False Certainty: Judicial Forcing of the Quantification of Risk

Diana R. H. Winters
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, forcing such quantification may undercut the benefits of judicial review. This Article looks at 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 that judges think that the quantification of risk is doing and the flaws in the process, and then turns to proposals for improving the judicial review of risk determinations.

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 decisionmaking. The quantification of risk becomes a proxy for reasonableness and a rhetorical reinforcement against the accusation of judicial overreach and extrajudicial action.

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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. Federal courts, however, confront risk often, notably in the contexts of reviewing agency action and assessing whether a party’s alleged increased risk of harm constitutes injury-in-fact. These courts, restricted to hearing cases or controversies involving actual or imminent injury, and charged with the delicate task of balancing deference with searching review, must negotiate the meaning and influence of risk on judicial determination.

It is understandable that courts find the quantification of risk to be appealing. 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.

Despite these perceived benefits, however, the quantification of risk does not fulfill its promise; to the contrary, it undercuts the purposes of

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3 See, e.g., Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 34 (D.C. Cir. 1976).
judicial review. Instead of ensuring that agencies adhere to their legislative mandates, insistence on the quantification of risk may force agencies to contradict precautionary directives.\(^4\) 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 decisionmaking. Courts sometimes 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 encourages courts, by making a determination on the acceptable amount of increased risk, to act legislatively—exactly the position courts are trying to avoid.

This Article looks at the judicial forcing of the quantification of risk in these two contexts: 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.\(^6\) But this dominance was originally 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.\(^8\)


\(^7\) The Benzene Case, 448 U.S. 607.

\(^8\) Wendy E. Wagner, The ‘Bad Science’ Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation, 66 Aut. Law & Contemp. Probs. 63, 119 (2003) (the Benzene case had the effect of increasing the “amount of evidence required for the agency to justify a standard, and “[t]his increase in the agency’s burden of proof ensured that fewer standards would be promulgated.”); U.S. GEN. ACCOUNTING OFFICE, CHEMICAL RISK ASSESSMENT: SELECTED FEDERAL AGENCIES’ PROCEDURES, ASSUMPTIONS, AND POLICIES (2001) 186 (“the agency only publishes two or three proposed or final rules per year”); see also Natural Resources Defense Council, Inc. v. EPA, 705 F. Supp. 698, 702-703 (D. D.C. 1989). The court criticizes EPA for foot dragging in promulgating standards for benzene emissions, and orders that final standards be published by 1990. Id. In the book In Search of Safety, the authors describe how 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, LAURA C. GREEN, & MARC J. ROBERTS, IN SEARCH OF SAFETY – CHEMICALS AND CANCER RISK (1988).
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 alleging such injury quantify her risk.9

Although these contexts are obviously quite different, judicial forcing of the quantification of risk is doing the same work in each context; and by, for the first time, highlighting these similarities, this Article exposes the flaws in this methodology. Although there is scholarly literature on the dangers of quantifying risk, courts’ insistence on quantification and the effects of this insistence on judicial review is understudied. This subject is important because the quantification of risk becomes a proxy for reasonableness and a rhetorical reinforcement against the accusation of judicial overreach and extrajudicial action. The seeming objectivity and simplified nature of quantification allow the court to view itself as comfortably fulfilling its function without overstepping its authority, and the need for interrogation is lost.

What, then, is the solution? In the context of the judicial review of agency action, the answer is not for courts to re-assess the evidentiary record. Judges do not have the expertise for this, nor is it within the scope of their authority.10 The creation of an independent advisory board, formed for the purpose of reviewing agency risk determinations, would go a long way toward ameliorating the problem.11 In the absence of such a board, however, 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, when a court is assessing 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 get into court.12 Other mechanisms exist to weed out frivolous

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12 Baur v. Veneman, 352 F.3d 625, 636-641 (2d Cir. 2003). A widely shared harm can still be particularized. Id. at 635.
cases. This is not the purpose of the injury-in-fact doctrine.\textsuperscript{13}

Part I of this Article describes these two scenarios where 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 Part discusses the history and practice of quantitative risk assessment in agency decisionmaking, 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 Part 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.

Part II of the Article turns to the perceived benefits of quantifying risk to judicial review, which include creating an objective measure; bridging the expertise gap; clearly communicating risk determinations to the public; and assisting the court to remain within its adjudicative role. This Part then addresses the detriments of quantifying risk, which include contradicting congressional will in passing health and safety-protective legislation; concretizing policy determinations and uncertain calculations as unalterable law; collapsing the merits determination into what should be a threshold decision; supporting the misdirection of resources; and confusing the public. Part II also looks at the purposes of judicial review, and demonstrates how the forcing of the quantification of risk undercuts these purposes.

Part III makes certain suggestions for improving judicial review of risk. It re-proposes the creation of an advisory board envisioned two decades ago by Justice (then Professor) Stephen Breyer two decades ago,\textsuperscript{14} and in the absence of such a board, notes the signals a court can watch for that indicate the need for a closer look at agency treatment of QRAs. It advocates that in the context of Article III standing, a plaintiff’s ability to show a credible risk of harm should be enough to satisfy the injury-in-fact requirement.

\section{Judicial Quantification of Risk}

\textsuperscript{13} Id. at 642.

\textsuperscript{14} Breyer, Vicious Circle 59-72.
This Part describes two scenarios where the quantification of risk plays a large part in judicial decisionmaking: First, courts are often called upon to assess the reasonableness of agency determinations that are based, at least partially, on quantitative risk assessments. This Part 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 Part does not suggest that these are the only situations where 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 must first assess the risks to the public health and safety posed by substances, events, or activities. “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 likelihood of a particular hazard occurring,” and second, the term risk assessment 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. This Paper uses the term “quantitative risk assessment,” or “QRA” to refer to the latter usage of the term.

1. Quantitative risk assessment.
   a. The practice and policy of quantitative risk assessment.

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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).

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QRA developed from techniques used by the Food and Drug Administration in the 1950s and 1960s 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.” The four steps of quantitative risk assessment are: (1) hazard identification, (2) dose-response evaluation, (3) exposure assessment, and (4) risk characterization. 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.” Although easy to describe, none of these steps is as straightforward as it seems.

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 must list, and regulate, air pollutants “emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.” To move forward, the EPA translates directives such as these into quantitative goals and, by doing so, determines the meaning of “endanger public health or welfare.” Second, QRA provides measurements that can be compared to each other, and can thus aid in regulatory prioritization. And third, QRA provides a clear and seemingly objective explanation for the agency’s regulatory

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19 Id.
20 See supra, p.__.
choices for the purposes of both judicial review and public consumption.

Quantitative risk assessment, however, is not an exclusively scientific enterprise: it involves policy judgments at each step. These policy judgments are necessary because any risk assessment inquiry is infused with uncertainty, stemming from gaps in scientific knowledge and questions about desirable policy outcome. “[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.”

The National Research Council’s Red Book, published in 1983, identified more than fifty science-policy decisions involved in risk assessment. For example, there are two ways in which hazards to humans are identified. The first is through the science of epidemiology, which is a 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.” In the case of cancer, however, this is difficult—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. The second method in hazard identification is animal studies, which has its own difficulties; such studies are limited in


26 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. During their lifetimes, one in three women, and one in two men will develop cancer. SIDDHARTHA MUKHERJEE, THE EMPEROR OF ALL MALADIES: A BIOGRAPHY OF CANCER xvi (2010). The word “cancer,” however, 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, scientific, and political potency that cancer is often described as the defining plague of our generation.” Id. at xvii.

27 Id; see also Siddhartha Mukherjee, Patrolling Cancer’s Borderlands, N.Y. TIMES, July 17, 2011, at SR8.
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.\textsuperscript{28}

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 how to translate animal results to humans.\textsuperscript{29} 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.

Exposure assessment, the third step of QRA, “determines just how much exposure to a [disease-causing agent] people actually confront.”\textsuperscript{30} This step involves the assessment of how much exposure is seen in a population, as well as the maximum individual risk (MIR).\textsuperscript{31} 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.”\textsuperscript{32} However, the use of the MEI is a conservative policy judgment, and critics say that its use leads to overregulation.\textsuperscript{33}

Each agency dealing with risk uses default assumptions to grapple with the uncertainties faced in risk assessment. Default assumptions are used to reduce the number of policy determinations made in each individual situation, or at least to standardize these determinations,\textsuperscript{34} but of course, the default assumptions themselves entail policy judgments. For example, EPA and FDA use default assumptions about how much water people drink daily, how much food they eat, and how much air they breathe.\textsuperscript{35}

\textsuperscript{28}Farber, et al. at 64.
\textsuperscript{29}Such questions are called “trans-scientific”—they are “questions which can be asked of science and yet cannot be answered by science.” Wagner at 1623 (citation omitted).
\textsuperscript{30}Rosenthal et al., supra note __, at 290.
\textsuperscript{31}Id.
\textsuperscript{32}Id.
\textsuperscript{33}Id. at 292.
\textsuperscript{34}Robert G. Hetes, *Science, Risk, and Risk Assessment and Their Role(s) Supporting Environmental Risk Management*, 37 ENVT. L. 1007, 1014 (2007) (noting “default assumptions are used [by EPA] to address inherent uncertainties and data gaps”).
\textsuperscript{35}Rosenthal et al., at 292. Recently, FDA estimated the amount of seafood that residents of the United States’ gulf coast eat, for the purpose of assessing the danger caused by cancer-causing chemicals in the seafood. These estimates have been challenged by the Natural Resources Defense Council, as have FDA’s assumptions regarding the average weight of Gulf Coast residents. See NRDC Press Release, FDA Underestimates Gulf Coast
These default assumptions are not standardized across agencies. Inter-agency inconsistencies have been repeatedly documented, and criticized, by governmental entities since the 1970s. For example, the agencies rely on differing assumptions regarding population exposure, and on different methods of extrapolating the high doses of agents that animals receive in controlled experiments to the lower doses that humans may receive. EPA generally uses conservative assumptions, erring on the side of protecting public health when faced with scientific uncertainty. A 1993 inter-agency 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,” a finding confirmed in 2001 by a GAO report on “Chemical Risk Assessment: Selected Federal Agencies’ Procedures, Assumptions, and Policies.”

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. 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.” The appearance that risk assessment is wholly scientific masks its endemic


37 Bagley & Revesz, at 1321.

38 Hetes at 1016.


40 U.S. GEN. ACCOUNTING OFFICE, CHEMICAL RISK ASSESSMENT: SELECTED FEDERAL AGENCIES’ PROCEDURES, ASSUMPTIONS, AND POLICIES (2001) [hereinafter 2001 GAO REPORT]; see also Bagley & Revesz, at 1321. The 2001 GAO REPORT comments “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, at 46.


42 Rosenthal et al. at 295.
policy determinations. Whether this masking is intentional or not, the appearance of scientific certainty is appealing to courts that review agency risk assessments.

b. The background to the prevalence of quantitative risk assessment in agency decisionmaking.

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 80s. 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 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 EPA and OSHA worked towards the development of formal “cancer principles” during the late 1970s. Both agencies looked to an extremely influential 1970 Report to the Surgeon General that suggested a policy of zero tolerance for exposure to carcinogens. Each agency, however, developed a markedly different approach to the regulation of carcinogens: 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.”

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43 See Wagner at 1637-1644. Wagner discusses the “unintentional science charade,” where “[p]ervasive agency use of hypertechnical risk assessment guidelines and complex computer models to set toxic risk standards . . . suggest an administrative preference for scientific precision and a simultaneous obliviousness to the multiple policy judgments needed to inform toxic risk calculations,” and the “intentional charade,” where “bureaucrats consciously disguise policy choices as science.”


45 Id. at 147.

46 Id. at 148-49.
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.”

OSHA’s approach seemed to be gaining primacy even though it was extremely unpopular with regulated entities. CPSC began using an approach modeled after OSHA’s, and OSHA published its final policy in 1980.

In the famous “Benzene case,” decided in 1980, OSHA’s approach was struck down by the United States Supreme Court. This case involved a 1979 standard promulgated by OSHA that reduced the amount of benzene allowable in the workplace from 10 parts per million to 1 part per million. In a divided opinion striking down the standard, Justice Stevens’ 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 impairment,” which, according to Justice Stevens, OSHA had not done.

Although not requiring that the agency 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,” the Court “strongly implied that quantitative risk assessment offered the agency a safe harbor against future challenges.”

Thomas McGarity writes that the “Benzene decision effectively resolved the science-policy battle in favor of the proponents of quantitative risk assessment.” The case legitimized and encouraged the use of QRA

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47 Id. at 150.
48 Id. at 151.
50 The Benzene Case, 448 U.S. 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. Justice Rehnquist also wrote separately, arguing that the OSHA standard violated the nondelegation doctrine. Id. at 671. 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 (1981).
51 The Benzene Case, 448 U.S. at 653.
52 Id. at 656.
53 McGarity, supra note __, at 164.
54 Id. at 165. See also Angelo, supra note __, at 1544 (stating the Benzene case
by agencies. It was followed by a National Research Council study on agency use of risk assessment in 1981, and an Office of Science and Technology Policy review of carcinogenic risk assessment in 1985. Moreover, during the early 1980s, the administrator of EPA, William Ruckelshaus, was a big booster of the technique.

The prevalence of and support for QRA can be explained partly by its rigid structure and seemingly 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 a means to defend their determinations when they are 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 yield[s] often uncertain results.”

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.” Deferential review is mandated by statute. Unless otherwise statutorily prescribed, a scenario addressed below, the judicial review of QRAs is governed by Section 706 of the Administrative Procedure Act, 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.” This is a highly deferential

“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.”).

55 Angelo, supra note __, at 1544-45.
56 Id. at 1545.
57 Id. at 1558.
58 Emily Hammond Meazell, Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science, 109 Mich. L. Rev. 733, 749 (2011) (“The textbook approach is to argue that an agency used ‘bad science’—that it ignored important scientific studies, that the agency’s own science involved flawed methodologies, that the agency did not do enough science, or that the science somehow dictated a different conclusion—in essence, that if the science had been ‘right,’ a different outcome would have resulted.”).
59 5 U.S.C. § 706. If the agency action was the result of formal adjudicative process,
standard, and courts must presume that the agency action is correct.  

If the court is reviewing agency interpretation of a statute, review is constrained by the *Chevron* doctrine, or other degrees of judicially created deference. *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,” 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.”  

Agency interpretations not found to require *Chevron* deference may nevertheless be entitled to some deference, especially when the regulatory scheme is complex and the agency has superior expertise in the field.  

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. The judiciary’s role is to oversee the boundaries of this activity—to ensure that administrative decisionmaking is made within its authority, that the decisionmaking is based on all pertinent information, and that the decision is reasonable in light of the evidence. Beyond that, however, a court walks the line of judicial policymaking, thus overstepping its own authority.  

Deference, however, does not mean a rubber stamp. The judiciary recognizes that oversight requires more than a cursory review of agency policy; “Rather, the reviewing court must assure itself that the agency decision was ‘based on a consideration of the relevant factors.’ Moreover, a court must engage in a ‘substantial inquiry’ into the facts, one that is ‘searching and careful.’”  

Courts maintain a higher level of deference the court uses a “substantial evidence” standard in its review. 5 U.S.C. § 706(2)(E).  

60 See, e.g., Miami-Dade County v. U.S. EPA, 529 F.3d 1049, 1058 (11th Cir. 2008); Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 33 (D.C. Cir. 1976).  


62 Chevron, U.S.A., Inc v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984). Lisa Schultz Bressman notes that “Although the relationship between the Chevron inquiry and the 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.”  


63 Mead, 533 U.S. at 235.  

64 Chevron, 467 U.S. at 865-866.  

65 *Id.*  

66 Ethyl Corp., 541 F.2d at 34 (citing Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 415 (1971)).
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. This higher level of deference also applies
when the agency determination involves an area of scientific uncertainty.
Nevertheless, the court must ensure that the record shows that the agency
has considered all of the relevant evidence before it, and agency
decisionmaking has been “rational.”

Courts, therefore, undertake a two-step process when reviewing
agency determinations. First, a court will examine the administrative record
and determine whether the agency took all of the relevant information into
account, or whether it inexplicably ignored something potentially pertinent.
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.

Second, a court will determine whether the agency’s decision was
made rationally, based on the information before it. For example, in *NRDC
v. EPA*, the Second Circuit held that 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. To assess each of these factors, a
court must look closely at the agency’s stated reasons for its action, without
substituting its own judgment for that of the agency.

It is clear why an adequate statement of reasons is a necessary
component of agency decisionmaking. The statement of reasons allows
interested parties to assess the challenged determination without needing to
engage in a potentially prohibitive review of the record. In addition, a

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67 See, e.g., City of Waukesha v. EPA, 320 F.3d 228, 247 (D.C. Cir. 2003). Also see
Meazell, Super Deference at 773. Meazell questions whether courts are really applying
what she calls “super deference,” as well as the wisdom of this approach.
68 See Ethyl Corp. v. EPA, 541 F.2d 1, 28 (D.C. Cir. 1976) (“Where 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, we will not demand rigorous step-
by-step proof of cause and effect.”).
70 Miami-Dade County, 529 F.3d at 1066.
71 Id. at *18.
72 See, e.g., League of Wilderness Defenders-Blue Mountains Defenders Biodiversity
Project v. U.S. Forest Service, 549 F.3d 1211, 1215 (9th Cir. 2008).
sufficient statement of reasons provides a court engaging in judicial review access to agency decisionmaking. A court may not, and in any event, could not replicate the agency’s decisionmaking process by assessing the entire factual record.\textsuperscript{73}

b. Specific statutory judicial review provisions.

The previous discussion of deference assumed that review is governed by § 706 of the APA. Certain statutes, however, contain specific review provisions, which further restrict a court’s discretion in its review of agency decisionmaking. One such statute is the Occupational Health and Safety Act of 1970 (“OSH Act”).\textsuperscript{74} When the Occupational Safety and Health Administration (“OSHA”) promulgates a new standard, the Secretary must “include a statement of the reasons for such action.”\textsuperscript{75} 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,” thereby limiting judicial review.\textsuperscript{76} Courts have interpreted this provision to apply to factual evidence as opposed to policy judgments.\textsuperscript{77}

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.\textsuperscript{78} “[T]he extrapolation of that determination from animals to humans is not really a factual matter.”\textsuperscript{79} Other circuits have grappled with the difficulty of separating factual

\textsuperscript{73} See Dry Color Mfrs. Ass'n, Inc. v. Department of Labor, 486 F.2d 98, 106 (3d Cir. 1973) (“In the context of a voluminous factual record . . . a conclusory statement of reasons places too great a burden on interested persons to determine and challenge the basis for the standard, and makes possible in any subsequent judicial review the use of posthoc rationalizations that do not necessarily reflect the reasoning of the agency at the time the standard was issued.”).

\textsuperscript{74} 29 U.S.C. § 655.

\textsuperscript{75} 29 U.S.C. § 655(e).

\textsuperscript{76} 29 U.S.C. § 655(f).

\textsuperscript{77} Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, 503 F.2d 1155, 1158 (3d Cir. 1974).

\textsuperscript{78} Id. at 1158-1159.

\textsuperscript{79} Id. at 1159.
findings from legislative policy judgments in the context of the OSH Act as well.\textsuperscript{80}

Because it is impossible to cleanly distinguish 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.\textsuperscript{81} “[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.”\textsuperscript{82}

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

\textsuperscript{80} See, e.g., United Steelworkers of America, AFL-CIO-CFC v. Marshall, 647 F.2d 1189, 1206-07 (D.C. Cir. 1981) (“The peculiar problem of reviewing the rules of agencies like OSHA lies in applying the substantial evidence test to regulations which are essentially legislative and rooted in inferences from complex scientific and factual data, and which often necessarily involve highly speculative projections of technological development in areas wholly lacking in scientific and economic certainty.”); Public Health Citizen Research Group v. Tyson, 796 F.2d 1479, 1485 (D.C. Cir. 1986) (“Statutes like the OSH Act, however, create a peculiar problem for reviewing courts. The statute instructs the reviewing court to apply the substantial evidence test, which is normally reserved for formal adjudications of fact. OSHA rulemaking, however, is a hybrid, combining formal and informal aspects of decisionmaking and including essentially legislative tasks as well.”); AFL-CIO v. OSHA, 965 F.2d 962, 970 (11th Cir. 1992) (“The substantial evidence test applies to review of policy decisions as well as factual determinations . . . even though policy decisions are ‘not so susceptible to verification or refutation by the record.’”) (citations omitted).

\textsuperscript{81} See American Iron and Steel Institute v. Occupational Safety and Health Admin. (“AISI”), 577 F.2d 825, 831 (3d Cir. 1978); Public Citizen Health Research Group v. U.S. Dept. of Labor, 557 F.3d 165, 175 (3d Cir. 2009).

\textsuperscript{82} Public Citizen Health Research Group, 557 F.3d at 175 (citing AISI, 577 F.2d at 834 (citing Indus. Union Dept', AFL-CIO v. Hodgson, 499 F.2d 467, 488 (D.C.Cir.1974)).
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.\(^{83}\)

This test imposes a seemingly objective inquiry over the necessarily subjective review of an agency decision based on both facts and policy determinations. Each step nominally allows the judiciary to assess the record 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.”\(^ {84}\) The Food, Drug, and Cosmetic Act “contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions,” which prescribe in which court appeals from agency action will be heard (district or court of appeals).\(^ {85}\)

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 decisionmaking, but are also signaled to do a searching review of the record to ensure rational decisionmaking. 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 to ensure that an agency has not acted arbitrarily or capriciously. QRAs are both highly technical and exactly structured. They thus provide a seemingly transparent and understandable answer to the question of whether an agency considered all of the relevant information. Moreover, the seemingly 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 appearance of arbitrariness. By deferring to an agency’s use of QRA, the court shows that it respects the agency’s superior technical expertise and the agency’s resolution of uncertainty. The court therefore

\(^{83}\) Public Citizen Health Research Group, 557 F.3d at 176 (citing AISI, 577 F.2d at 830).
\(^{85}\) In re Natural Resources Defense Council, 645 F.3d 400, 404 (D.C. Cir. 2011).
remains within its appropriate role, properly negotiating the balance between deference and searching review.

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

d. The failure to defer.

There are, of course, situations where courts do not defer to agency decisionmaking, 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 decisionmaking was inappropriate. These signals include the agency’s non-compliance with a strong statutory command, documented intra-agency disagreement, and an allegation that the agency is acting outside of its jurisdictional authority.

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

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86 See, e.g., Miami-Dade County v. EPA, 529 F.3d 1049, 1071 (11th Cir. 2008); Kennecott Greens Creek Min. Co. v. Mine Safety and Health Admin., 476 F.3d 946, 952 (D.C. Cir. 2007).
87 See, e.g., American Farm Bureau Federation v. EPA, 559 F.3d 512, 528 (D.C. Cir. 2009) (court upheld EPA’s decision not to rely on a risk assessment, while overturning other aspects of EPA’s determinations); NRDC v. EPA, 2011 WL 4336673, at *20 (2d Cir. 2011) (court overturned agency’s use of a lowered safety factor for children and infants in one risk assessment because of lack of adequate explanation, but upheld the agency’s other risk assessments).
88 See, e.g., American Farm Bureau Federation v. EPA, 559 F.3d 512, 528 (court denied petition seeking review of EPA’s decision not to rely on a specific risk assessment); American Trucking Assoc., Inc. v. EPA, 283 F.3d 355, 373 (D.C. Cir. 2002) (court deferred to EPA’s adequately explained decision to ignore risk assessment).
89 559 F.3d 512 (D.C. Cir. 2009).
90 Id. at 515. The court upheld certain other standards, finding that these were not arbitrary, capricious, or otherwise contrary to law.
standards.\textsuperscript{91}

When 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 this case.\textsuperscript{92} The court also found that EPA did not adequately explain why it no longer relied on short-term studies, as it had a decade earlier.\textsuperscript{93} These disagreements, between EPA and an independent advisory board and between EPA and an earlier version of itself, signaled to the court that there was the possibility that the promulgated standards rested on shaky ground. EPA’s failure to explain these disagreements to the court’s satisfaction confirmed this suspicion.\textsuperscript{94}

In \textit{Natural Resources Defense Council v. EPA}, the court vacated and remanded part of an EPA order that assessed the risk of a carcinogenic pesticide.\textsuperscript{95} The court found that EPA did not adequately explain why it had used a safety factor of 3X instead of a safety factor of 10X, as was mandated by statute.\textsuperscript{96} This failure to explain was arbitrary and capricious.\textsuperscript{97} EPA had failed to comply with a clear statutory directive, and the court therefore overturned EPA’s use of its risk assessment.

Similarly, in \textit{Les v. Reilly} and \textit{Public Citizen v. Young}, two courts of appeals refused to allow the FDA or the EPA to read an implicit \textit{de minimis} exception into the Delaney Clause: the provision of the Food, Drug, and Cosmetic Act that prohibits all food and color additives found to induce cancer.\textsuperscript{98} In \textit{Public Citizen v. Young}, the D.C. Circuit reluctantly held that

\textsuperscript{91} Id. at 521.
\textsuperscript{92} Id.
\textsuperscript{93} Id. at 522.
\textsuperscript{94} The court remanded the standards for reconsideration. It did not vacate the standards because “EPA’s failure to explain itself is in principle a curable defect.” Id. at 528. See also Public Citizen v. Heckler, 653 F. Supp. 1229, 1235 (D. D.C. 1987) (FDA recommended that interstate sales of raw milk be banned; Secretary of Health and Human Services rejected FDA’s recommendation; court found Secretary’s action to be arbitrary and capricious).
\textsuperscript{95} 2011 WL 4336673 (2d Cir. 2011).
\textsuperscript{96} Id. at *18. The Food Quality Protection Act (FQPA), passed in 1996, requires 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.” Id. at *3 (citing 21 U.S.C. § 346a(b)(2)(C)(i)). A different margin of safety may be used by EPA “only if, on the basis of reliable data, such margin will be safe for infants and children.” Id. In \textit{NRDC v. EPA}, petitioners alleged, and the court agreed, that EPA had not explained why the lesser margin used would be safe for infants and children.
\textsuperscript{97} 2011 WL 4336673, at *18.
\textsuperscript{98} Les v. Reilly, 968 F.2d 985 (9th Cir. 1992); Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987).
FDA had erred in reading a *de minimis* policy into the color additives Delaney Clause. The court found that the agency had correctly characterized the risks posed by the dyes at issue as trivial, and that “if the statute were to permit a *de minimis* exception, this would appear to be a case for its application.”\(^9\) 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.”\(^1\)

Here, however, the court held that it could not agree that the Delaney Clause allowed for a *de minimis* interpretation. 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.\(^2\) In *Les v. Reilly*, in 1992, the Ninth Circuit extended the D.C. Circuit’s interpretation to food additives, and overturned EPA regulations allowing pesticides with a trivial carcinogenic risk to be used as food additives.\(^3\)

The D.C. and Ninth Circuit’s refusals to defer to 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.\(^4\) There are several statutory exceptions to the Delaney clause,\(^5\) and there had been several recent

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\(^9\) Id. at 1112. The lifetime cancer risk for Orange No. 17 was calculated at one in 19 billion, and the lifetime cancer risk for Red No. 19 as one in nine million. Id. at 1111.

\(^1\) 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 1112-1113. 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.

\(^2\) Id. at 1113-1117.

\(^3\) 968 F.2d 985.


\(^5\) These exceptions include the “DES exception” and the saccharin exception. In 1962, Congress amended the Delaney Clause to make it inapplicable to DES, a synthetic estrogen that aids in livestock growth. See 21 U.S.C. § 360b(d)(1)(H); Hess & Clark, Division of Rhodia, Inc. v. FDA, 495 F.2d 975, 979 (1974). 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 seven times, through 2001. See Richard A. Merrill, *FDA’s Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?* 5 YALE J. ON REG. 1, 5 (1988). Doubts as to saccharin’s carcinogenicity began to arise in the 1990s. PETER BARTON HUTT, RICHARD A. MERRILL,
judicial decisions encouraging discretion in defining “food additive.” Moreover, the courts recognized that there was 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). In addition, the D.C. Circuit itself had, previously, established what almost amounted to a presumption in favor of construing statutes to have de minimis clauses. 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 even in the absence of any of the signals described above. The most famous of these cases is Industrial Union Dept., AFL-CIO v. American Petroleum Institute, the “Benzene Case,” which is noteworthy for its particularly interventionist and non-deferential 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, and argued with the agency’s interpretation of the scientific data it had collected. Here, there was

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LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 1163 n.3 (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. Id.

105 See Monsanto Co. v. Kennedy, 613 F.2d 947, 953-54 (D.C. Cir. 1979) (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.”); Scott v. FDA, 728, F.2d 322, 323 (6th Cir. 1984) (affirming FDA’s approval of a color additive containing a carcinogenic constituent).


107 Public Citizen v. Young, 831 F.2d at 1113.


109 Id. at 642 (stating that before regulating, OSHA must find that “the workplaces in question are not safe. But ‘safe’ is not the equivalent of ‘risk-free.’”).

110 Id. at 634 (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
neither a “clear” statutory command to which the Court could point (the
OSH Act was ambiguous on the question presented), nor was there intra-
age agency disagreement. The Court’s lack of deference to the agency has
received much criticism,\textsuperscript{111} as has the plurality’s misguided attempt
to buttress its conclusions with justifications based on risk assessment. For
example, Justice Stevens “neglected to mention the extent of exposure to
the risk-producing activity, one of the most elementary concepts of risk
assessment,”\textsuperscript{112} “[t]he opinion effectively equated uncertain risk with
insignificant risk,” and the burden-shifting undertaken by the plurality may
have been based on an imperfect reading of the APA.\textsuperscript{113}

\textbf{B. \textit{The Quantification of Increased Risk of Harm for
the Purpose of Article III Standing}}

Agencies quantify risk for the purpose of crafting regulations that
are protective of public health and safety while not stifling to economic
growth. 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. 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 quantitative risk
assessment is a measurable, coherent, structured analysis that demonstrates
to a court that an agency is doing its job.

These qualities—objectivity, expertise bridging, and authority

\textsuperscript{111} See Meazell, supra note __, at 163 (collecting some criticism of the case); Thomas
O. McGarity, \textit{The Story of the Benzene Case: Judicially Imposed Regulatory Reform
through Risk Assessment}, in \textit{ENVIRONMENTAL LAW STORIES} 142, 165 (Richard J. Lazarus
& Oliver A. Houck eds., 2005) (noting a deferential approach emphasizing § 6(b)(5), as
OSHA had done, “would have avoided the embarrassment of a judicially created and
incoherently defined concept of ‘significant risk.’ ”).

\textsuperscript{112} McGarity at 164; see also John D. Graham, Laura C. Green, & Marc J.
ambiguity of ‘significant risk’ in the plurality opinion may reflect the twin evils of
ignorance and opportunism.”).

\textsuperscript{113} Howard A. Latin, \textit{The Feasibility of Occupational Health Standards: An Essay on
explains that the APA imposes the burden of proof on the proponent of a rule except “as
otherwise provided by statute,” and he questions whether the OSH Act implicitly shifts the
burden. \textit{Id}. 

reinforcement—transform risk from amorphous and subjective to measurable and objective. It is for this reason that certain courts require risk to 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 sought.\textsuperscript{114} These are threshold requirements. Whether or not the person prevails is a different matter than whether or not that person can bring their suit in federal court.\textsuperscript{115}

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.\textsuperscript{116} 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.”\textsuperscript{117}

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.”\textsuperscript{118} Probabilistic injury is based on the idea that a plaintiff is at increased risk of harm due to defendant’s actions, and that this increased risk constitutes a harm in and of itself.\textsuperscript{119} In reality, these two

\begin{itemize}
\item \textsuperscript{114} Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).
\item \textsuperscript{115} Amnesty Intern. USA v. Clapper, 638 F.3d 118, 131 (2d Cir. 2011).
\item \textsuperscript{116} And in fact, if a plaintiff waits until the harm has actually taken place before bringing suit, she may run into a statute of limitations problem. See, e.g., Ayers v. Township of Jackson, 525 A.2d 287, 297 (N.J. 1987).
\item \textsuperscript{117} Brandt v. Village of Winnetka, Ill., 612 F.3d 647, 649 (7th Cir. 2010).
\item \textsuperscript{119} Claire Finkelstein argues for the Risk Harm Thesis, which “suggests that exposing someone to a risk of harm itself harms him,” in Is Risk a Harm, 151 U. Pa. L. Rev. 963 (2003). She argues that “exposure to risk is a setback to a legitimate interest,” which is the definition of harm, and finds evidences that in certain cases the legal system supports this
\end{itemize}
categories of harm run together, although courts will balance the magnitude
of the harm against its probability of occurring in the probabilistic injury
case. In other words, the worse the injury, the less likely it need be to
suffice for injury-in-fact. In one probabilistic injury case, plaintiffs
alleged that the forest in which they recreated was at increased risk of a
catastrophic wildfire because of a governmental policy. The D.C. 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.”
Cases involving medical claims may also be brought based on probabilistic
injury.

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.” It is as a result of these concerns that the D.C. Circuit requires
plaintiffs to quantify their increased risk as a prerequisite to obtaining
standing. Other courts, however, do not require quantification. This Part
discusses the differing approaches of two circuits, the Second and the D.C.,
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.

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112 Baur, 352 F.3d at 687.
111 Mountain States Legal Foundation v. Glickman, 92 F.3d 1228, 1234 (D.C. Cir.
1996). See also LaFleur v. Whitman, 300 F.3d 256, 270 (2d Cir. 2002) (citizen had
standing to challenge the construction of a fuel producing facility based on the possibility
that the construction of the facility to cause the air that she breathed to contain more
pollutants).
112 See Baur, 352 F.3d at 641 (“[T]he 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.”); see also
113 Public Citizen, Inc. v. National Highway Traffic Safety Admin., 489 F.3d 1279,
1295 (D.C. Cir. 2007).
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 the contexts of food and drug safety, fraudulent tax advice, and government surveillance. 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.”

In *Baur v. Veneman*, which is the Second Circuit’s “principal ‘probabilistic injury’ case,” the court overturned the district court’s denial of standing to the plaintiff, Michael Baur. Baur had sued the Department of Agriculture to reverse its policy allowing downed cattle into the food supply. 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. 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 downed cattle policy. 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.

The Second Circuit reversed, 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” to

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124 Baur v. Veneman, 352 F.3d 625
125 Denney v. Deutsche Bank AG, 443 F.3d 253, 264-65 (2d Cir. 2006) (“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”).
126 Amnesty Intern., 638 F.3d at 134. District courts within the Second Circuit have also allowed increased risk of harm to satisfy the injury-in-fact requirement in cases based on the threat of future identity theft, and the defendant’s failure to secure plaintiff prisoner’s wheelchair properly when he was being transported. *Caudle v. Towers, Perrin, Forster & Crosby*, 2008 WL 4104035, at *5 (S.D.N.Y. 2008); *Shariff v. Goord*, 2006 U.S. Dist. LEXIS 49957, at *10, 20 (W.D.N.Y. 2006).
127 Amnesty Intern., 638 F.3d at 133.
129 352 F.3d at 628.
130 Id. at 628.
131 Id. at 628-629.
132 Id. at 628.
satisfy the Article III requirements.\textsuperscript{133} The court held that, like 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 Food, Drug, and Cosmetic Act, was to protect consumers from the very type of injury that Baur alleged.\textsuperscript{134}

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 factors a court should look to when determining an increased-risk-of-harm standing question.\textsuperscript{135} Notably, however, the court made no attempt to quantify the increase in risk faced by Baur, nor has it required quantification in later probabilistic injury cases. In \textit{Denney v. Deutsche Bank AG}, 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. 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.\textsuperscript{136} Although an audit, and the potential tax penalties which were the ultimate harm feared, were not “certainly impending,” the plaintiffs were subject to an increased risk that this chain of events would take place.

And in \textit{Amnesty International USA v. Clapper}, 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.”\textsuperscript{137} 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.\textsuperscript{138} Nor did the dissent

\textsuperscript{133} \textit{Id.} at 634-635. Here the court assumes that risk itself is a cognizable harm, which is, of course, not entirely uncontroversial. See Finkelstein, \textit{Is Risk a Harm}, supra note __. The Federal Meat Inspection Act and the Federal Food, Drug, and Cosmetic Act protect against the disease that Baur feared, not the increased risk thereof.

\textsuperscript{134} \textit{Id.} at 634-635. Here the court assumes that risk itself is a cognizable harm, which is, of course, not entirely uncontroversial. See Finkelstein, \textit{Is Risk a Harm}, supra note __.

\textsuperscript{135} \textit{Amnesty Intern. USA v. Clapper}, 2011 WL 4381737, at *28 (Sept. 28, 2011) (Livingston, J., dissent from denial of rehearing en banc). Judge Livingston here criticizes the majority opinion in this case as ignoring these important factors, and dramatically expanding the category of probabilistic injuries that merit standing. \textit{Id.}

\textsuperscript{136} \texttextit{Amnesty Intern.,} 638 F.3d at 140.

\textsuperscript{137} \textit{Denney}, 443 F.3d at 265. The court also found that the future-risk plaintiffs had suffered injury-in-fact because they had taken action based on the fraudulent tax advice, including incurring costs in rectifying the mistakes that they had made.

\textsuperscript{138} \textit{Id.} at 138.
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. It focused instead on the fact that the conduct targeted by the plaintiffs was only feared, not impending.139

In all of these cases, the ultimate injury feared by the plaintiffs was uncertain. In Baur and Amnesty International, even the exposure to the harm-causing agent (mad cow disease, government surveillance) was uncertain. Nevertheless, the imminence of the exposure—not that of the injury—was found to satisfy the requirements of injury-in-fact.140 And, in none of these cases did the court seek quantification of this increased risk.

2. The D.C. Circuit and increased risk of harm claims

The D.C. Circuit takes a stricter approach to increased risk of harm claims. When a petitioner seeks review of governmental action in the D.C. Circuit, he must “support ‘by affidavit or other evidence’ each of the three elements of Article III standing.”141 Under narrow circumstances, the court has allowed increased-risk-of-harm claims to satisfy the injury-in-fact requirement. 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.’ ”142

The court is wary of increased-risk-of-harm claims, fearing that to allow 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-constititutional 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.”143 The court has not categorically precluded such claims,144 but

139 Amnesty Intern., 2011 WL 4381737, at *28 (Livingston, J., dissent from denial of rehearing en banc).
140 Baur, 352 F.3d at 641.
143 Id. (citation omitted).
144 At least one Judge on the Circuit believes that such claims should be categorically denied, however. Then Judge, now Chief Judge David B. Sentelle wrote in 2008 that there is an “ill fit between judicial power and that sort of future event and possible harm. The
requires that the increase in risk be quantified.

In Public Citizen, Inc. v. National Highway Traffic Safety Administration, 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 under inflated.\textsuperscript{145} 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 otherwise would be prevented if NHTSA were to adopt Public Citizen's proposals.”\textsuperscript{146}

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.\textsuperscript{147} 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.\textsuperscript{148}

After briefing, the court dismissed Public Citizen’s petition, finding that the organization had failed to establish standing. 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. Public Citizen challenged three aspects of the safety standard. First, it challenged the failure of the warning system to work with replacement tires, and its statistician quantified the difference in risk of injury between a system that worked with replacement tires, and one that did not, like

\textsuperscript{145} Public Citizen, Inc., 513 F.3d at 236. In 2000, Congress passed the Transportation Recall Enhancement, Accountability, and Documentation Act to address vehicle accidents caused by tire blowouts. The Act required the NHTSA to promulgate a regulation requiring new vehicles to warn operators when tires were significantly under inflated. \textit{Id.} at 235.

\textsuperscript{146} \textit{Id.} at 237 (citation omitted).

\textsuperscript{147} \textit{Id.} at 238.

\textsuperscript{148} \textit{Id.}
NHTSA’s. 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 and with the same system, but one that included the publication of a list of the tires that the system did work with. This latter alternative had been proposed by Public Citizen at an earlier point in the litigation, 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.”

Second, Public Citizen challenged the twenty-minute lag time between under-inflation of tires and the activation of a warning light. 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.”

And third, Public Citizen challenged the warning light’s trigger at 25% under-inflation. The court, however, found the organization’s calculations to be flawed and unreliable. Finding none of Public Citizen’s calculations of increased risk to be acceptable, the court dismissed the petition.

In this case, the court signals its distaste for the probabilistic-injury doctrine as a basis for Article III standing, commenting that “[i]f 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.’” The court also indicated its dislike of the concept by agreeing with petitioner regarding the difficulty of quantification, yet still requiring quantification.

Public Citizen, as the D.C. Circuit’s most recent probabilistic-injury case, shows the court’s “increasingly negative view of probabilistic injury.” Moreover, the court has mandated the quantification of

149 Id. at 239.
150 Id. (citing Public Citizen’s briefs).
151 Id. 240-41.
152 Id. at 241.
153 Id. (citation omitted).
154 Id. at 240.
155 Sturkie at 10462. The D.C. Circuit also expressed unease with the probabilistic injury concept in Virginia State Corp. Com'n v. F.E.R.C., 468 F.3d 845, 848 (D.C. Cir. 2006) (“Reliance on standing in the form of probabilistic injury-here, an increase in the
increased risk, and “has made abundantly clear that it expects to see quantitative risk assessments in appropriate cases,” but has itself expressed ambivalence about the adequacy of this method in the assessment of whether probabilistic injury constitutes injury-in-fact.

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.” 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 to address the anticipated harm itself. 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.

It is important to note two things about these cases at the outset. First, exposure is certain. Plaintiffs in these cases have unquestionably 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 cases such as Baur, where the petitioner challenged USDA policy. Although Baur was certainly exposed to the faulty governmental policy that he challenged, his exposure to the foodborne 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. It was uncertain whether the organization’s members would actually be exposed to the feared risk—the under-inflation of tires without the activation of a warning light—and it was also uncertain what the resulting injury might be.

Second, medical monitoring is the remedy to an underlying tort.

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.”). See Sturkie at 10463.

156 See, e.g. Virginia State Corp., 468 F.3d at 848.
157 Sturkie at 10471.
158 Public Citizen, 513 F.3d at 240.
161 Id.
162 Id. at 572 (“medical monitoring is more properly considered one of a number of
and this type of claim is located in federal court in the context of a diversity action. 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.

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. 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.” Courts are reluctant to recognize enhanced risk claims based on unquantified injury, and many require that future injury be “reasonably certain.” In contrast, a claim for medical-monitoring expenses is different than a claim for enhanced risk: “It 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.”

In Sutton v. St. Jude Medical S.C., Inc., 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. Sutton, and the class of people for whom he sued, had not yet suffered injury from the allegedly defective device, and they sought medical possible remedies to an underlying tort, rather than a separately actionable tort”).

Id. at 569.

Id. at 572 n.3 (“plaintiffs 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 Telectronics Pacing Sys., Inc., 168 F.R.D. 203 (S.D. Ohio 1996)).

Ayers, 525 A.2d at 304.

Id. at 306.

Id. at 308. In Ayers, residents brought a nuisance action against their town after toxic pollutants from a landfill contaminated their water. A jury found for plaintiffs and awarded the cost of future medical surveillance, among other awards. The New Jersey Supreme Court affirmed the award for medical monitoring based on enhanced risk, while affirming 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 298-299. 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.

Sutton, 419 F.3d at 569.
monitoring for future harm. 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.”

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. 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.

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.” The court pointed to another such case with an increased risk of harm requiring medical monitoring, in which a district court in Minnesota implicitly found standing for “plaintiffs requesting medical monitoring for side effects from implanted heart valves.” In that case, the plaintiffs were able to show that they had a 700% increase in risk because of the implanted heart valves. Nevertheless, the Sixth Circuit found such a showing to be unnecessary, and that the inquiry conflated the threshold determination of standing with the merits of the case.

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 these claims and are divided as to the standing

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169 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. The Sixth Circuit declined to reach the issue, as it had not been reached by the district court. The Sixth Circuit did, however, opine that such claims were proper under Tennessee law. Id. at 575-576, 576 n. 7.

170 Id. at 571.

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

172 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.

173 Id. at 575.

174 Id. at 573. The finding was implicit because the court ruled on the merits, not discussing standing.

175 Id. at 575.

176 Id.
of plaintiffs unable to show present injury.

In *Krottner v. Starbucks Corporation*, three employees of Starbucks sued the company after a laptop containing their unencrypted personal information was stolen from one of the company’s stores. 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.

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. 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.” 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.

In *Reilly v. Ceridian Corporation*, the Third Circuit, in contrast to the Ninth, refused to grant standing to plaintiffs who alleged that they were at increased risk of identity theft after the security breach of a payroll-processing firm that had their personal information. The court held that plaintiffs’ “allegations of hypothetical, future injury” were not adequate to satisfy the Article III requirements. The court surveyed other courts’ rulings in the same context, and, citing to two district court cases, concluded that most had denied standing. 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*.

The court, however, also criticized the reasoning of the Ninth and

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177 628 F.3d 1139 (9th Cir. 2010).
178 Id. at 1141.
179 Id. at 1143.
180 Id.
181 Id. The Sixth Circuit had commented in a similar case that “the risk of future identity theft was ‘somewhat hypothetical and conjectural.’ ” See Lambert v. Hartman, 517 F.3d 433, 437 (6th Cir. 2008).
182 2011 WL 6144191 (3d Cir. 2011).
183 Id. at *4.
184 Id. at *4-*.5.
Seventh Circuits, calling their rationale “skimpy.” Disagreeing with those circuits’ analogizing of data-security-breach cases to defective medical device cases and toxic substances cases, the court pointed out two differences: First, in the latter types of cases there had certainly been an injury, although the manifestation of the injury was uncertain, whereas in the data-security-breach cases there was no injury if there was no misuse of data. And second, there is a difference between cases dealing with human health and the environment and those that do not. The court commented that “[c]ourts resist strictly applying the ‘actual injury’ test when the future harm involves human suffering or premature death,” 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-security-breach cases. For these reasons, the Third Circuit held data-security-breach cases separate from toxic substance or faulty medical device exposure cases.

In the data-security-breach cases we see a circuit divide, between courts that are willing to allow standing for plaintiffs with an increased risk of identity theft, and those that are not. None of the courts attempt to quantify the increase in risk faced by the victims of the data-security breach. At first blush, it seems impossible to quantify a data security breach’s victim’s increase in risk. 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 further consideration, 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.

II. THE PROS AND CONS OF QUANTIFYING RISK

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185 Id. at *5.
186 Id. at *6. 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 is uncertain and the court must determine whether to allow a claim for compensation for the enhanced risk.
187 Id.
188 Id. at *6. This ignores the longstanding and extensive repercussions of identity theft, such as damage to one’s credit, which monetary compensation may not remedy.
The previous Part described two scenarios where 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. Second, certain courts require that increased risk of harm be quantified before allowing probabilistic injury to satisfy the Article III standing requirements. 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 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, thereby endorsing both the agency’s science and underlying 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 objectiveness 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 decisionmaking process, and some courts require risk to be measured quantitatively to satisfy Article III standing requirements. 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 allows a court 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 apparent when Congress sets a numerical goal that an agency must reach or explain its failure to do so. For example, EPA is responsible for determining tolerance levels for pesticide residues on food products, as regulated by the FDCA. The Food Quality Protection Act (FQPA), passed in 1996, requires that 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 reason, EPA must use “an additional tenfold margin of safety.” 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.”

In *Natural Resources Defense Council* v. EPA, NRDC appealed EPA’s denial of its petition seeking the revocation of EPA’s tolerance of dichlorvos, an insecticide. EPA had applied a threefold safety factor in its risk assessments, not the tenfold factor mandated by statute. The agency argued that “a 3X safety factor was ‘more than adequate’ because of ‘the slight adverse effect observed . . .’” The Second Circuit found that 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,” which was the statutory mandate, and found this failure to be arbitrary and capricious under the

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189 21 U.S.C. § 346a(a)-(c).
191 *Id.*
192 *Id.* at *14.
The court therefore vacated the parts of EPA’s order that assessed the risk of dichlorvos using the threefold safety factor.

The court here was able to determine that 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. 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 EPA has faced during its four-year implementation [of the FQPA] effort.” Indeed, the 10X factor was the product more of policy than scientific judgments, and was resisted to a certain extent by EPA itself. Nevertheless, in NRDC v. EPA, we see that the 10X 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. The safety of infants and children was a primary driver behind the passage of the FQPA.

**AFL-CIO v. OSHA**, 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 assessing whether the agency has complied with its statutory mandate. In this case, multiple parties challenged OSHA’s promulgation of an air-contaminant standard that set permissible exposures to various toxic substances. The court, finding that the agency had adequately quantified neither 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, vacated the standard and remanded it to the agency.

Although the agency need not calculate “the exact probability of harm,” the court in AFL-CIO concluded that the agency needed to provide some quantification of risk for each substance regulated. The court

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195 NRDC v. EPA, at *17.
196 Id. at *18.
198 Id. at 148-151.
199 Id. at 113; NRDC v. EPA, at *2.
200 American Federation of Labor and Congress of Indus. Organizations v. Occupational Safety and Health Administration, 965 F.2d 962 (11th Cir. 1992).
201 Id. at 968, 975-976.
202 The Benzene Case, 448 U.S. at 655.
followed the holding of the Benzene case,\footnote{Discussed supra at pg. __.} 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.’ ”\footnote{Id. at 972 (citing to the Benzene case, 448 U.S. at 614-615).} 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.”\footnote{AFL-CIO v. OSHA, 965 F.2d at 975.}

What we see in both \textit{NRDC v. EPA} and \textit{AFL-CIO v. OSHA}, therefore, is the judiciary’s reliance on quantification as an objective measure to assess whether the agency has complied with its statutory mandate. In \textit{NRDC}, Congress had set forth a quantitative measure to be followed by the agency, and in \textit{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 decisionmaking and this deference tends to be stronger in areas of scientific evaluation and technical expertise.\footnote{See supra, pg. __; Meazell, Super Deference, 109 Mich. L. Rev. at 734; Miami-Dade County 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.”).} 

Quantification helps to bridge this expertise gap between agency decisionmakers and the judiciary by signaling that the agency has actually given a hard look to the evidence in front of it. Although a quantitative risk assessment involves much technical information, its steps are structured and clear. Even without a thorough understanding of the science involved, a generalist can grasp whether the steps have been followed and whether the information flows logically. We saw this in \textit{AFL-CIO v. OSHA}, where the court explained that it needed some quantification of risk to be able to assess whether the agency had done its job.\footnote{AFL-CIO v. OSHA, 965 F.2d at 975.}
On the other hand, quantification also makes the expertise gap more manifest. A court, when confronted with a quantitative risk assessment, may be reminded of its own generalist background, and acknowledge the futility of anything but deferential review. In *Asbestos Information Association* v. *OSHA*, OSHA promulgated an emergency temporary standard for asbestos fibers, which, because of its emergency posture, did not go through ordinary notice and comment procedures. 208 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. 209 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.” 210 Because of the complexity of a record “that would tax the competency of any court,” the Fifth Circuit 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].” 211 Quantification, by clearly marking the expertise gap, therefore enables courts to stay within their appropriate role by forcing deference. 212

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 it is actual and imminent to the plaintiff herself at the very least. 213

### 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 non-

208 727 F.2d 415, 417 (5th Cir. 1984).
209 *Id.* at 418.
210 *Id.* at 421.
211 *Id.* See also Simpson v. Young, 854 F.2d 1429, 1434 (D.C. Cir. 1988) (“A re-weighing by this court of the mass of scientific evidence presented to the FDA would not only be inappropriate as a matter of law, but impossible as a practical matter.”).
212 *See* infra., Part ___; American Cyanamid Co. v. Food and Drug Administration, 606 F.2d 1307, 1319 n. 117 (D.C. Cir. 1979).
213 Cf. William A. Fletcher. The Structure of Standing, 98 Yale L. J. 221, 231 (1988) (“If we put to one side people who lie about their states of mind, we should concede that anyone who claims to be injured is, in fact, injured if she can prove the allegations of her complaint. If this is so, there can be no practical significance to the Court’s ‘injury in fact’ test because all people sincerely claiming injury automatically satisfy it.”).
specialized audience to simplify and to categorize risk. In *Asbestos Information Association*, the court 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. The loss of these eighty lives constituted a “grave danger” such that the agency could issue an emergency standard, 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.” The agency’s quantification of the immediate risk faced by workers made the abstract into the concrete, 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.” The quantification of risk adds to this function, permitting the public access to the end product of an agency’s decision-making process.

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. Probabilistic harm raises the specter of activist judges making law. Recall,

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214 *See* Stephen Breyer, *Breaking the Vicious Circle – Toward Effective Risk Regulation* (Harvard University Press 1993) 35. Justice Breyer explains that the public uses heuristic devices, or rules of thumb, to understand risk—which understanding is not always based on rational bases. Justice Breyer also points to the difficulty that the average layperson has in understanding the mathematical probability of risk. *Id.* at 36. 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.

215 *Asbestos Info. Assoc.*, 727 F.2d at 425.

216 *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). OSHA is required to act on a temporary rule within six months, hence OSHA’s eighty lives over six months calculation.

217 *Id.* at 425 (citing the Benzene case, 448 U.S. at 656 n. 62).

218 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.*

219 Meazell, Super Deference, at 778.
for example, Judge Sentelle of the D.S. 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,” and his admonition that “[i]f we do not soon abandon this idea of probabilistic harm, we will find ourselves looking more and more like legislatures rather than courts.”

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 affirmation if a rational basis exists for the agency's decision,” with “a ‘substantial inquiry’ into the facts, one that is ‘searching and careful.’” 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.

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, and its complexity makes deference acceptable, or even necessary.

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220 Public Citizen, 513 F.3d at 242 (Sentelle, J. concur) (citing Public Citizen, 489 F.3d 1279, 1295 (D.C. Cir. 2007) (quoting DaimlerChrysler v. Cuno, 547 U.S. 332 (2006)).
221 Id.
223 AFL-CIO v. OSHA, 965 F.2d 962, 975 (11th Cir. 1992) (citing the Benzene case, 448 U.S. at 655).
224 See Public Citizen Health Research Group 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. Public Citizen argued that OSHA had underregulated Cr(VI). A separate petitioner, the Edison Electric Institute (“EEI”), 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. The court denied both petitions. *Id.* at 169.
225 See Asbestos Info. Assoc. v. OSHA, 727 F.2d 415, 421 (5th Cir. 1984).
B. The Detriments of Quantifying Risk

Although the quantification of risk is certainly useful to courts, and some of its perceived benefits are real, it 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 a 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.” This legislation allows for a certain measure of uncertainty in any decision to regulate. 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 for benzene, disagreeing with OSHA’s interpretation of its guiding statute, the Occupational Safety and Health Act of 1970. The OSH Act has two provisions regarding health and safety standards. The general safety standard, § 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

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227 See, e.g. the Benzene case, 448 U.S. at 692-693 (Marshall, J., dissent) (the OSH Act was designed to allow OSHA to regulate toxic substances in the face of scientific uncertainty: “Recognizing that existing knowledge may be inadequate, Congress did not require the Secretary to wait until definitive information could be obtained.”

228 The Benzene Case, 448 U.S. 607, 613 (1980).
employment.” However, standards dealing with toxic materials or harmful physical agents are also subject to § 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.”

When dealing with a carcinogen, OSHA interpreted § 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. Contrary to OSHA’s interpretation of the statute, Justice Stevens, writing for a plurality, found that § 3(8) required a threshold determination of significant risk to health before § 6(b)(5) kicked in, even in regards to toxic substances. In regards to benzene, OSHA had not shown that such a significant risk existed at the previous standard.

The four-Justice dissent disagrees 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.’” 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 impossible to determine.” 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.”

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230 § 655(b)(5).
231 448 U.S. at 613.
232 Id. at 639-40.
233 Id. at 614-15.
234 Id. at 692 (Marshall, J., dissent) (citing Congressional record).
235 Id. at 704-705.
236 Id. at 712. See also D.D. Bean & Sons Co. v. Consumer Product Safety Commission, 574 F.2d 643, 650-651 (1st Cir. 1978). In D.D. Bean & Sons Co., the First Circuit set aside parts of a CPSC rule regarding the manufacture of matchbooks. The court held that the agency had not put forward sufficient evidence “substantiating any degree of
Courts have interpreted “significant risk” to require a certain measure of quantification.\textsuperscript{237} 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.\textsuperscript{238} 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,”\textsuperscript{239} 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.\textsuperscript{240}

2. Forcing the quantification of risk may elide the influence of policy determinations and the impact of uncertainty in agency decisions.

Every quantitative risk assessment is the product not only of scientific determinations, but also of numerous unstated policy judgments.\textsuperscript{241} The attempt to assess the risk of any particular hazard is riddled with uncertainty,\textsuperscript{242} resulting from gaps in our scientific knowledge. For example, in regards 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.”\textsuperscript{243}

Using the quantification of risk as shorthand for the reasonableness of agency action and as a proxy for adequate explanation can have the effect risk,” involved in the current design of matchbooks, even though common sense indicated that such hazard was present.

\textsuperscript{237} See, e.g. AFL-CIO v. OSHA, 965 F.2d at 975.

\textsuperscript{238} See also Howard A. Latin, Significance of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty, 10 Ecol. L.Q. 339, 341 (1982).

\textsuperscript{239} McGarity, supra note 44, at 164; see also John D. Graham, Laura C. Green, & Marc J. Roberts, In Search of Safety – Chemicals and Cancer Risk 113 (1988) (“The ambiguity of ‘significant risk’ in the plurality opinion may reflect the twin evils of ignorance and opportunism.”).

\textsuperscript{240} Howard A. Latin, The Feasibility of Occupational Health Standards: An Essay on Legal Decisionmaking Under Uncertainty, 78 NW. U. L. REV. 583, 589-90 (1983). Latin explains that the APA imposes the burden of proof on the proponent of a rule except “as otherwise provided by statute,” and he questions whether the OSH Act implicitly shifts the burden. Id.

\textsuperscript{241} See supra, pg. __; Wagner, The Science Charade, at 1623.


\textsuperscript{243} Rosenthal et al., supra note __, at 279.
of erasing the influence of policy on agency decisionmaking 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 of which steps incorporate policy judgments. Judicial review and increased deference to these QRAs because of their technical complexity reifies these policy determinations into scientific truths.

For example, in *City of Waukesha v. EPA*, the D.C. Circuit upheld a rule promulgated by the EPA under the Safe Water Drinking Act regarding the levels of radionuclides in public water systems. The petitioners challenged the merits of the rule, among other things, arguing that EPA did not use the “best available science,” as it was required to do. 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.”

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 brushed into their mouths to sharpen the tips.” Although EPA had used this data a decade earlier in promulgating radionuclide standards, petitioners charged that the agency impermissibly ignored this data here. Instead, the agency relied on “alternative epidemiological data from studies of Hiroshima and Nagasaki atomic bomb survivors.”

The court, after painstakingly listing a summary of the data relied upon, concluded that EPA had adequately explained its rejection of the

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244 Wagner, at 1618.
245 Agencies are of course aware of this increased deference. In her famous piece, The Science Charade, Wendy Wagner argues that “agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions.” Wagner, at 1617.
246 320 F.3d 228 (D.C. Cir. 2003).
247 *Id.* at 231.
249 *Id.* at 247.
250 *Id.* at 248.
The court deferred to 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.” In other words, the structure dictated the outcome. Because EPA properly adhered to the risk-assessment model, its choices were impervious to challenge. Elided here is any possible notion of policy 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. “Court decisions automatically generate legal precedents and legal rules,” and this can lead to arbitrary and imperfect regulatory outcomes.

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. In other words, it is a threshold determination, to be adjudicated before a court can entertain the merits of the plaintiff’s claim. Moreover, a plaintiff need not be able to prove the

251 Id. at 248-249.
252 Id. at 248 (citing National Wildlife Federation v. EPA, 286 F.3d 554, 565 (D.C. Cir. 2002)).
253 See, e.g. Scott v. FDA, 728 F.2d 322 (6th Cir. 1984) (Sixth Circuit affirmed 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) (court ruled on whether EPA could base a standard on a particular technical standard).
254 Breyer, Vicious Circle 58 (“A legal rule that flows from a court decision . . . may also lead the agency to turn to other, less fair, more complicated ways to achieve its objectives.”).
257 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
merits of her claim at this stage. 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.\textsuperscript{258}

Requiring that a plaintiff quantify her increased risk for the purpose of satisfying the standing requirements may force the plaintiff to try, prematurely, to prove the merits of her case.\textsuperscript{259} 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.”\textsuperscript{260} This is exactly, however, what a plaintiff is forced to do if required to quantify his increased risk at the pleading stage.\textsuperscript{261} 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 \textit{sua sponte} at the summary judgment stage, then the plaintiff may be required to show her 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.”\textsuperscript{262}

One thing to keep in mind when discussing the quantity of evidence in the proceedings, and can be raised \textit{sua sponte} by the court. Chermerinsky 61. However, standing is most often adjudicated at the outset of a lawsuit, in the motion to dismiss phase.\textsuperscript{258} Warth v. Seldin, 422 U.S. at 498; Fed. R. Civ. Pro. 26.

\textsuperscript{259} See Sutton v. St. Jude, 419 F.3d at 575 (requiring a plaintiff to quantify her increased risk of harm to show injury-in-fact “is to prematurely evaluate the merits of her claims”).

\textsuperscript{260} Baur v. Veneman, 352 F.3d 625, 642 (2d Cir. 2003) (citing to Bennett v. Spear, 520 U.S. 154, 168 (1997) (noting that at the pleading stage, standing will be upheld where a plaintiff provides some support for his claim of standing and it is possible to “presume facts under which [the plaintiff] will be injured”).

\textsuperscript{261} 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, see, \textit{e.g.} Ayers v. Township 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), the positing of increased risk as an injury-in-fact, allowing a plaintiff access to the judicial system, is a different matter.

\textsuperscript{262} Baur, 352 F.3d at 642. The \textit{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.”).
needed to show standing at the pleading stage is that the effects of *Bell Atlantic v. Twombly* and *Ashcroft v. Iqbal*—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.’” 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.”

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. However, it is certainly possible that courts will begin to require more evidence from plaintiffs alleging increased risk of harm as a basis for injury-in-fact, including the quantification of the increased risk.

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 quantitative risk assessment and injury-in-fact contexts, involves complex scientific and highly technical analysis. This analysis is appealing to courts for various reasons, discussed above.

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 v. EPA*, the court spends approximately 6000 words of its opinion on the merits of the EPA standards for radionuclides in public water systems. It is clear that the court has thoroughly and extensively engaged with the record. The upshot of this comprehensive review, however, was to uphold the standards both in

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264 *Id.*


266 320 F.3d 228, 247-258 (D.C. Cir. 2003).
false certainty: judicial forcing of the quantification of risk
deferecne to the EPA’s rational choice of scientific models, and because
the EPA’s decision was not arbitrary and capricious.  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.

Moreover, the quantification of risk may skew agency priorities to
address more 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.
Increasing the “amount of evidence required for the agency to justify a
standard,” “ensured that fewer standards would be promulgated.”

5. Forcing the quantification of risk may actually mislead the public.

267 Id. at 248.
268 Id. at 257.
269 See Sierra Club v. Costle, 457 F.2d 298, 410 (D.C. Cir. 1981).  In this 150 page
decision regarding standards promulgated by the EPA under the Clean Air Act, the court
wrote the following:

“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 modeles, 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.”

When an agency quantifies risk and a court affirms this calculation, the end result is communicated to the public as a certainty, concealing the considerable uncertainty and subjective decisionmaking constituting this outcome. “Most people have considerable difficulty understanding the mathematical probabilities involved in assessing risk,” 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 cancer risk—EPA, FDA, OSHA, and CPSC—uses default assumptions to grapple with the uncertainties faced in carcinogenic risk assessment. Default assumptions are not standardized across agencies. These inter-agency inconsistencies have been repeatedly documented, and criticized, by governmental entities since the 1970s. Notwithstanding these inconsistencies, however, agency conclusions are communicated to the public as certainties.

For example, the FDA calculated acceptable levels of contaminants in Gulf Coast seafood after a massive oil spill in 2010. The Natural Resources Defense Council challenged these calculations, asserting that FDA relied on outdated science, and filed a petition with the agency requesting that the standard be changed. One of NRDC’s arguments was that EPA, as well as some officials within FDA, called for stricter standards. If FDA denies NRDC’s petition, NRDC can bring suit in federal court to challenge the denial. A court would review FDA’s risk assessment with its customary deference, and whether or not FDA’s calculations were correct, an affirmation of them as reasonably considered would enshrine these standards as correct. The uncertainty noted by NRDC would remain for members of the affected public to negotiate individually.

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

271 Breyer, Vicious Circle 35-36.
272 See supra, p. ___.
273 See supra., pg. ___.
275 Id.
276 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, at ___.B
Judicial review over 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, 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.”

Judicial forcing of the quantification of risk undermines these benefits. As mentioned above, forcing the quantification of risk may contradict legislative intention because the evidence required of agencies weakens the precautionary nature of the statutory mandates with which the agencies are charged with administering. The deferential review of highly technical determinations can also have the effect of undercutting legitimacy. The masking of policy judgments as scientific decisions leaves room for self-interested representation and political maneuvering.

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 courts seek an objective measure of when increased risk of harm constitutes an actual case or controversy, the quantification of risk puts courts in the business of deciding a threshold number – a point at which increased risk becomes unacceptable. This is (a) the province of the agencies, (b) a determination better left for the merits, and (c) just as shaky a foundation as the notion of probabilistic injury itself. The D.C. Circuit conceded as much in its refusal to actually reach the question of what amount of increased risk would constitute injury-in-fact.

III. 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? Surely the answer to the judicial review problem is not that courts should start reassessing the scientific evidence

278 Wagner, The Science Charade, The Science Charade, 95 Colum. L. Rev. at 1650-72.
279 Public Citizen, 513 F.3d at 240.
themselves—judges have neither the expertise to do so, nor the authority.\textsuperscript{280} Instead, this problem should be solved extrajudicially, by an independent advisory board created to review agency risk determinations. In the absence of such a board, however, courts should look for signals in the record indicating that a closer look 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.

Regarding increased risk of harm as a basis for injury-in-fact, it cannot be that any plaintiff alleging any conceivable increased risk of harm should be allowed into court. But the Second Circuit’s is the better rule. If a court accepts increased risk of harm as a basis for injury-in-fact in the relevant context—i.e. food and drug safety suits\textsuperscript{281}—than, 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 D.C. Circuit\textsuperscript{282} is avoidable through other justiciability doctrines. Injury-in-fact need not do all of the work.

\textbf{A. Improving the Judicial Review of Quantitative Risk Assessment}

1. The need for an independent scientific advisory board to review QRAs.

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.\textsuperscript{283} 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.”\textsuperscript{284} These characteristics, along with inter-agency 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.\textsuperscript{285}

Breyer explained that this body could develop through incremental change, perhaps even through changes in the structure of the Office of

\textsuperscript{280} 5 U.S.C. § 706; Chevron, 467 U.S. at 842-843.
\textsuperscript{281} See Baur v. Veneman, 353 F.3d 625, 634.
\textsuperscript{283} Stephen Breyer, Breaking the Vicious Circle 59-60 (1993).
\textsuperscript{284} Id. at 60, 62.
\textsuperscript{285} Id. at 60-61.
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Information and Regulatory Affairs, which, then and now, provides oversight over agency regulatory activity. Breyer noted that at the time he was writing, OIRA was focused on the cost effectiveness of regulation and lacked a core of scientific experts—which is still the case today—and he proposed to add health and science personnel, and give the agency an explicit mandate regarding the rationalization of risk regulation.

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 these QRAs. If this body were modeled after the EPA’s Scientific Advisory Board (SAB), which Breyer advocates, the relevant agency would have to heavily weight the board’s determinations and provide a written explanation in the event that it acted contrary to the CPAB’s recommendations. This additional layer of review would help

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286 Id. at 79; OIRA is “a centralized agency with command over the regulatory state.” Bagley and Revesz, at 1329.

287 In 2006, the Office of Management and Budget (OMB), OIRA’s umbrella organization, drafted a Risk Assessment Bulletin, laying out standardized guidelines for risk assessment by all agencies. Sidney A. Shapiro, OMB and the Politicization of Risk Assessment, 37 ENVTL. L. 1083, 1084 (2007). The purported goal of the Bulletin was “to enhance to technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards.” Curtis Copeland, The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking, 33 FORDHAM URB. L.J. 1257, 1301 (citing OFFICE OF MGMT. & BUDGET, PROPOSED RISK ASSESSMENT BULLETIN (2006), http://www.whitehouse.gov/omb/inforreg/proposed_risk_assessment_bulletin_010906.pdf.). In 2007, the National Research Council (NRC) of the National Academy of Sciences, which had reviewed the Bulletin, advised that OMB withdraw the Bulletin. The NRC had a problem with almost every line in the proposed bulletin. OMB withdrew the Bulletin. Shapiro, at 1085. 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.

288 Breyer, at 79.

289 According to its Charter, the SAB is a scientific/technical advisory committee which provides advice to EPA on: (a) “[t]he adequacy and scientific basis of any proposed criteria document, standard, limitation, or regulation under the [various statutes administered by EPA];” (b) “[t]he scientific and technical adequacy of Agency programs, guidelines, documents, methodologies, protocols, and tests;” (c) “[n]ew or revised scientific criteria or standards for protection of human health and the environment;” (d) “[n]ew information needs and the quality of Agency plans and programs for research, development and demonstration; and” (e) “[t]he relative importance of various natural and anthropogenic pollution sources.” EPA Science Advisory Board: Charter, U.S ENVIRONMENTAL PROTECTION AGENCY. http://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/currentcharter?OpenDocument (last visited Oct. 3, 2011).

290 Breyer, at 68.
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 . . .”291

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.292 These 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; OIRA’s time for review of regulations is also circumscribed.293
Moreover, it is probable that the time necessary for judicial review would
be shortened, in that 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 QRAs is not warranted.

The information contained in a quantitative risk assessment can be
impenetrable to non-scientists.294 Moreover, QRAs are highly structured.
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

291 Id. at 72.
292 Breyer addresses 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 it 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 (5) it is not practical—Breyer
argues that his suggestions can be implemented incrementally. Breyer, at 73-79.
294 See Sierra Club v. Costle, 457 F.2d at 410 (“We are not engineers, computer
modelers, economists or statisticians, although many of the documents in this record
require such expertise and more.”).
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 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 carefully considered. 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 v. EPA, the D.C. Circuit granted a petition for review of certain EPA air quality standards, and remanded the standards to the agency.\(^{295}\) In granting the petition, the court notes that (1) the Clean Air Scientific Advisory Committee (CASAC), an independent scientific review committee, disagreed with the air-quality level that EPA had set, and that (2) the EPA had changed its own position on the relevant studies to consider when setting standards.\(^{296}\) And in Natural Resources Defense Council v. EPA, the Second Circuit found inadequate EPA’s explanation of its noncompliance with the Food Quality Protection Act’s command to use an additional tenfold margin of safety.\(^{297}\)

In contrast, the court noted in American Trucking Associations, Inc. v. EPA, in upholding air quality standards promulgated by EPA, that agency staff’s recommendations were consistent with the agency’s final determination.\(^{298}\) And in Environmental Defense Fund, Inc. v. EPA, 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.”\(^{299}\) The court ultimately upheld the Administrator’s decision.

In sum, in the absence of a centralized review board for risk regulation, a court charged with reviewing a quantitative risk assessment

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\(^{295}\) 559 F.3d 512 (D.C. Cir. 2009).
\(^{296}\) Id. at 521.
\(^{297}\) NRDC v. EPA, 2011 WL 4336673, at *18 (2d Cir. 2011).
\(^{298}\) 283 F.3d 355, 371 (D.C. Cir. 2002).
\(^{299}\) 489 F.2d 1247, 1253 (D.C. Cir. 1973).
should be inclined to delve deeper if there is disagreement within the agency or among agencies,\textsuperscript{300} if there is inconsistency within the agency over time, and 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.” As the D.C. 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.”\textsuperscript{301}

\section*{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 D.C. Circuit’s. As the Second Circuit noted, “In 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.’”\textsuperscript{302}

In response to the D.C. 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,”\textsuperscript{303} courts can look to other jurisdictional doctrines. These include causation and redressability, mootness and ripeness, and prudential standing doctrines such as the zone-of-interests test.\textsuperscript{304} Moreover, it is important to keep in mind that “Article III standing requirements are not intended as a screen for potentially frivolous lawsuits,”\textsuperscript{305} 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.

\footnotesize{\textsuperscript{300} For example, as with the assessment of Gulf Coast seafood. \textit{See infra}, at p. __. \textsuperscript{301} Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 28 (D.C. Cir. 1976). \textsuperscript{302} Baur v. Veneman, 352 F.3d 625, 637 (2d Cir. 2003). \textsuperscript{303} Public Citizen, Inc. v. National Highway Traffic Safety Admin., 489 F.3d 1279, 1295 (D.C. Cir. 2007). \textsuperscript{304} Baur, 352 F.3d at 636. \textsuperscript{305} \textit{Id.} at 642.}
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 add increased assurance that the party’s injury is actual or imminent, but rather excludes potentially worthwhile plaintiffs from court, conflates a threshold determination with a merits analysis, and makes the injury-in-fact requirement do 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.