed to establish a sufficient risk of harm associated with the device to survive dismissal for lack of standing.”²²⁷

The Sixth Circuit reversed, holding that Sutton’s allegation of an increased risk of harm because of implantation with the device at issue was adequate to satisfy the injury-in-fact requirement.²²⁸ The court compared Sutton’s situation to that of someone exposed to toxic emissions and saw “no reason to require” that the actual injury be immediately pending.²²⁹

Notably, the court refused to require quantification of increased risk as a requirement for standing, stating that to “require a plaintiff to so clearly demonstrate her injury in order to confer standing is to prematurely evaluate the merits of her claims.”²³⁰ The court pointed to another increased risk of harm requiring medical monitoring case in which a district court in Minnesota implicitly found standing for “a plaintiff requesting medical monitoring for side effects from implanted heart valves.”²³¹ In that case, the plaintiffs were able to show that they had a 700% increase in risk because of the implanted heart valves.²³² Nevertheless, the Sixth Circuit found such a showing to be unnecessary and found that the inquiry conflated the threshold determination of standing with the merits of the case.²³³

4. The Enhanced Risk of Identity Theft

Another increasingly common claim that involves the increased risk of harm is brought by individuals who have had personal information stolen and believe that they are at increased risk of future identity theft. Courts are grappling with the nature of

224. 419 F.3d 568 (6th Cir. 2005).

225. *Sutton*, 419 F.3d at 569.

226. *Id.* Whether or not Tennessee law (the relevant law here) permitted claims seeking medical monitoring without a present physical injury remained an open question after this opinion, although defendants asserted that it did not. *Id.* at 575–76. The Sixth Circuit declined to reach the issue, as it had not been reached by the district court. *Id.* The Sixth Circuit did, however, advise the district court on remand that such claims were most likely proper under Tennessee law. *Id.* at 575–76 n.7.

227. *Id.* at 571.

228. *Id.* at 575. The court also found that traceability and redressability, the other Article III standing requirements, were met. *Id.*

229. *Id.* at 572. This conclusion of the court lends support to the probabilistic nature of Sutton’s injury—the court saw the harm as the risk and the remedy as monitoring. *Id.*

230. *Id.* at 575.

231. *Id.* at 575 (citing *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396 JRTFLN, 2003 WL 1589527, at *1 (D. Minn. Mar. 27, 2003), *rev’d and remanded*, 425 F.3d 1116 (8th Cir. 2005)). The finding was implicit because the court ruled on the merits, not discussing standing. *In re St. Jude Med.*, 2003 WL 1589527, at *11.

232. *Sutton*, 419 F.3d at 575 (citing *In re St. Jude Med.*, 2003 WL 1589527, at *1).

233. *Id.*

these claims and are currently divided as to the standing of plaintiffs unable to show present injury.

In *Krottner v. Starbucks Corporation*,²³⁴ three employees of Starbucks sued the company after a laptop containing their unencrypted personal information was stolen from one of the company's stores.²³⁵ None of the employees alleged that the information had been misused so as to cause them financial loss, although one of the plaintiffs alleged that someone had unsuccessfully attempted to open a new bank account using his social security number.²³⁶

The Ninth Circuit compared the increased-risk-of-harm claim to similar claims brought in other contexts, including environmental claims and medical monitoring claims, and held that the plaintiffs did have Article III standing to bring their claims in federal court.²³⁷ The court found that "Plaintiffs-Appellants have alleged a credible threat of real and immediate harm stemming from the theft of a laptop containing their unencrypted personal data."²³⁸ Surveying other circuits, the court noted that the Seventh Circuit had recognized increased-risk-of-harm claims in the identity theft context as a basis for injury in fact, while the Sixth Circuit did not.²³⁹

In *Reilly v. Ceridian Corp.*,²⁴⁰ the Third Circuit, in contrast to the Ninth, refused to grant standing to plaintiffs who alleged that they were at an increased risk of identity theft after the security breach of a payroll processing firm that had their personal information.²⁴¹ The court held that the plaintiffs' "allegations of hypothetical, future injury" were not adequate to satisfy the Article III requirements.²⁴² The court surveyed other courts' rulings in the same context, and, citing to two district court cases, concluded that most courts had denied standing.²⁴³ Distinguishing *Krottner*, and the earlier Seventh Circuit case that had also granted standing, the court explained that the plaintiffs in those cases had suffered more credible threats of harm than did the plaintiffs in *Reilly*.²⁴⁴

The court, however, also criticized the reasoning of the Ninth and Seventh Circuits, calling their rationale "skimpy."²⁴⁵ Disagreeing with those circuits' analogizing of data security breach cases to defective medical device cases and toxic substance exposure cases, the court pointed out two differences.²⁴⁶ First, in the latter

234. 628 F.3d 1139 (9th Cir. 2010).

235. *Krottner*, 628 F.3d at 1140–41.

236. *Id.* at 1141.

237. *Id.* at 1142–43.

238. *Id.* at 1143.

239. *Id.* at 1142–43; *see also* *Lambert v. Hartman*, 517 F.3d 433, 437 (6th Cir. 2008) (commenting that the risk of future identity theft "is somewhat 'hypothetical' and 'conjectural'").

240. 664 F.3d 38 (3d Cir. 2011).

241. *Reilly*, 664 F.3d at 40.

242. *Id.* at 41.

243. *Id.* at 43.

244. *Id.* at 44.

245. *Id.*

246. *Id.* at 45. Of course, in all of these cases the exposure is certain, whether to a toxin, a faulty medical device, or a data breach. The ultimate injury, however, is uncertain and the court must determine whether to allow a claim for compensation for the enhanced risk.

types of cases there had certainly been an injury, although the manifestation of the injury was uncertain, whereas in the data-breach cases there was no injury if there was no misuse of data.²⁴⁷ Second, the court found that medical-device and toxic-tort cases present specific “human health concerns” that are not found in data-breach cases.²⁴⁸ The court commented that “[c]ourts resist strictly applying the ‘actual injury’ test when the future harm involves human suffering or premature death,”²⁴⁹ and posited that monetary compensation would not return plaintiffs to their original position in environmental or health cases, where it would be adequate compensation in data-breach cases.²⁵⁰ For these reasons, the Third Circuit held data-breach cases separate from toxic-substance-exposure or medical-device-exposure cases.²⁵¹

In the data-breach cases, we see a circuit divide between courts willing to allow increased-risk-of-identity-theft plaintiffs standing to bring their claims, and those that do not. None of the courts attempt to quantify the increase in risk faced by the victims of the data-breach. At first blush, it seems inconceivable to quantify the increase in risk for a victim of a data security breach. There are too many unknowns involved in the equation—who stole the data, why the data was stolen, and how the data can be used. Moreover, a baseline risk of identity theft would have to be established.

With a second look, however, the differences between data security breach cases and environmental, faulty medical device, and toxic exposure cases are not so great. In all of these cases the enhanced risk is certain although the ultimate injury may not be. And all of these cases involve great uncertainty, both in the baseline calculation of risk and the variables contributing to the increase in risk.

III. THE PROS AND CONS OF QUANTIFYING RISK

The previous Section described two scenarios in which courts review the quantification of risk: first, courts review the quantitative risk assessments used by federal agencies in fashioning risk management regulation. This review is extremely deferential.²⁵² Second, certain courts require that increased risk of harm be quantified before allowing probabilistic injury to satisfy the Article III standing requirements.²⁵³ The quantification of risk is appealing to courts because of its perceived benefits: (1) it provides a seemingly objective measure of risk that can be compared to alternatives, (2) it allows the judiciary to bridge its expertise gap regarding scientific subject matter, (3) it allows risk and judicial resolution of conflict to be easily communicated to the public with, again, a seemingly objective veneer, and (4) it reassures courts that they remain within their proper adjudicative role and are not impermissibly acting in a legislative or

247. *Id.*

248. *Id.*

249. *Id.*

250. *Id.* at 45–46. This ignores the longstanding and extensive repercussions of identity theft, such as damage to one’s credit, which monetary compensation may not remedy.

251. *Id.* at 46.

252. See *supra* Part II.A.2.a for an analysis of the extremely deferential nature of judicial review of the quantitative risk assessments used by federal agencies in fashioning risk management regulation.

253. See *supra* Part II.B.2 for an analysis of the requirement by certain courts that increased risk of harm be quantified before allowing probabilistic injury to satisfy Article III standing requirements.

executive role.

However, forcing the quantification of risk in the judicial setting—through the increased deference provided to agencies using QRA and by requiring it from federal plaintiffs—actually undercuts the purposes of judicial review. Courts are cursorily reviewing, and giving their imprimatur, to agency science that comprises both scientific and policy decisions. And in regards to federal plaintiffs, courts seeking the quantification of increased risk have put themselves in the business of assessing what constitutes an acceptable amount of increased risk for actual and concrete injury. This enterprise is as tenuous as these courts find the concept of probabilistic injury to be.

Judicial forcing of the quantification of risk is misguided for several reasons. In the context of the judicial review of agency determinations, it may (1) contradict health and safety-protective statutory directives by requiring more proof of harm than Congress intended, (2) reify uncertain determinations and arbitrarily reached conclusions as bright-line rules, and (3) lead to the misguided use of resources because of the skewing of priorities towards quantifiable harms. In the context of assessing standing requirements, forcing the quantification of increased risk paints a façade of objectivity over a subjective determination and conflates the merits with the threshold determination. In both contexts, the forcing of quantification will have the effect of confusing, or even deceiving, the public, by putting forward a model of scientific calculation that is based on shaky ground.

A. *The Perceived Benefits of the Quantification of Risk*

Courts most often defer to an agency's treatment of a quantitative risk assessment that is used as a component in its decision-making process, and some courts require risk to be measured quantitatively to satisfy Article III standing requirements.²⁵⁴ It is easy to see why quantification of risk is appealing to courts, and this Part discusses these perceived benefits.

1. Quantification Provides an Objective Measure of Risk

Quantification provides a court with an objective method to measure whether an agency is complying with its statutory mandate, and to assess whether increased risk complies with constitutional standing requirements. By using numbers, judges can try to distance their personal proclivities from their judgments.

This is most clearly apparent when Congress has set a numerical goal, which the agency must reach or explain its failure to do so. For example, the EPA is responsible for determining tolerance levels for pesticide residues on food products, as regulated by the FFDCA.²⁵⁵ The Food Quality Protection Act (FQPA), passed in 1996, requires that the EPA “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue,” and for that

254. See *supra* Parts II.A.2.a and II.B.2 for an analysis of the deferential nature of judicial review of the quantitative risk assessments used by federal agencies in fashioning risk management regulation, and an analysis of the requirement by certain courts that increased risk of harm be quantified before allowing probabilistic injury to satisfy Article III standing requirements, respectively.

255. 21 U.S.C. § 346a(a)–(c) (2006).

reason, the EPA must use “an additional tenfold margin of safety.”²⁵⁶ The EPA “may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.”²⁵⁷

In *Natural Resources Defense Council*, the Natural Resources Defense Council (NRDC) appealed the EPA’s denial of its petition seeking the revocation of the EPA’s tolerance of dichlorvos, an insecticide.²⁵⁸ The EPA had applied a threefold safety factor in its risk assessments, not the tenfold factor mandated by statute.²⁵⁹ The Agency argued that “a 3X safety factor was more than adequate because of the slight adverse effect . . . observed.”²⁶⁰ The Second Circuit found that the EPA had failed to explain how its lesser safety factor took into account “potential pre- and post-natal toxicity and completeness of the data with respect to infants and children,”²⁶¹ which was the statutory mandate, and found this failure to be arbitrary and capricious under the APA.²⁶² The court therefore vacated the parts of the EPA’s order that assessed the risk of dichlorvos using the threefold safety factor.²⁶³

The court here was able to determine that the EPA did not follow its statutory mandate because it had failed to explain its divergence from a clear numerical prescription—the tenfold safety factor for infants and children.²⁶⁴ The court did not opine on the wisdom of the tenfold safety factor, and it is notable that the “so-called ‘10X’ question is probably the most controversial issue that the EPA has faced during its four-year implementation [of the FQPA] effort.”²⁶⁵ Indeed the tenfold factor was the product more of policy than of scientific judgments and was resisted to a certain extent by the EPA itself.²⁶⁶ Nevertheless, in *Natural Resources Defense Council*, we see that the tenfold safety standard fulfills its function by signaling to the court that the EPA has not adequately explained its divergence from the mandated safety factor and therefore may not be paying adequate attention to the safety of infants and children, which was a primary driver behind the passage of the FQPA.²⁶⁷

AFL-CIO v. OSHA,²⁶⁸ decided by the Eleventh Circuit in 1992, provides another example of a court’s review of an agency’s quantification of risk for the purpose of

256. *Id.* § 346a(b)(2)(C)(ii).

257. *Id.*

258. *Natural Res. Def. Council v. EPA*, 658 F.3d 200, 201 (2d Cir. 2011).

259. *Id.* at 216.

260. *Id.* at 214 (internal quotation marks omitted) (quoting Order Denying NRDC’s Objections and Requests for Hearing, 73 FR 42683-01, 42695 (July 23, 2008)).

261. *Id.* at 215–16 (citing 21 U.S.C. § 346a(b)(2)(C)(ii)).

262. *Natural Res. Def. Council*, 658 F.3d at 217–18.

263. *Id.* at 218.

264. *Id.*

265. Thomas O. McGarity, *Politics by Other Means: Law, Science, and Policy in EPA’s Implementation of the Food Quality Protection Act*, 53 ADMIN. L. REV. 103, 140 (2001).

266. *Id.* at 148–51.

267. See *Natural Res. Def. Council*, 658 F.3d at 201 (describing the NRDC’s argument that the EPA did not adequately explain why it did not apply the “tenfold children’s safety factor,” which was required under the FQPA).

268. 965 F.2d 962 (11th Cir. 1992).

assessing whether the agency has complied with its statutory mandate.²⁶⁹ In this case, multiple parties challenged OSHA's promulgation of an air-contaminant standard that set permissible exposures to various toxic substances.²⁷⁰ The court vacated the standard and remanded it to the Agency, finding that the Agency had neither adequately quantified the risk posed by each toxic substance that it was regulating under its new standard, nor the amount that the risk would be reduced if the new standards were put into place.²⁷¹

Although the Agency need not calculate "the exact probability of harm,"²⁷² the court in *AFL-CIO* concluded that OSHA needed to provide some quantification of risk for each substance regulated.²⁷³ The court followed the holding of the Benzene case,²⁷⁴ where the Supreme Court had interpreted the section of the OSH Act defining safety standards to require that "OSHA make a threshold finding that a significant risk of material health impairment exists at the current levels of exposure to the toxic substance in question . . . and that a new, lower standard is therefore 'reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'"²⁷⁵ The *AFL-CIO* court explained that without quantification, "OSHA has not demonstrated, and this court cannot evaluate, how serious the risk is for any particular substance, or whether any workers will in fact benefit from the new standard for any particular substance."²⁷⁶

What we see in both *Natural Resources Defense Council* and *AFL-CIO*, therefore, is the judiciary's reliance on quantification as an objective measure to assess whether an agency has complied with its statutory mandate. In *Natural Resources Defense Council*, Congress had set forth a quantitative measure to be followed by the EPA, and in *AFL-CIO*, the court saw quantification as providing necessary content to the Supreme Court's interpretation of the OSH Act.

2. Quantification and the Expertise Gap

As described above, courts defer to agency decision making, and this deference tends to be stronger in areas of scientific evaluation and technical expertise.²⁷⁷ Quantification helps to bridge this expertise gap between agency decision makers and the judiciary by signaling that the agency has actually given a hard look to the evidence in front of it. Although a QRA involves much technical information, its steps are structured and clear. A generalist can grasp whether the steps have been followed and

269. *AFL-CIO*, 965 F.2d at 968–69.

270. *Id.* at 969.

271. *Id.* at 986–87.

272. *Id.* at 973 (quoting *Indus. Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607, 655 (1980)).

273. *Id.*

274. See *supra* notes 53–62 and accompanying text for a discussion of the Benzene case.

275. *AFL-CIO*, 965 F.2d at 972–73 (quoting *Indus. Union Dep't*, 448 U.S. at 615).

276. *Id.* at 975 (emphasis omitted).

277. See, e.g., *Miami-Dade Cnty. v. EPA*, 529 F.3d 1049, 1065 (11th Cir. 2008) ("[C]ourts must be extremely deferential when an agency's decision rests on the evaluation of complex scientific data within the agency's technical expertise." (internal quotation marks omitted)); Meazell, *supra* note 64, at 734 (referring to the standard of review that judges employ when reviewing agency decisions as "super deference"). See *supra* Part II.A.2.a for a discussion of the deferential standard courts employ when reviewing agency decisions.

whether the information flows logically, even without a thorough understanding of the science involved. We saw this in *AFL-CIO*, where the court explained that it needed some quantification of risk to be able to assess whether the Agency had done its job.²⁷⁸

On the other hand, however, quantification also makes the expertise gap more manifest. A court, when confronted with a QRA, may be reminded of its own generalist background and acknowledge the futility of anything but deferential review. In *Asbestos Information Association v. OSHA*,²⁷⁹ OSHA promulgated an emergency temporary standard for asbestos fibers, which, because of its emergency posture, did not go through ordinary notice and comment procedures.²⁸⁰ The court held that OSHA had improperly used its emergency powers and revoked the standard so that it could be promulgated through notice-and-comment rulemaking.²⁸¹ One of the results of the absence of normal rulemaking procedures was that the court was presented with a raw record, unlike one where “adversary proceedings have narrowly focused the facts and issues in dispute.”²⁸² Because of the complexity of the record, “that would tax the competency of any court,” the Fifth Circuit here was left only the task of asking whether OSHA “carried out [its] essentially legislative task in a manner reasonable under the state of the record before [it].”²⁸³ Quantification, by clearly marking the expertise gap, therefore enables courts to stay within their appropriate role by forcing deference.²⁸⁴

And in the context of whether increased risk of harm satisfies the injury-in-fact requirement, the quantification of increased risk indicates to the court that the lawsuit before it is more than a fishing expedition. The fact that harm can be quantified—whatever the quantification actually is—demonstrates that, at a minimum, it is actual and imminent to the plaintiff.²⁸⁵

3. Quantification and Communication to the Public

Quantification also has the benefit of being easily communicated to the public. It acts as a heuristic device, allowing the judiciary and a nonspecialized audience to simplify and to categorize risk.²⁸⁶ In *Asbestos Information Association*, the court

278. *AFL-CIO*, 965 F.2d at 975.

279. 727 F.2d 415 (5th Cir. 1984).

280. *Asbestos Info. Ass'n*, 727 F.2d at 417.

281. *Id.* at 418.

282. *Id.* at 421.

283. *Id.* (alterations in original) (quoting *Aqua Slide 'n' Dive Corp. v. Consumer Prod. Safety Comm'n*, 569 F.2d 831, 838 (5th Cir. 1978)); see also *Simpson v. Young*, 854 F.2d 1429, 1434 (D.C. Cir. 1988) (noting that it would be “inappropriate as a matter of law” and “impossible as a practical matter” for the court to re-evaluate volumes of scientific evidence provided to a federal agency).

284. See *Am. Cyanamid Co. v. FDA*, 606 F.2d 1307, 1319 n.117 (D.C. Cir. 1979) (stating that courts should decide the legal question of whether scientific tests are conclusively inadequate on their face, not the scientific question of the methodological adequacy of the tests). See *infra* Parts III.B.4–5 for a discussion of the facial inadequacy of test methods.

285. Cf. William A. Fletcher, *The Structure of Standing*, 98 YALE L.J. 221, 231 (1988) (noting that, without additional proof, the injury in fact test fails because any person sincerely claiming an “injury” would automatically satisfy it—quantification, however, can provide that proof).

286. See BREYER, *supra* note 10, at 35 (explaining that the average person has difficulty understanding risk, which results in an increased use of irrational and unreliable heuristic devices, or rules of thumb—and

explained that OSHA justified its issuance of an emergency temporary standard with the claim that an immediate lowering of the asbestos permissible exposure level as opposed to waiting would save eighty lives over a period of six months.²⁸⁷ The loss of these eighty lives constituted a “grave danger” such that the Agency could issue an emergency standard,²⁸⁸ and the court noted that the question of what “constitutes a risk worthy of Agency action is a policy consideration that belongs, in the first instance to the Agency.”²⁸⁹ The Agency’s quantification of the immediate risk faced by workers made the abstract into the concrete,²⁹⁰ which was then available for public consumption.

A judicial opinion distills and simplifies the enormously complex risk assessment process for the public. It has been suggested that one important role of courts in reviewing agency action is to act as translators—to “provid[e] generalist accounts of specialized information for largely nonscientific consumers.”²⁹¹ The quantification of risk adds to this function, permitting the public access to the end product of the decision-making processes of agencies.

4. Quantification Helps Courts Remain in Their Proper Adjudicative Role

When adjudicating claims of probabilistic injury, courts express anxiety over whether they are overstepping the bounds of their proper authority and infringing on that of the legislative or executive branches.²⁹² Probabilistic harm raises the specter of activist judges making law. Recall, for example, Judge Sentelle of the District of Columbia Circuit’s reminder that “the probabilistic approach to standing now being applied in increased-risk cases expands the “proper—and properly limited”—constitutional role of the Judicial Branch beyond deciding actual cases or controversies; and . . . entail[s] the Judiciary exercising some part of the Executive’s responsibility to take care that the law be faithfully executed,”²⁹³ and his admonition that “[i]f we do not soon abandon this idea of probabilistic harm, we will find ourselves looking more

also pointing to the difficulty that the average layperson has in understanding the mathematical probability of risk). However, a judicial opinion erases the need for the public to figure out the mathematical probability of risk—it transmits a simplified outcome, eliding the uncertainty and complexity that lie beneath. Mezell, *supra* note 64, at 778–79.

287. *Asbestos Info. Ass’n*, 727 F.2d at 425.

288. *Id.* at 424. The OSH Act allows OSHA to pass an emergency temporary standard if “employees are exposed to grave danger,” and if “such emergency standard is necessary.” 29 U.S.C. § 655(c)(1) (2006). OSHA is required to act on a temporary rule within six months, hence OSHA’s eighty lives over six months calculation. *Id.* § 655(c)(3).

289. *Asbestos Info. Ass’n*, 727 F.2d at 425 (citing *Indus. Union Dep’t v. Am. Petroleum Inst.*, 448 U.S. 607, 656 n.62 (1980)).

290. In this case, the court ultimately invalidated the emergency standard, finding the Agency’s application of a long-term risk assessment to the timeframe of six months to be speculative, among other things. *Id.*

291. Mezell, *supra* note 64, at 778.

292. See *supra* Part II.B.2 for a discussion of the D.C. Circuit’s concerns in overstepping its judicial mandate.

293. *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin.* (*Pub. Citizen II*), 513 F.3d 234, 242 (D.C. Cir. 2008) (Sentelle, J., concurring) (omission in original) (alteration in original) (quoting *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin.* (*Pub. Citizen I*), 489 F.3d 1279, 1295 (D.C. Cir. 2007)).

and more like legislatures rather than courts.”²⁹⁴

Courts are also concerned with remaining within their proper role when reviewing agency action. They must carefully balance a “highly deferential” standard of review that “forbids the court’s substituting its judgment for that of the agency, . . . and requires affirmance if a rational basis exists for the agency’s decision,” with “a ‘substantial inquiry’ into the facts, one that is ‘searching and careful.’”²⁹⁵ We saw the Eleventh Circuit walking this line in *AFL-CIO* by repeating the Supreme Court’s direction that an agency has “no duty to calculate the exact probability of harm,” but must still provide some quantification of risk.²⁹⁶

The quantification of risk provides a bulwark against judicial overreaching in both contexts. In the former, the quantification of risk provides evidence that the claimed injury (which comprises enhanced risk) is actual and immediate, such that a court adjudicating the dispute is fulfilling its traditional role. In the latter, a quantitative risk assessment is evidence of reasonable agency action and adequate explanation by the agency. A recap of a QRA shows that a court is taking a searching look at the facts,²⁹⁷ and its complexity makes deference acceptable, or even necessary.²⁹⁸

B. *The Detriments of Quantifying Risk*

Although the quantification of risk is certainly useful to courts, the quantification of risk is problematic in some circumstances, and is, on balance, detrimental to the judicial function. Forcing the quantification of risk may contradict congressional will in passing health- and safety-protective legislation, concretize policy determinations and uncertain calculations as unalterable law, conflate an on-the-merits determination into what should be a threshold decision, support the misguided direction of resources, and have the effect of confusing the public.

1. The Quantification of Risk May Contradict Legislative Intention

During the 1960s and 1970s, Congress passed a significant amount of the legislation that regulates risks to the public and the environment, much of which authorizes agencies “to act on the basis of anticipated harm.”²⁹⁹ This legislation allows

294. *Id.*

295. *Ethyl Corp. v. EPA*, 541 F.2d 1, 34–35 (D.C. Cir. 1976) (quoting *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415–16 (1971)).

296. *AFL-CIO v. OSHA*, 965 F.2d 962, 975 (11th Cir. 1992) (citing *Indus. Union Dep’t v. Am. Petroleum Inst.*, 448 U.S. 607, 655 (1980)).

297. *See* *Pub. Citizen Health Research Grp. v. OSHA*, 557 F.3d 165 (3d Cir. 2009). In this case, Public Citizen, a consumer protection group, challenged a standard issued by OSHA regarding the occupational exposure of workers to hexavalent chromium (Cr(VI)), a toxic and carcinogenic substance. *Id.* at 169. Public Citizen argued that OSHA had underregulated Cr(VI). *Id.* A separate petitioner, the Edison Electric Institute, argued that, to the contrary, OSHA had actually been overinclusive in its regulations and should not have included certain coal and nuclear electric power plants in its regulation. *Id.* at 186. The court denied both petitions. *Id.*

298. *See* *Asbestos Info. Ass’n v. OSHA*, 727 F.2d 415, 421 (5th Cir. 1984) (explaining that because of the complexity of the record, the court must, to some degree, concede contentions made by the Agency).

299. Sidney A. Shapiro, *OMB and the Politicization of Risk Assessment*, 37 ENVTL. L. 1083, 1087 (2007); *see also* Kirk T. O’Reilly, *Science, Policy, and Politics: The Impact of the Information Quality Act on*

for a certain measure of uncertainty to be present in any decision to regulate.³⁰⁰ Judicial forcing of the quantification of risk, through the increased deference given to quantitative risk assessments, may, in certain circumstances, contradict these legislative directives by discouraging agencies from regulating unless risk can be proven.

For example, in the Benzene case, the Supreme Court struck down OSHA's workplace standard regulating benzene, disagreeing with OSHA's interpretation of its guiding statute, the OSH Act of 1970.³⁰¹ The OSH Act has two provisions regarding health and safety standards. The general safety standard, section 3(8), defines an "occupational safety and health standard" as setting conditions "reasonably necessary or appropriate to provide safe or healthful employment and places of employment."³⁰² However, standards dealing with toxic materials or harmful physical agents are also subject to section 6(b)(5), which provides that such a standard should "most adequately assure[], to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."³⁰³

When dealing with a carcinogen, OSHA interpreted section 6(b)(5) to require the agency to "set an exposure limit at the lowest technologically feasible level that will not impair the viability of the industries regulated," because "no safe exposure level can be determined" for carcinogens.³⁰⁴ Contrary to OSHA's interpretation of the statute, Justice Stevens, writing for a plurality, found that section 3(8) required a threshold determination of significant risk to health before section 6(b)(5) kicked in, even with regard to toxic substances.³⁰⁵ In regard to benzene, OSHA had not shown that such a significant risk existed at the previous standard.³⁰⁶

The four-Justice dissent disagreed with the plurality's interpretation of the OSH Act, explaining that the Act was written to protect the health of American workers, especially from "health hazards of 'unprecedented complexity' that had resulted from chemicals whose toxic effects 'are only now being discovered.'"³⁰⁷ Following this mandate, OSHA should have been permitted to regulate based on its finding that there would be benefits from a stricter safety standard, that "those benefits 'may' be appreciable, but that the dose-response relationship of low levels of benzene exposure and leukemia, nonmalignant blood disorders, and chromosomal damage was

Risk-Based Regulatory Activity at the EPA, 14 BUFF. ENVTL. L. J. 249, 250 (2007) (describing how the Toxic Substance Control Act authorizes regulations based on risks to human health or the environment); Sidney A. Shapiro & Rena Steinzor, *Capture, Accountability, and Regulatory Metrics*, 86 TEX. L. REV. 1741, 1741 (2008) (describing the proliferation of regulatory agencies).

300. See, e.g., *Indus. Union Dep't*, 448 U.S. at 692–93 (Marshall, J., dissenting) (explaining that the OSH Act was designed to allow OSHA to regulate toxic substances in the face of scientific uncertainty, in that Congress allowed the Secretary to act before obtaining definitive information).

301. *Id.* at 614–15.

302. Occupational Health and Safety Act of 1970 § 3(8), 29 U.S.C. § 652(8) (2006).

303. *Id.* § 6(b)(5). The section is codified at 29 U.S.C. § 655(b)(5).

304. *Indus. Union Dep't*, 448 U.S. at 613.

305. *Id.* at 639–40.

306. *Id.* at 614–15.

307. *Id.* at 692 (Marshall, J., dissenting) (quoting S. REP. NO. 91-1282, at 2 (1970)).

impossible to determine.”³⁰⁸ Instead, according to the dissent, the plurality had imposed the threshold requirement of “significant risk,” which “represents a usurpation of decisionmaking authority that has been exercised by and properly belongs with Congress and its authorized representatives.”³⁰⁹

Courts applying the Benzene case have interpreted “significant risk” to require a certain measure of quantification.³¹⁰ However, according to the dissent, this requirement thwarts the original and plain meaning of the OSH Act, which was meant to protect American workers from potent, but uncertain, toxic threats.³¹¹ Moreover, the plurality’s imposition of a significant risk threshold is based on a misunderstanding of risk itself. Critics have noted that Justice Stevens “neglected to mention the extent of exposure to the risk-producing activity, one of the most elementary concepts of risk assessment,”³¹² that “[t]he opinion effectively equated *uncertain* risk with *insignificant* risk,” and that the burden shifting undertaken by the plurality may have been based on a cramped reading of the APA.³¹³

2. Forcing the Quantification of Risk May Elide the Influence of Policy Determinations and the Impact of Uncertainty on Agency Decisions

Every quantitative risk assessment is the product of numerous policy judgments in addition to scientific determinations.³¹⁴ The attempt to assess the risk of any particular hazard is riddled with uncertainty, resulting from gaps in our scientific knowledge.³¹⁵ For example, with regard to carcinogens, “[c]ancer risk estimates are predictions of an unknown future, rather than estimates of the future behavior of a known phenomenon” and “are based on extrapolated probabilities, not on past frequencies.”³¹⁶

Using the quantification of risk as shorthand for the reasonableness of agency action and as a proxy for adequate explanation can have the effect of hiding the

308. *Id.* at 704–05.

309. *Id.* at 712 (internal quotation mark omitted); *see also* D.D. Bean & Sons Co. v. Consumer Prod. Safety Comm’n, 574 F.2d 643, 650–51 (1st Cir. 1978) (holding that, in case involving safety regulations promulgated by the CPSC, the Agency did not put forth evidence “substantiating any degree of risk” involved in the design of matchbooks, and thus could not enact regulations—though commonsense indicated the presence of a hazard).

310. *See, e.g.*, AFL-CIO v. OSHA, 965 F.2d 962, 975 (11th Cir. 1992) (vacating an OSHA standard, in part, because the Agency failed to quantify or explain the risk posed by certain regulated substances).

311. *Indus. Union Dep’t*, 448 U.S. at 692 (Marshall, J., dissenting); *see also* Howard A. Latin, *The “Significance” of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty*, 10 *ECOLOGICAL L.Q.* 339, 341 (1982) (describing the outcome of the *Benzene* case and the consequences of the holding).

312. McGarity, *supra* note 6, at 164; *see also* GRAHAM ET AL., *supra* note 8, at 113 (“The ambiguity of ‘significant risk’ in the plurality opinion may reflect the twin evils of ignorance and opportunism.”).

313. Latin, *supra* note 138, at 589–90 (emphases omitted) (explaining that the APA imposes the burden of proof on the proponent of a rule except “as otherwise provided by statute,” and questioning whether the OSH Act implicitly shifts the burden).

314. *See id.* at 590 (explaining how policy considerations frequently play decisive roles in a hybrid rulemaking context); Wagner, *supra* note 5, at 1623 (detailing an example of how an inquiry will include scientific questions, and trans-scientific questions, which require policy judgments).

315. *See, e.g.*, Daniel A. Farber, *Uncertainty*, 99 *GEO. L.J.* 901, 903 (2011) (explaining how uncertainty is “where the likelihood of the peril is nonquantifiable”).

316. Rosenthal et al., *supra* note 14, at 279.

influence of policy on agency decision making and making the determination appear more certain than it warrants. Agencies translate vague statutory mandates, such as a directive to avoid “unreasonable risk,” into quantitative goals, and then design quantitative risk assessments to meet these goals, both steps of which incorporate policy judgments.³¹⁷ Judicial review and increased deference to these QRAs because of their technical complexity reifies these policy determinations into scientific truths.³¹⁸

For example, in *City of Waukesha v. EPA*,³¹⁹ the District of Columbia Circuit upheld a rule promulgated by the EPA under the Safe Drinking Water Act regarding the levels of radionuclides in public water systems.³²⁰ The petitioners challenged the merits of the rule, arguing among other things, that the EPA did not use the “best available science,” as it was required to do.³²¹ In reviewing the merits of the rule, the court noted that it “will give an extreme degree of deference to the agency when it is ‘evaluating scientific data within its technical expertise,’” but would also make sure that “the EPA has examined the relevant data and has articulated an adequate explanation for its action.”³²²

In challenging the merits of the rule, petitioners claimed that the EPA did not adequately consider certain data in its risk assessment, namely “studies of watch dial painters who, in the early 20th century, ingested radium-226 and radium-228 when they inserted luminescent paint brushes into their mouths to sharpen the tips.”³²³ Although the EPA had used this data a decade earlier in promulgating radionuclide standards, petitioners charged that the Agency impermissibly ignored this data here.³²⁴ Instead, the Agency relied on “alternative epidemiological data from studies of Hiroshima and Nagasaki atomic bomb survivors.”³²⁵

The court, after painstakingly listing a summary of the data relied upon, concluded that the EPA had adequately explained its rejection of the watch dial painter data because the Agency found “relative advantages . . . in the bomb survivor studies,” and because it “adequately responded to comments critiquing its reliance on the bomb studies.”³²⁶ For these reasons, among others, the court upheld the radionuclide rules.³²⁷

The court deferred to the EPA’s choice of model in its risk assessment because it bore a “rational relationship to the characteristics of the data to which it is applied.”³²⁸ In other words, the structure dictated the outcome. Because the EPA properly adhered

317. Wagner, *supra* note 5, at 1618.

318. See *id.* at 1617 (explaining that agencies are aware of this increased deference to QRAs, and that this results in their “exaggerat[ing] the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions”).

319. 320 F.3d 228 (D.C. Cir. 2003).

320. *City of Waukesha*, 320 F.3d at 231.

321. *Id.*

322. *Id.* at 247 (quoting *Huls Am., Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996); *Int’l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992)).

323. *Id.*

324. *Id.*

325. *Id.* at 248.

326. *Id.* at 248–49.

327. *Id.* at 258.

328. *Id.* at 248 (quoting *Nat’l Wildlife Fed’n v. EPA*, 286 F.3d 554, 565 (D.C. Cir. 2002)).

to the risk assessment model, its choices were impervious to challenge. Elided here is any possible notion of subjective judgment or uncertainty in the choice of atomic bomb survivors from fifty years prior over watch dial painters from a century prior, to set current standards for the public water supply.

Moreover, judicial review can serve to reify agency action that may be based on arbitrary scientific determinations by issuing judgment on the appropriateness of technical determinations.³²⁹ “[C]ourt decisions automatically generate legal precedents and legal rules,”³³⁰ and this can lead to arbitrary and less-than-ideal regulatory outcomes.³³¹

3. Requiring the Quantification of Risk in the Context of an Injury-in-Fact Determination May Prematurely Force a Merits Determination

Whether a plaintiff has Article III standing is a question of the court’s subject matter jurisdiction.³³² In other words, it is a threshold determination, to be adjudicated before a court can entertain the merits of the plaintiff’s claim.³³³ Moreover, a plaintiff need not be able to prove the merits of her claim at this stage.³³⁴ A lawsuit is structured so as to provide the plaintiff who is entitled to have the court hear his or her claim the opportunity to procure information to which she did not have access before the suit was filed.³³⁵

Requiring that a plaintiff quantify her increased risk for the purpose of satisfying the standing requirements may force the plaintiff, prematurely, to prove the merits of her case.³³⁶ If the case is still at the pleading stage when standing is contested, a plaintiff should not be required to “present . . . specific scientific evidence or statistical verification to prove that the risk actually exists.”³³⁷ This is exactly, however, what a

329. *See, e.g.*, *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984) (affirming the FDA’s decision to exempt constituents of color additives from the reach of the FDCA’s Delaney Clause, which prohibits carcinogenic food and color additives); *see also* *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000) (finding that the EPA’s decision to base a standard for safe drinking water on a particular technical standard was in excess of statutory authority).

330. BREYER, *supra* note 10, at 58 (“A legal rule that flows from a court decision [may] produce more rational results. But it may also lead the agency to turn to other, less fair, more complicated ways to achieve its objectives.”).

331. *See* Sunstein, *supra* note 131, at 526 (providing examples of areas where judicial review has produced regulatory irrationality).

332. ERWIN CHERMERINSKY, *FEDERAL JURISDICTION* 61 (5th ed. 2007).

333. *See* *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (“In essence the question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues.”). Because standing is a jurisdictional issue, it can be raised at any point in the proceedings, and can be raised *sua sponte* by the court. CHERMERINSKY, *supra* note 332, at 61.

334. *See* *Warth*, 422 U.S. at 500 (“[S]tanding in no way depends on the merits of the plaintiff’s contention that particular conduct is illegal . . .”).

335. *See* FED. R. CIV. P. 26 (providing general discovery provisions and procedure for federal courts).

336. *See* *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 (6th Cir. 2005) (requiring a plaintiff to quantify her increased risk of harm to show injury in fact “is to prematurely evaluate the merits of her claims”).

337. *Baur v. Veneman*, 352 F.3d 625, 642 (2d Cir. 2003) (citing *Bennett v. Spear*, 520 U.S. 154, 168 (1997)).

plaintiff must do if required to quantify increased risk at the pleading stage.³³⁸ Because standing can be adjudicated at any point in a proceeding, the scale of proof that must be shown varies. For example, if a court raises Article III standing at the summary judgment stage, then the plaintiff may be required to show increased risk to a higher level of detail. She has been through discovery. However, as the Second Circuit noted,

allegation of a credible risk may be sufficient at the pleading stage without further factual confirmation or quantification of the precise risk at issue. Adopting a more stringent view of the injury-in-fact requirement in environmental cases and food and drug safety suits would essentially collapse the standing inquiry into the merits.³³⁹

One thing to keep in mind when discussing the quantity of evidence needed to show standing at the pleading stage is that the effects of *Bell Atlantic Corp. v. Twombly*³⁴⁰ and *Ashcroft v. Iqbal*³⁴¹—two recent Supreme Court cases clarifying pleading requirements—on standing requirements at the pleading stage are as yet unknown. In *Iqbal*, decided in 2009, the Court stated that “[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’”³⁴² “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.”³⁴³

Courts are currently grappling with how the plausibility standard put forward in *Iqbal* and *Twombly* will interact with questions of subject matter jurisdiction such as standing.³⁴⁴ However, it is possible that courts will require more evidence from plaintiffs alleging increased risk of harm as a basis for injury in fact, including quantification of the increased risk.

338. In this regard, claiming increased risk of harm as a basis for standing is in a different posture than asserting an enhanced-risk claim as a tort action. While it may be difficult for a court to contemplate awarding damages under state law for an unquantified enhanced-risk claim, the positing of increased risk as an injury in fact, allowing a plaintiff access to the judicial system, is a different matter. See, e.g., *Ayers v. Twp. of Jackson*, 525 A.2d 287, 308 (N.J. 1987) (denying cause of action under the New Jersey Tort Claims Act for an unquantified enhanced risk of disease claim).

339. *Baur*, 352 F.3d at 642. The *Baur* court also states that “Article III standing requirements are not intended as a screen for potentially frivolous lawsuits, for there is certainly no independent constitutional barrier to the federal courts entertaining unsuccessful claims.” *Id.*

340. 550 U.S. 544 (2007).

341. 556 U.S. 662 (2009).

342. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

343. *Id.* (citing *Twombly*, 550 U.S. at 556).

344. See, e.g., *Coal. for a Sustainable Delta v. Fed. Emergency Mgmt. Agency*, 711 F. Supp. 2d 1152, 1158 (E.D. Cal. 2010) (analyzing the effect of the *Twombly* and *Iqbal* standards upon Ninth Circuit precedent regarding standing); *Eugster v. Wash. State Bar Ass’n*, No. CV 09–357–SMM, 2010 WL 2926237, at *2 (E.D. Wash. July 24, 2010) (citing *Twombly* and *Iqbal* when discussing the standard of review for determining whether a party has standing in federal court). In addition, the impact of *Twombly* and *Iqbal* on 12(b)(6) motions is currently being studied. See Patricia W. Hatamyar, *The Tao of Pleading: Do Twombly and Iqbal Matter Empirically?*, 59 AM. U. L. REV. 553, 584 (2010) (reporting an empirical study of 12(b)(6) motions after *Twombly* and *Iqbal*).

4. Forcing the Quantification of Risk May Lead to an Inefficient Use of Judicial Resources and the Misdirection of Agency Resources

The quantification of risk, in both the context of quantitative risk assessment and injury in fact, involves complex scientific and highly technical analysis. This analysis is appealing to courts for various reasons, discussed above.³⁴⁵

However, the review of this technical material may result in the expenditure of vast amounts of judicial resources, with very little reward. For example, in *City of Waukesha*, the court spent approximately six thousand words in its opinion discussing the merits of the standards promulgated by the EPA for radionuclides in public water systems.³⁴⁶ It is clear that the court thoroughly and extensively engaged with the record. The upshot of this comprehensive review, however, was to uphold the standards in deference to the EPA's rational choice of scientific models, because the EPA's decision was not arbitrary and capricious.³⁴⁷ This case highlights the massive time investment needed to review quantitative risk assessments for the purpose of ascertaining only the rationality of the methods used, not the correctness of the outcome.³⁴⁸

Moreover, the quantification of risk may skew agency priorities to address easily quantifiable harms so that regulation is more likely to pass judicial review. The Benzene case's enshrining of quantitative risk assessment as the dominant methodology to show the necessity of health or safety regulation had the effect of reducing the amount of regulation passed.³⁴⁹ Increasing the "amount of evidence required for the agency to justify a standard," "ensured that fewer standards would be

345. See *supra* Part III.A for a discussion on the perceived benefits of the quantification of risk.

346. *City of Waukesha v. EPA*, 320 F.3d 228, 247–58 (D.C. Cir. 2003).

347. *Id.* at 248–49, 255.

348. See *Sierra Club v. Costle*, 657 F.2d 298, 410 (D.C. Cir. 1981) (finding the EPA's newly enacted standards to control air pollution under the Clean Air Act reasonable). In this 133-page decision regarding standards promulgated by the EPA under the Clean Air Act, the *Costle* court wrote:

We reach our decision after interminable record searching (and considerable soul searching). We have read the record with as hard a look as mortal judges can probably give its thousands of pages. We have adopted a simple and straight-forward standard of review, probed the agency's rationale, studied its references (and those of appellants), endeavored to understand them where they were intelligible (parts were simply impenetrable), and on close questions given the agency the benefit of the doubt out of deference for the terrible complexity of its job. We are not engineers, computer modelers, economists or statisticians, although many of the documents in this record require such expertise—and more.

Cases like this highlight the critical responsibilities Congress has entrusted to the courts in proceedings of such length, complexity and disorder. Conflicting interests play fiercely for enormous stakes, advocates are prolific and agile, obfuscation runs high, common sense correspondingly low, the public interest is often obscured.

We cannot redo the agency's job So in the end we can only make our best effort to understand, to see if the result makes sense, and to assure that nothing unlawful or irrational has taken place. In this case, we have taken a long while to come to a short conclusion: the rule is reasonable.

Id. (footnote omitted).

349. See *Wagner, supra* note 8, at 119.

promulgated.”³⁵⁰

5. Forcing the Quantification of Risk May Mislead the Public

When an agency quantifies risk, and a court affirms this calculation, the end result is communicated to the public as a certainty. What is lost, however, is the considerable uncertainty and subjective decision making constituting this outcome. “Most people have considerable difficulty understanding the mathematical probabilities involved in assessing risk,”³⁵¹ and are therefore open to the conclusions conveyed by experts. A court’s distillation and reification of the quantification of risk only adds a layer of authoritativeness to these pronouncements.

For example, there is inter- and intra-agency inconsistency in carcinogenic risk assessment. Each agency dealing with carcinogenic risk—EPA, FDA, OSHA, and CPSC—uses default assumptions to grapple with the uncertainties faced in carcinogenic risk assessment.³⁵² Default assumptions are not standardized across agencies.³⁵³ These interagency inconsistencies have been repeatedly documented, and criticized, by governmental entities since the 1970s.³⁵⁴ Notwithstanding these inconsistencies, however, agency conclusions are communicated to the public as certainties in light of the scientific expertise and methodologies used in creating risk assessments.

In one incidence of this, the FDA calculated acceptable levels of contaminants in Gulf Coast seafood after a massive oil spill in 2010.³⁵⁵ The NRDC challenged these calculations, asserting that the FDA relied on outdated science, and filed a petition with the Agency requesting that the standard be changed.³⁵⁶ One of the things argued by the NRDC was that the EPA, as well as some officials *within* the FDA, called for stricter standards.³⁵⁷ If the FDA denies the NRDC’s petition, the NRDC may bring suit in federal court to challenge the denial. A court would review the FDA’s risk assessment with its customary deference,³⁵⁸ and whether the FDA’s calculations were correct or not, an affirmation of them as reasonably considered would enshrine these standards as correct. The uncertainty highlighted by the NRDC would remain for members of the affected public to negotiate individually.

350. *Id.*

351. BREYER, *supra* note 10, at 36.

352. See *supra* note 16 and accompanying text for the standard of risk assessment regarding carcinogenic materials.

353. See *supra* notes 37–43 and accompanying text for a discussion of risk assessment regarding default assumptions within agencies.

354. See *supra* notes 37–43 and accompanying text for a discussion of risk assessment regarding default assumptions within agencies.

355. Miriam Rotkin-Ellman, *FDA’s Bad Science: Agency Allows Unsafe Levels of Contaminants in Seafood*, SWITCHBOARD (Oct. 12, 2011), http://switchboard.nrdc.org/blogs/mrotkinellman/fdas_bad_science_agency_allows.html.

356. *Id.*

357. *Id.*

358. It is possible, however, that the presence of inter- and intra-agency discord could signal to the court that a closer look is warranted. See *supra* Part II.A for a discussion of judicial review in instances of inter- and intra-agency disagreement.

C. *How Quantifying Risk Undercuts the Purposes and Benefits of Judicial Review*

Judicial review of administrative action serves multiple purposes. Cass Sunstein divides the commonly recognized benefits of judicial review into four categories, two of which are relevant here: (1) “Legality,” which is to ensure that agencies comply with legislative mandates,³⁵⁹ and (2) “Legitimacy,” which “is associated with such conventional notions as ensurance of legality, protection against arbitrariness and selectivity, promotion of procedural regularity, and ensurance against the twin evils of factional tyranny and self-interested representation.”³⁶⁰

Judicial forcing of the quantification of risk undermines these benefits, however. As mentioned above, forcing the quantification of risk may contradict the legislative intent by weakening the precautionary nature of statutory mandates.³⁶¹ The deferential review of highly technical determinations can also have the effect of undercutting legitimacy.³⁶² The masking of policy judgments as scientific decisions leaves room for self-interested representation and political maneuvering.³⁶³

Forcing the quantification of increased risk when increased risk is alleged as a basis for injury in fact also undermines the goals to which the judiciary aspires. Although seeking an objective measure of when increased risk of harm constitutes an actual case or controversy, the quantification thereof puts courts in the business of deciding a threshold number—a point at which increased risk becomes unacceptable. This determination is (a) the province of the agencies, (b) better left for the merits, and (c) just as shaky a foundation as is the notion of probabilistic injury itself. The District of Columbia Circuit has conceded as much in its refusal to actually reach the question of what amount of increased risk would constitute injury in fact.³⁶⁴

IV. PROPOSALS

If the overly deferential review of quantitative risk assessment and a quantification requirement in the context of increased risk as a basis for injury in fact work at cross purposes with the beneficial aspects of the judicial enterprise, what next? The answer to the judicial review problem is not that courts should start reassessing the scientific evidence themselves—judges do not have the expertise to do so, nor is such action within the scope of their authority.³⁶⁵ Instead, this problem should be solved extrajudicially, by an independent advisory board created for the purpose of reviewing agency risk determinations. In the absence of such a board, however, courts should

359. Sunstein, *supra* note 131, at 522–23.

360. *Id.* at 525.

361. See *supra* Part III.B.1 for a discussion of the possibility of contradicting legislative intent when forcing the quantification of risk.

362. See Wagner, *supra* note 5, at 1661–67 (criticizing courts by arguing that they encourage the mischaracterization of policy issues as being “resolvable by science”).

363. *Id.* at 1650–72.

364. See *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin. (Pub. Citizen II)*, 513 F.3d 234, 238–41 (D.C. Cir. 2008) (finding statistics offered by the plaintiff to be too unreliable to prove the injury in fact necessary to support standing).

365. 5 U.S.C. § 706 (2006); *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842–44 (1984).

look for signals in the record indicating that a closer examination is needed. These signals include inter- or intra-agency discord, inconsistency in the agency's own determinations, and a twisted statutory interpretation that evades a strong statutory command.

And, regarding increased risk of harm as a basis for injury in fact, the answer is not that any plaintiff alleging any conceivable increased risk of harm should be allowed into court. But, the Second Circuit's is the better rule.³⁶⁶ Specifically, if a court accepts increased risk of harm as a basis for injury in fact under that rule in the relevant context—i.e. food and drug safety suits³⁶⁷—then, at the pleading stage, a plaintiff able to show that she faces a credible risk should be allowed to get into court. The slippery slope evoked by the District of Columbia Circuit³⁶⁸ is avoidable through other justiciability doctrines. Injury in fact need not do all of the work.

A. *Improving the Judicial Review of Quantitative Risk Assessment*

1. The Need for an Independent Scientific Advisory Board to Review Quantitative Risk Assessments

In 1992, Justice (then-Professor) Stephen Breyer proposed that a “small, centralized administrative group, charged with a rationalizing mission,” could help to solve problems that federal agencies faced in regulating risk.³⁶⁹ This administrative body would “bring together people familiar with science, risk analysis, economics, and administration,” and would be charged with the “mission of building an improved, coherent risk-regulating system.”³⁷⁰ These characteristics, along with interagency jurisdiction, protection from political machinations, the authority to carry out its decisions, and a measure of prestige to attract qualified individuals, would help to create a coherent strategy toward risk by federal agencies.³⁷¹

Breyer explained that this body could come about through incremental change, and perhaps even come into being through changes in the structure of the Office of Information and Regulatory Affairs (OIRA), which, then and now, provides oversight over agency regulatory activity.³⁷² Breyer noted that at the time he was writing, OIRA was focused on the cost-effectiveness of regulation and lacked a core of scientific experts³⁷³—which is still the case today³⁷⁴—and he proposed to add health and science

366. *E.g.* Baur v. Veneman, 352 F.3d 625, 634 (2d Cir. 2003).

367. *Id.*

368. Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin. (*Pub. Citizen I*), 489 F.3d 1279, 1294–95 (D.C. Cir. 2007).

369. BREYER, *supra* note 10, at 59–60.

370. *Id.* at 62.

371. *Id.* at 60–61.

372. *Id.* at 69, 79; *see also* Bagley & Revesz, *supra* note 39, at 1329 (explaining that centralized agencies such as OIRA have command over the regulatory state).

373. BREYER, *supra* note 10, at 69.

374. In 2006, the Office of Management and Budget (OMB), OIRA's umbrella organization, drafted a proposed Risk Assessment Bulletin, laying out standardized guidelines for risk assessment by all agencies. *See generally* OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, PROPOSED RISK ASSESSMENT BULLETIN (2006), available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg>

personnel and give the agency an explicit mandate regarding the rationalization of risk regulation.³⁷⁵

Such an administrative body, whether positioned within OIRA or not, would be uniquely positioned to review agency QRAs, and to therefore minimize, if not eliminate, the need for courts to expend resources on reviewing QRAs. If this body were modeled after the EPA's Scientific Advisory Board (SAB),³⁷⁶ which Breyer advocates,³⁷⁷ the relevant agency would have to heavily weigh the board's determinations, and provide a written explanation in the event that it acted contrary to the board's recommendations. This additional layer of review would help courts immeasurably, and this group,

better equipped to investigate general, science-related facts than a court, and operating in the present legal world of 'restrained' judicial review, might find the practical scope of that authority growing, gradually supplanting the (additional, same-standard) review by a court and thereby transforming the group into a kind of administrative court.³⁷⁸

There are at least two major criticisms that can be leveled against such a board: (1) another layer of review will only delay important regulatory action, and (2) such a body would paralyze regulatory action by highlighting scientific uncertainty.³⁷⁹ These

/proposed_risk_assessment_bulletin_010906.pdf. The purported goal of the Bulletin was "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards." Curtis W. Copeland, *The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking*, 33 *FORDHAM URB. L.J.* 1257, 1301 (quoting OFFICE OF MGMT. & BUDGET, *supra*, at 3). In 2007, the National Research Council (NRC) of the National Academy of Sciences, which had reviewed the Bulletin, advised that OMB withdraw the Bulletin. Shapiro, *supra* note 299, at 1085. The NRC had a problem with almost every line in the proposed bulletin. *Id.* OMB withdrew the Bulletin. *Id.* Sidney Shapiro argues that this fiasco demonstrates two things: (1) the lack of scientific expertise within OMB, and (2) the political motivation of OMB to utilize risk assessment as an anti-regulatory tool. *Id.*

375. BREYER, *supra* note 10, at 79.

376. According to its Charter, the SAB is a scientific/technical advisory committee which provides advice to the EPA on:

- a. The adequacy and scientific basis of any proposed criteria document, standard, limitation, or regulation under the [various statutes administered by the EPA];
- b. The scientific and technical adequacy of Agency programs, guidelines, documents, methodologies, protocols, and tests;
- c. New or revised scientific criteria or standards for protection of human health and the environment;
- d. New information needs and the quality of Agency plans and programs for research, development and demonstration; and
- e. The relative importance of various natural and anthropogenic pollution sources.

EPA SCIENCE ADVISORY BOARD, EPA, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CHARTER (2011).

377. BREYER, *supra* note 10, at 68–69.

378. *Id.* at 72.

379. Breyer anticipated and addressed the following additional objections to his proposed board: (1) it is undemocratic because it would take power from Congress—Breyer shows that it would only organize the power that the Executive branch already has, not add to it; (2) it would be elitist—Breyer disagrees with this label and feels that the selection process would attract qualified and competent individuals; (3) it would be ineffective—Breyer points to the unique, unifying mission of this Agency; (4) it is politically unacceptable—Breyer argues that more rational risk regulation would increase public trust in the agency; and

concerns are valid, and any recommendation to add a layer of review to the already glacial regulatory process should be carefully scrutinized.

As to delay, the board's charter could include a time limit on its review, as OIRA's time for review of regulations is also circumscribed.³⁸⁰ Moreover, it is feasible that the time necessary for judicial review would be shortened, because many of the issues covered by the judiciary would have been addressed by the board. And as to the possible contribution to regulatory paralysis, the board's focus on consistency across agencies should instigate action as much as, or more than, it will thwart action.

2. In the Absence of a Centralized Board Reviewing Risk Regulation, Courts Should Seek Signals to Indicate When Deference to Quantitative Risk Assessment is Not Warranted

The information contained in a QRA can be impenetrable to nonscientists.³⁸¹ Moreover, QRAs are highly structured.³⁸² Therefore, the presence of a QRA can indicate to a court that the agency has fulfilled its duty by considering all available evidence and that it has acted rationally. However, QRAs mask policy determinations and large amounts of uncertainty under a veneer of "science." Highly deferential judicial review can only reify these elisions.

What, then, should a court faced with a QRA do? There are certain signals that a court should look for as indicators that a QRA deserves a closer look. First, a court should look for inter- or intra-agency discord. Second, inconsistency in an agency's own pronouncements should be looked at closely. And third, the presence of a strong and clear statutory pronouncement in the face of a seemingly conflicting determination is a sign indicating that deeper review may be necessary.

For example, in *American Farm Bureau Federation* the District of Columbia Circuit granted a petition for review of certain EPA air quality standards and remanded the standards to the Agency.³⁸³ In granting the petition, the court notes that (1) CASAC, an independent scientific review committee, disagreed with the air quality level that the EPA had set, and that (2) the EPA had changed its own position on the relevant studies to consider when setting standards.³⁸⁴ And in *Natural Resources Defense Council*, the Second Circuit determined that the EPA's explanation of its noncompliance with the FQPA's command to use an additional tenfold margin of safety was inadequate.³⁸⁵

In contrast, the court in *American Trucking Associations, Inc. v. EPA*,³⁸⁶ upheld

(5) the transition would not be practical—Breyer argues that his suggestions can be implemented incrementally. *Id.* at 73–79.

380. See Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sept. 30, 1993) (outlining the guidelines for review for the OMB and OIRA).

381. See *Sierra Club v. Costle*, 657 F.2d 298, 410 (D.C. Cir. 1981) ("We are not engineers, computer modelers, economists or statisticians, although many of the documents in this record require such expertise—and more.")

382. See *supra* Section III for a discussion of the pros and cons of quantitative risk assessments.

383. *Am. Farm Bureau Fed. v. EPA*, 559 F.3d 512, 515 (D.C. Cir. 2009).

384. *Id.* at 521.

385. *Natural Res. Def. Council v. EPA*, 658 F.3d 200 (2d Cir. 2011).

386. 283 F.3d 355 (D.C. Cir. 2002).

air quality standards promulgated by the EPA and noted that the Agency staff's recommendations were consistent with the Agency's final determination.³⁸⁷ And in *Environmental Defense Fund, Inc. v. EPA*,³⁸⁸ the court noted that the hearing examiner had come to a contrary conclusion than did the EPA Administrator, and the court grappled with how to handle this: "We intend only to recognize that evidence supporting a conclusion may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the Board's than when he has reached the same conclusion."³⁸⁹ The court ultimately upheld the Administrator's decision.³⁹⁰

In sum, in the absence of a centralized review board for risk regulation, a court charged with reviewing a quantitative risk assessment should be inclined to delve deeper if there is disagreement within the agency or among agencies,³⁹¹ if there is inconsistency within the agency over time, or if the agency determination appears to conflict with a strong statutory command. And, in the absence of one of these signals, a court should not find the absence of quantification to be its own signal. Instead, if "a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator," a court should not "demand rigorous step-by-step proof of cause and effect."³⁹² As the District of Columbia Circuit explained almost four decades ago, "[s]uch proof may be impossible to obtain if the precautionary purpose of the statute is to be served."³⁹³

B. *Probabilistic Injury as a Basis for Injury in Fact*

If probabilistic injury is to be permitted to satisfy the injury-in-fact requirement, a qualitative test, like the Second Circuit's, is better than a quantitative one, like the District of Columbia Circuit's. As the Second Circuit noted, "[i]n evaluating the degree of risk sufficient to support standing . . . we are mindful that 'Supreme Court precedent teaches us that the injury in fact requirement . . . is qualitative, not quantitative, in nature.'"³⁹⁴

In response to the District of Columbia Circuit's concern that under an expansive probabilistic injury doctrine, "after an agency takes virtually *any* action, virtually *any* citizen—because of a fractional chance of benefit from alternative action—would have standing to obtain judicial review of the agency's choice,"³⁹⁵ courts can look to other

387. *Am. Trucking Ass'n*s, 283 F.3d at 371–72.

388. 489 F.2d 1247 (D.C. Cir. 1973).

389. *Env't. Def. Fund*, 489 F.2d at 1253 (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951)).

390. *Id.* at 1257.

391. Compare *supra* note 38, which discusses the National Resources Defense Council's challenge of the FDA's assessment of Gulf Coast seafood.

392. *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976) (footnote omitted).

393. *Id.*

394. *Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003) (second omission in original) (quoting *Ass'n of Cmty. Orgs. for Reform Now v. Folwer*, 178 F.3d 350, 357–58 (5th Cir 1999)).

395. *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin. (Pub. Citizen I)*, 489 F.3d 1279, 1295 (D.C. Cir. 2007).

jurisdictional doctrines. These include causation and redressability, mootness and ripeness, and prudential standing doctrines such as the zone of interests test.³⁹⁶ Moreover, it is important to keep in mind that “Article III standing requirements are not intended as a screen for potentially frivolous lawsuits,”³⁹⁷ and the question of whether a plaintiff can prove her claim is irrelevant to the standing inquiry. Instead, courts should look to whether the plaintiff faces a direct risk of harm that is more than merely speculative for the purpose of the injury-in-fact requirement.

V. CONCLUSION

This Article shows that courts try to make risk more concrete, and hence more amenable to adjudication, by requiring that agencies and individuals quantify risk, but that this call for quantification actually undercuts the purposes of judicial review. Instead of enforcing the legality and legitimacy of agency action, forcing the quantification of risk by agencies undermines these goals. And requiring parties to quantify increased risk of harm for the purpose of Article III standing does not assure that the party’s injury is actual or imminent. Rather, such a requirement excludes potentially worthwhile plaintiffs from court, conflates a threshold determination with a merits analysis, and forces the injury-in-fact requirement to perform a task for which it was not intended.

The need for courts to negotiate risk will remain a part of the judicial function, both in the review of agency action and in the analysis of probabilistic harm. Instead of requiring the quantification of risk, courts should note the presence of factors, such as intra-agency discord, that indicate that a closer look at an agency’s treatment of a quantitative risk assessment may be warranted. And a party alleging a credible harm, even one that is unquantifiable, should satisfy the injury-in-fact requirement. In these ways, courts can better handle their role vis-à-vis risk than through forced quantification.

396. *Baur*, 352 F.3d at 636.

397. *Id.* at 642.

