

Information Quality Act Opponents Are Post-Modern Precautionary Principle Proponents

Due diligence reveals that the most vocal IQA critics belong to the progressive wing of the legal academy and serve as “Member Scholars” at the Center for Progressive Reform (“CPR”).¹ CPR is a deeply ideological organization that shrouds its true political agenda within a public interest mission ostensibly oriented toward environment, health and safety protection.² To this end, CPR Member Scholars have argued that federal agency implementation of the Information Quality Act would deny agencies of their ability to employ adequate regulatory protections in implementation of Congress’ precautionary intent gleaned (reinterpreted) from 1970’s-era environmental, health and safety legislation.³

However, close scrutiny of CPR organizational and Member Scholar reports, articles and representations strongly suggest that CPR’s actual mission has been far more ambitious. Arguably, it is to replace America’s traditional common law, neo-liberal economic, social, philosophical and political Enlightenment-era *values*,⁴ which include the key tenets of Anglo-American “contentious justice” (rather than continental “preventive justice”⁵) and national constitutional individual rights-based liberty (rather than social democracy),^{6 7 8 9} with a post-modern European sustainable development regulatory framework.^{10 11} Such a framework seeks aggressive protection of public health and the environment at the expense of private property rights,¹² and eschews rational use of cost-effective¹³ scientific protocols and deployment of novel technologies capable of addressing emerging public health, environmental and safety challenges.^{14 15 16}

1. *CPR IQA Opponents*

CPR “scholar” and UC Berkeley (and former UC Davis) Professor of Law, Holly Doremus, for example, has argued that the IQA’s procedural requirement that wildlife agencies seek independent rigorous peer review of studies they rely upon as the basis for Endangered Species Act listing decisions, critical habitat determinations, and recovery plans could alter the process by which ESA decisions are made.¹⁷ Professor Doremus has concluded that stakeholders have used the IQA, for the most part, not to dispute the scientific data *per se*, but to challenge the *policy* (risk management) judgments that have been made based on interpretations and applications of that data.¹⁸ She also claims that external peer review is “a very imperfect tool for [...] ensuring scientific integrity [...] and a]t its best [...] bears only an indirect relationship to scientific integrity, which is an individual, and unverifiable virtue.”¹⁹

In addition, Professor Doremus has argued that “[t]he best [peer] reviewers can do is to evaluate whether the judgments made fall within the broad range of professionally acceptable ideas [which] can reveal extreme departures from acceptable norms with sufficient devotion to time and effort [...] if the reviewers themselves both have the requisite experience and actively practice the virtues of objectivity and skepticism.”²⁰ Therefore, “[o]utside peer review should be employed [only] when there is strong reason to doubt the scientific integrity or credibility of an agency [policy] decision with important conservation or economic consequences, but it should

not be considered a panacea.”²¹ Consequently, considering that the “threat of judicial review and professional norms together already provide sufficient incentives to keep agenc[y scientific judgments] within [the] broad [professional] boundaries [of journal-style peer review], [Professor Doremus and Chicago-Kent College of Law Professor and CPR “scholar”, A. Dan Tarlock, have argued that] journal-style peer review adds very little to the equation.”²²

Professor Doremus’ argument against the utility of IQA-mandated peer review, however, rings hollow to the extent that the ostensibly agreed upon scientific data upon which federal agency interpretations and applications are ultimately based had previously been cherry-picked, manipulated or otherwise distorted by politically-minded agency personnel for policymaking purposes.²³ And, CPR’s argument against the IQA’s vesting OMB with additional centralized oversight and enforcement authority to ensure agency adherence with robust data quality/peer review standards appears rather feeble, when one considers the true intent of organizations such as CPR and doctrinaire technical ‘experts’ embedded in federal agencies like EPA and NOAA to artfully disguise policy judgments made with respect to scientific data on the basis of a hazard, or general risk determination and/or risk perception (i.e., precaution) in terms of risk.²⁴

CPR “scholar” and University of Texas School of Law Professor, Wendy Wagner, has argued that Congress enacted statutes to address dangerous products and waste “on the basis of anticipated harm,” and by doing so, effectively “rejected the common law paradigm” of *post hoc* redress of harm.²⁵ According to Professor Wagner, most such statutes were enacted “with the explicit purpose of bypassing heavy burdens of proof and allowing agencies to regulate on the basis of limited scientific evidence. The possibility of certain catastrophic harms, such as mass exposures to toxic substances, makes this precautionary approach economically rational in many situations.”²⁶ Consequently, in her estimation, the common law’s requirement that causal evidence of harm be established before granting recovery “effectively exculpated most defendants” [due] to substantial scientific unknowns about the long-term effects their activities. Congress appreciated these inherent limitations in the common law and developed a broad regulatory system *that regulates potential hazards without requiring definitive evidence of harm as a prerequisite for regulatory control*” (emphasis added).²⁷ Thus, in contrast to Congress’ intent as expressed in these substantive law statutes, “the IQA risks counteracting these statutory commands to err on the side of public health by providing regulatory parties with an added mechanism for challenging scientific evidence before regulations take effect.”²⁸

In a 2003 paper, Professor Wagner argues that the IQA is unwarranted because, as of such time, there was little to no evidence of federal agency use of ‘unreliable science’ to inappropriately support a final regulation.²⁹ She cites “EPA’s conscious but ‘indisputably wrong’ decision to not adjust its model for assessing exposure to potentially hazardous air pollutants around the properties of particular pollutants,” based on EPA’s application of the precautionary principle, as the “only clear example of bad science used in a rulemaking.”³⁰ She notes that commissioned expert reports have generally validated the quality of EPA science, save for a few minor problems, and that an expert panel’s prior assessment of EPA shortcomings with respect to analytical modeling and assumptions had concluded that they were *insignificant*.³¹ Far from being insignificant, however, the 1992 assessment emphasized that EPA was perceived as “lack[ing] adequate safeguards to prevent [...] [s]cience [from be[ing]] adjusted to fit policy,” that “EPA, like many other scientific organizations, does not give sufficient attention to

validating the models, scientific assumptions, and databases it uses,” and that EPA “[s]cience activities to support regulatory development – particularly those carried out by the program and regional offices – do not always have adequate, credible quality assurance, quality control, or peer review.”³² Professor Wagner cites an additional 2000 study performed by the National Academy of Sciences that she claims referenced only one weakness in EPA’s scientific peer review practices – namely, that “still more independence was needed between project managers and the peer-review process.”³³

What Professor Wagner failed to mention, however, was that the NAS report expressly stated that, “[o]ur committee shares the SAB’s [EPA Science Advisory Board’s] concern about the potential conflicts of interest of EPA peer-review leaders and decision-makers.”³⁴ Apparently, such concern had been triggered by a 1999 EPA Office of Inspector General Report which had concluded that “the management controls [then] in place were insufficient to ensure that EPA program offices and contractors adequately screened peer reviewers for independence and potential conflict of interest.”³⁵ Professor Wagner clearly failed to recognize the critical connection between the peer reviewer selection process and the substantive peer reviews performed by selected peer reviewers, especially where scientific assessments are used to justify major agency regulations. Contrary to Professor Wagner’s assertions, such connection only further justified Congress’ enactment of the IQA. Unfortunately, even since the IQA’s enactment, a number of agency reports have focused on how EPA’s limited science resources and its failure to comply with various IQA peer reviewer selection and substantive peer review standards have hampered its ability to produce reliable agency science.³⁶

In an effort to derail the IQA, CPR “scholar” and Mercer University George School of Law Professor, Stephen M. Johnson, has cited Carol Browner, former Clinton EPA Administrator and former Director of the Obama White House Office of Energy and Climate Change Policy, as describing how the IQA threatens “*the traditional precautionary approach* that the government has taken toward environmental protection” (emphasis added).³⁷ However, Professor Johnson noticeably omitted reference to how Ms. Browner had “used children’s health rhetoric to limit the [political] maneuvering room of her opponents” with respect to how EPA reinterpreted 1970’s legislation to justify its use of said approach.³⁸

Professor Johnson also has argued that, “[s]ince the enactment of the Information Quality Act [...] businesses have frequently challenged *precautionary decisions by government agencies* by arguing that the data on which the agencies are relying to support their decisions does not meet the quality standards of the law” (emphasis added).³⁹ Professor Johnson documents how this, in turn, had resulted in federal agencies reversing their prior precautionary decisions. For example, during 2002-2004, in response to IQA petitions for correction and subsequent administrative appeals: 1) NOAA had disavowed its prior adoption of a national climate assessment pursuant to the U.S. Global Change Research Act to avoid IQA coverage;⁴⁰ 2) the Department of Interior’s Fish and Wildlife Service had withdrawn a listing of the slickpot peppergrass (*Lepidium papilliferum*)⁴¹ and had decided not to list a the Greater Sage Grouse⁴² under the Endangered Species Act; 3) the EPA had decided to delay the imposition, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) of stricter controls on the chemical substance atrazine pursuant,⁴³ to remove a soil database from the internet,⁴⁴ and to weaken EPA guidance associated with the use of asbestos in automobile brakes;⁴⁵ and 4) the Department of Health & Human

Services had decided to no longer rely on a World Health Organization/Foreign Agricultural Service report recommending lower sugar intake as part of the Department's dietary guidelines.⁴⁶ In addition, Professor Johnson has noted that during early 2006, OMB, in consultation with the White House Office of Science and Technology Policy, had issued for public comment a proposed bulletin (technical guidance)⁴⁸ intended "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards [...] build[ing] on OMB's Information Quality Guidelines and Information Quality Bulletin on Peer Review,"⁴⁹ which IQA opponents had severely criticized as placing children's health at risk.⁵⁰

Furthermore, University of Texas School of Law Professor, Thomas O. McGarity, Wake Forest University School of Law Professor Sidney Shapiro, and University of Maryland School of Law Professor Rena I. Steinzor, all CPR "scholars," have similarly argued that industry has used the Information Quality Act as a vehicle to bypass substantive environment, health and safety laws and "to challenge basic assumptions about protection and precaution that are established in those statutes" (emphasis added).⁵¹ In other words, these IQA critics claim that IQA petitioners have used requests for information correction as a disguised means to "challenge[] policy decisions that agencies are authorized [by such statutes] to make – particularly those which take a precautionary approach to uncertainty" (emphasis added).⁵² Consequently, these critics represent that the "IQA threatens to undermine the precautionary approach mandated by Congress in such statutes by subjecting individual regulatory decisions to strict evidentiary standards" (emphasis added),⁵³ that require quantitative in lieu of qualitative data, especially in the case of risk assessments.⁵⁴

Moreover, CPR "scholars" Wendy Wagner, Thomas McGarity and Holly Doremus have sought to discredit the IQA by focusing on its alleged impacts on regulatory science at both the agency and judicial levels. With respect to agency-level impacts,⁵⁵ Professor Wagner has argued that IQA requests for correction and reconsideration effectively impose an "evidentiary screening process" on regulatory agencies that approximates the imperfect judicial screening of scientific evidence in private litigation consistent with the U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*^{56 57} She is concerned that the remedies stakeholders often request involve the "complete exclusion or withdrawal of the challenged information from public databases" irrespective of the need to preserve credible portions of such information.⁵⁸ Professor Doremus has expressed similar concerns. She opines that the IQA essentially imposes a *Daubert*-like evidentiary screening process on federal regulatory agencies, which appears to have had "an indirect chilling effect on information consumption."⁵⁹ As a result, some federal agencies have adopted an informal "'exclusionary rule' for scientific evidence they perceive as not up to their stringent interpretation of the *Daubert* standards. When EPA began the process of revising its air quality criteria for lead, for example, it invited submission only of 'research studies that have been published, accepted for publication, or presented at a public scientific meeting,'" a standard that would exclude far more evidence than *Daubert* itself."

With respect to judicial impacts, Professor McGarity has expressed concern that judges' "limited competence in areas involving scientific data and analysis, complex modeling exercises, and large uncertainties," the hybrid nature of science and policy-informed risk assessments, and the "*Daubertization*" of agency risk assessments [will] [...] run[] directly counter to the

[regulatory] precautionary policies animating most health, safety, and environmental statutes” (emphasis added).⁶⁰ In addition, Professor Wagner has argued that if trial courts applying *Daubert* conclude that “animal studies are insufficient to create a jury question on causation” because of a lack of direct line of evidence demonstrating potential harm to humans, and appellate courts use such cases as precedent, they could also exclude most of an agency’s basic studies, *thereby undercutting the commands of the precautionary legislation.*”⁶¹

Presumably, Professors McGarity, Wagner and Doremus would have no difficulty placing such determinations at the feet of a lay jury, as the Seventh Circuit Court of Appeals effectively did in the recent case of *Schultz v. Akzo Nobel Paints*.⁶² In *Shultz*, the Circuit Court agreed to admit into evidence the “scientific” opinion of plaintiff’s expert witness (an oncologist) that was based on an unproven application of the EPA risk assessment (Monte Carlo) model,^{63 64} which neither Circuit Court nor the District Court had ensured had been adequately validated at the regulatory level in conformance with the IQA’s rigorous peer review standards. If the court had done so, it would have discovered that EPA has long used a weight-of-evidence approach to classify how likely an agent is to be a human carcinogen,⁶⁵ and that EPA had more recently “developed weight-of-evidence classification systems for some other kinds of toxic effects, such as developmental effects,”⁶⁶ which had been found to be inadequately supported by scientific data and analyses.^{67 68} Arguably, the Court’s holding in *Shultz* will permit use of the weight-of-evidence approach to show proof of mere *general* causation⁶⁹ or risk in the absence of actual quantitative data of specific harm, which would be tantamount to a showing of harm based only on a product’s intrinsic hazards. This is likely why the district court had previously ruled that the oncologist’s conclusion had rested on a “no threshold” *precautionary* assumption.⁷⁰

Notwithstanding such criticisms, these critics have had to concede that the IQA’s enactment has led to federal agencies like EPA and OMB paying greater attention to scientific quality.⁷¹ For example, during 2003-2004, such agencies pursued at least three regulatory science quality control initiatives. These include EPA’s issuance of assessment factors and considerations for evaluating the quality and relevance of scientific and technical information consistent with EPA’s IQA Guidelines and an EPA Administrator memorandum calling on EPA’s Council for Regulatory Environmental Modeling to issue guidelines ensuring that agency use of environmental computer modeling comports with EPA IQA Guidelines.⁷² They also included OMB’s issuance of a proposed Peer Review Bulletin.⁷³ However, as Section VI of this article shows, perceptions can be deceiving.

2. CPR Precautionary Principle Proponents

Clearly, CPR “scholar” criticisms of the peer review screening mechanism the IQA imposes on federal regulatory agencies are closely related to the simultaneous efforts of the same and other CPR “scholars” to facilitate the importation into and/or reinterpretation within U.S. environmental, health and safety law of the “strong” precautionary principle as a central and overriding national risk management framework grounded in notions of strict liability. Such a framework goes well beyond both the common law and international law concepts of ‘prevention’ which address predictable and foreseeable risks which can, to some extent, be quantified/calculated.⁷⁴ It also goes beyond the accepted international interpretation of

precaution contained in Principle 15 of the Rio Declaration which the World Trade Organization held is reflected in Article 5.7 of the Sanitary and Phytosanitary (“SPS”) Agreement.⁷⁵

For example, CPR “scholar” and University of Utah S.J. Quinney College of Law Professor, Robin Kundis Craig, for instance, has long promoted U.S. ratification of multilateral environmental treaties, such as the United Nations Convention on the Law of the Sea, and endeavored to secure amendment of U.S. oceans and environmental policy for purposes of employing domestically the sustainable development concepts of Chapter 17⁷⁶ of United Nations Agenda 21.^{77 78} In addition, she has argued in favor of reinterpreting related extant U.S. federal environmental statutes, such as the Clean Water Act,⁷⁹ the Coastal Zone Management Act⁸⁰ and the Magnuson-Stevens Fishery Conservation and Management Act,⁸¹ as reflecting Congress’ precautionary intent, consistent with the strong version of Europe’s precautionary principle. Her long sought objective has been to secure UNCLOS ratification without federal implementing legislation which can be achieved by enabling federal agencies to promulgate conforming regulations unilaterally.

CPR “scholar” and University of Richmond School of Law Professor, Noah Sachs, has advocated in favor of formal U.S. adoption of Europe’s “strong” precautionary principle, which he describes as “shift[ing] the burden of proof on the safety of a product or activity from government regulators to private firms.”⁸² It is Professor Sachs’ opinion that, the ‘strong’ burden-of-proof-reversing precautionary principle-based regulation should be established in U.S. law as an administrative presumption or default to restrict or curtail an activity or product that poses a serious threat to human health or environment, where scientific uncertainty precludes a full understanding of the nature and extent of such threat.⁸³ In his estimation, if scholarship critical of the ‘strong’ precautionary principle authored by influential scholars and policy makers is permitted to establish its illegitimacy in U.S. policy and law, which is likely to occur if risk regulation scholarship continues to defend “weak” versions of the precautionary principle,⁸⁴ then true substantive reform of U.S. environmental and health statutes such as the Toxic Substances Control Act (“TSCA”) and federal agency implementing regulations is unlikely to occur.⁸⁵ He counters critics’ objections, including those of this author,⁸⁶ in revisionist fashion by arguing that ‘strong’ precaution “is already deeply rooted in U.S. law [...] form[ing] the basis for numerous licensing, permitting and preapproval programs that are cornerstones of public health and environmental protection in the United States, [...] including] the Food and Drug Administration’s review process for new drugs.”⁸⁷ He likewise rationalizes that the ‘strong’ precautionary principle is “not inflexible, extreme, or cost insensitive,” and is “not antithetical to a weighing of the costs and benefits of regulatory action.”⁸⁸

CPR “scholar,” and CUNY School of Law Professor, Rebecca Bratspies, has argued that the U.S.-Canada arbitral panel’s “us[e of] preliminary measures to prevent harm while information sufficient to create a permanent regime fair to all parties is developed” in the 1941 *Trail Smelter* transboundary pollution case engenders a “(semi)precautionary legacy [that] resonates profoundly in modern international environmental law.”⁸⁹ Indeed, she has cited precautionary decision-making as one of several emerging international norms about the environment that had arisen since 1992 in support of sustainable development.⁹⁰ Professor Bratspies has also praised the precautionary principle as “stand[ing] for the ‘common sense idea that public and private interests should act to prevent harm’” and as a necessary “antidote and antonym to cost-benefit

analysis.”⁹¹ To her credit, Professor Bratspies has noted that, “[a]s precautionary decisionmaking has gathered steam, a backlash led by scholars and officials in the United States has emerged.”⁹² She points out *inter alia* that “[c]ritics [...] decry the precautionary principle as imposing unnecessary costs to address remote and improbable harms. The basis for this critique is obvious. Precautionary regulation restricts human actions and imposes costs that cannot be grounded in unambiguous scientific evidence.”⁹³ She also has emphasized how these and other critics are “[t]ypically motivated by the assumption that economic expansion and technological innovation increase overall social welfare, [and] perceive the precautionary principle as an unwelcome and technically unsound deviation from science-based regulation, and [...] to be little more than a non-tariff trade barrier in disguise.”⁹⁴

In addition, Professor Bratspies has advocated in favor of employing the precaution principle to stop the widespread use of corn genetically modified to express the toxins of *Bacillus thuringiensis* - soil bacteria commonly found in the environment (“Bt corn”) - which enable the plants to kill certain classes of insects, including some significant agricultural pests. Although Bt crops sustain less insect damage and are able to produce a higher yield per acre,⁹⁵ she argues that “proper precautions” must be taken to prevent “[i]ndividual, short-term, rational decisions” to increase use of Bt corn from “creat[ing] a downward spiral of lost Bt susceptibility” (resistance).⁹⁶ To such extent, Professor Bratspies has revisited U.S. environmental law and concluded that, “[i]n the context of gm crops, Congress has given the agencies a precautionary mandate. USDA and EPA are charged with protecting the public, and *FIFRA in particular is a precautionary statute*. Both agencies have identified Bt resistance as an adverse environmental consequence” (emphasis added).⁹⁷ Although USDA and EPA recognized the risk of insect resistance these crops posed, she argued that the scientific uncertainty surrounding “how to prevent the risks” and attendant harms required the use of a precautionary regulatory scheme.⁹⁸ In particular, she called for the incorporation of default assumptions into risk assessments that reflect the statutory scheme in question. Since the statutory and regulatory scheme in question “seem[ed] to mandate a precautionary approach to regulating gm crops [...] regulation should [have] incorporate[d] [reasonable] estimates [of harm] as a baseline of precaution and not permit less protective options, based on rosier scenarios, to prevail because of uncertainty.”⁹⁹ Professor Bratspies has taken a similar position with respect to aquaculture of transgenic salmon. Although “the Trojan gene possibility is largely based on computer simulations of nonsalmonid reproduction, and on extrapolation from behavioral studies [...]. There is, however, definitely a big question mark here—an unknown that must be carefully considered before permitting widescale production of transgenic salmon. This issue is exactly the kind of situation for which the precautionary principle was designed.”¹⁰⁰

CPR “scholar”, and UC Berkeley Professor of Law, Holly Doremus readily acknowledges that “[p]recautionary and scientific approaches to decision-making [...] are indeed distinct,” but endeavors to relate them in complimentary ways.¹⁰¹ She argues that the conventional Rio Declaration formulation of the precautionary principle, which is essentially preventive in nature, is limited and incomplete because it is designed only to address novel activities or technologies that pose poorly understood risks.¹⁰² Professor Doremus envisions “[a]t least three classes of natural resource management decisions justify[ing] a precautionary approach.” They include decisions: 1) where “inaction or maintenance of the status quo itself presents significant risks to the natural world”¹⁰³; 2) where “inaction is impractical for socioeconomic reasons”¹⁰⁴; and 3)

which “although individually small and essentially irreversible, are repeated often enough to produce cumulatively significant impacts, and over a long enough period of time to permit learning and adjustment.”¹⁰⁵

CPR “scholar”, and UC Riverside Professor of Philosophy, Carl Cranor, meanwhile, previously endeavored to explain and promote the precautionary principle to a broad public audience as a plausible risk management mechanism in an indirect effort to refute the concerns of its critics.¹⁰⁶ Remarkably, Professor Cranor has argued that, “[a]lthough [the PP] leaves the *burden of proof* on an advocate of acting against a serious threat to the public or workforce health or the environment, it does vaguely specify a slightly reduced *standard of proof* before cost effective action can be taken. Moreover it appears to presume that “threats of serious or irreversible damage” to valued states of affairs create a reason for considering action to address the threat.”¹⁰⁷ He also misrepresents the scope of the PP, claiming that since the PP “remains quite vague on these several dimensions [...] it is hardly as radical as the Food, Drug and Cosmetic Act that implicitly presumes that drugs pose risks to human health until established otherwise in pre-clinical and clinical trials” (i.e., pursuant to the “Delaney Clause”).¹⁰⁸ Professor Cranor’s efforts to ‘domesticate’ the precautionary principle for wholesale consumption must be carefully scrutinized given the current placement of these views on the website of the NOAA Great Lakes Sea Grant Extension Office at the Great Lakes Environmental Research Laboratory.

In addition, Professor Cranor had strategically secured a role as plaintiff’s ‘expert’ witness on scientific methodology in the case of *Milward v. Acuity Specialty Products Group, Inc.*¹⁰⁹ As a result, he successfully persuaded the judiciary, in at least the First Federal Appellate Circuit, to reduce *Daubert* evidentiary science standards in the courtroom from the ‘strength-of-the-line-of-evidence’ standard (i.e., causation) to the ‘weight-of-the-evidence’ or ‘inference-to-the-best explanation’ standard (i.e., correlation),¹¹⁰ thereby paving the way for introduction of dubious precautionary principle-based studies for consideration by juries.¹¹¹ ¹¹²As Professor Cranor proudly noted,¹¹³ these efforts have since resulted in the *National Research Council’s* prompt revision¹¹⁴ of the Federal Judicial Center’s¹¹⁵ *Reference Manual on Scientific Evidence*¹¹⁶ to reflect this regional change in judicial perspective, namely, that “[n]o serious argument can be made that the weight of the evidence approach is inherently unreliable.”¹¹⁷ ¹¹⁸No doubt, such expedient reporting is intended to encourage an even greater philosophical change across the whole of the federal judiciary.

Finally, Georgetown University Law Center Professor of Law and CPR Member “scholar” Lisa Heinzerling possesses a similar view of the precautionary principle. Professor Heinzerling is a former official in the current administration’s EPA¹¹⁹ “widely credited with crafting the legal strategy of a coalition of states and environmental groups in *Massachusetts v. EPA* [as well as...subsequently] “craft[ing] a suite of [EPA] regulations to address climate change”¹²⁰ based “on a trove of materials” upon which the former administration’s EPA had been sitting that included “a *proposed endangerment finding*, a proposal to regulate greenhouse gas emissions from motor vehicles, a proposed reporting rule for greenhouse gases, a proposal on renewable fuel standards” (emphasis added).¹²¹ Professor Heinzerling has aggressively advocated, from a legal and moral perspective,¹²² for the replacement of regulatory economic-cost-benefit analysis with “a *European-style precautionary principle*,”¹²³ ¹²⁴ especially with respect to climate change.¹²⁵ She also has cited as problematic how courts, in implementing *Daubert*, have

highlighted the dissimilar purposes of administrative regulation and tort law as justification for excluding as unreliable or irrelevant evidence on the issue of causation federal agency risk assessments *estimating* the risks posed by hazardous substances and activities.¹²⁶ Consistent with her promotion of the precautionary principle, Professor Heinzerling has argued that courts in tort cases should instead take a “‘preventive’ [actually, a *precautionary*] perspective [which] choice reflects not just ‘causation’ as a strictly factual matter but also *policy considerations* about how to allocate the burden of *scientific uncertainty* between plaintiffs and defendants” (emphasis added).¹²⁷

¹ See The Center for Progressive Reform, *CPR Member Scholars*, available at: <http://www.progressivereform.org/scholarGateway.cfm>.

² See The Center for Progressive Reform, *CPR’s Values*, available at: <http://www.progressivereform.org/aboutCPR.cfm#main>.

³ See John S. Applegate, Robert L. Glicksman, Tom O. McGarity, Sidney A. Shapiro, Amy Sinden, Rena I. Steinzor, and Robert R.M. Verchick, *Reinvigorating Protection of Health, Safety, and the Environment The Choices Facing Cass Sunstein*, Center for Progressive Reform, CPR White Paper #901 (Jan. 2009), *supra* at pp. 8-9.

⁴ See Lawrence A. Kogan and Richard D. Otis, Jr., *Science for the Picking*, Canada Free Press (July 26, 2014), available at: <http://canadafreepress.com/index.php/article/64852>; Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European “Fashion” Export the United States Can Do Without*, 17 *Temple Political & Civil Rights Law Review* 491-504 (Spring 2008), available at: <https://nebula.wsimg.com/1db38ca6345f6bf88b5b35ec35113e24?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>; Lawrence A. Kogan, *Exporting Precaution: How Europe’s Risk-Free Regulatory Agenda Threatens American Free Enterprise*, Washington Legal Foundation Monograph (Nov. 2005), at pp. 96-101, available at: http://www.wlf.org/publishing/publication_detail.asp?id=1701.

⁵ See Lawrence A. Kogan, *Effort to Expand “Authentic Acts” in Europe Imperils Economic Freedom*, Washington Legal Foundation Legal Backgrounder, Vol. 24 No. 6 (Feb. 13, 2009), at pp. 2, 3, available at: http://www.wlf.org/publishing/publication_detail.asp?id=2046 (discussing the distinction between preventive and contentious justice, and between the common law and civil notions of precaution).

⁶ See Peter Goldsmith, Hamish Gow and Nesve Turan, *Is it Safe? Post-Market Surveillance versus Ex-ante Signalling*, Department of Agricultural and Consumer Economics, University of Illinois at Urbana Champaign (2002), at 5-6, at: <http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=6BB8E1D9213D025A30B8F158039F7CA6?doi=10.1.1.2.01.9594&rep=rep1&type=pdf>.

⁷ See Svetozar Pejovic, *From Social Democracy to Liberal Socialism: A Property Rights Analysis of the Transition in Europe*, CRCE Briefing Paper (April 2010), available at: <http://www.crce.org.uk/briefings/briefing%20paper%20pejovic.pdf>. See also Svetozar (Steve) Pejovich, *On Liberalism, Capitalism, The Rule of Law, and the Rule of Men*, Discussion Paper Prepared for CRCE Conference on the Rule of Law in the Market Economy Slovenia (October 2-4, 2008), at pp. 2-4; Svetozar Pejovich and Enrico Colombatto, *The Rule of Law and the Economic Functions of the Constitution*, Chap. 6, at p. 100, 113-114, in “Law, Informal Rules and Economic Performance: The Case for Common Law,” Edward Elgar Pub (August 30, 2008) (permission for citation obtained), Editorial Review on Amazon.com website, at: <http://www.amazon.com/Law-Informal-Rules-Economic-Performance/dp/1845428730>; Svetozar (Steve) Pejovich, *On Liberalism, Capitalism, The Rule of Law, and the Rule of Men*, Prepared for discussion at Workshop in Philosophy, Politics and Economics at George Mason University, (Oct. 9, 2007), available at: <http://econfaculty.gmu.edu/pboettke/workshop/archives/fall07/Pejovich.pdf>; Svetozar (Steve) Pejovich, *Private Property—A Prerequisite for Classical Capitalism* 12 (2005), Prepared for the Hayek Institute Conference on The Roots of Capitalism (Vienna, Austria Oct. 16-18, 2005), available at: <http://www.easibulgaria.org/docs/Pejovic.doc>, quoted in World Intellectual Property Organization, COMMENTS ON THE REPORT ON THE INTERNATIONAL PATENT SYSTEM RECEIVED FROM MEMBERS AND OBSERVERS OF THE SCP, SCP/12/3Rev.2 - Annex III, pp. 19-26, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2-annex3.pdf.

⁸ See Elizabeth Katz, *German High Court Has More Power Over Legislature, Grimm Says*, University of Virginia Law Blog (March 9, 2006) at: http://www.law.virginia.edu/html/news/2006_spr/grimm.htm; Tom Allen, *Compensation for Property Under the European Convention on Human Rights*, 28 MICH. J. INT'L. L. 287, 288, 305-307 (2007), available at: <http://law.bepress.com/expresso/eps/1875/>, quoted in World Intellectual Property Organization, COMMENTS ON THE REPORT ON THE INTERNATIONAL PATENT SYSTEM RECEIVED FROM MEMBERS AND OBSERVERS OF THE SCP, SCP/12/3Rev.2 - Annex III, pp. 19-26, *supra*.

⁹ See Charlemagne, *Brussels rules OK: How the European Union is becoming the world's chief regulator*, The Economist (Sept. 20, 2007), available at: <http://www.economist.com/node/9832900> (distinguishing between the American and European models of risk regulation).

¹⁰ See Barbara Stark, *Sustainable Development and Postmodern International Law: Greener Globalization?*, 27 William & Mary Environmental Law and Policy Review 137, 151-154 (2002), available at: <http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1181&context=wmelpr>.

¹¹ See Lise-Lotte Hellöre and Björn Vikström, *Newspapers on Sustainable Development – A Postmodern Business Perspective*, 14 Electronic Journal of Business Ethics and Organization Studies No. 2 (2009), available at: http://ejbo.jyu.fi/pdf/ejbo_vol14_no2_pages_21-30.pdf (discussing the shift from modern era environmental protection to post-modern era sustainable development).

¹² See, e.g., Lawrence A. Kogan, *Global Efforts to 'Rebalance' Private and Public Interests in Intellectual Property*, Presentation on the Panel "International Changes in IP: Is it Chaos or the New Normal?", Annual Meeting of the Intellectual Property Law Section of the New York State Bar Association (NY, NY Jan. 28, 2014), available at: <http://www.nysba.org/AM2014IPSPRGM/>; http://www.koganlawgroup.com/uploads/LKogan_-_The_Global_Effort_to_Rebalance_Private_and_Public_Interests_in_Intellectual_Property_-_NYSBA_IP_Secti.pdf;

(discussing, in part, how global sustainable development environmental initiatives have contributed to a diminution in the scope of intellectual property rights protection within and beyond the United States); Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European "Fashion" Export the United States Can Do Without*, 17 Temple Political & Civil Rights Law Review 491, 530-532 (Spring 2008), *supra*.

¹³ See John S. Applegate, Robert L. Glicksman, Tom O. McGarity, Sidney A. Shapiro, Amy Sinden, Rena I. Steinzor, and Robert R.M. Verchick, *Reinvigorating Protection of Health, Safety, and the Environment The Choices Facing Cass Sunstein*, Center for Progressive Reform, CPR White Paper #901 (Jan. 2009), *supra* at pp. 1-2.

¹⁴ *Id.* See also Center for Progressive Reform, *A New Progressive Agenda for Public Health and the Environment*, (Christopher H. Schroeder and Rena Steinzor Eds. Jan. 2005), at pp. 4, 7, 9, available at: http://www.progressivereform.org/articles/NPA_501.pdf.

¹⁵ See David Hunter (CPR Member Scholar; Associate Professor of Law, American University Washington College of Law), *Meeting Low Expectations at Rio+20* (June 19, 2012), available at: <http://www.progressivereform.org/CPRBlog.cfm?idBlog=0519CC50-D973-C04E-EE2877C6C6689465>; See also Mary Jane Angelo, Rebecca Bratspies, David Hunter, John H. Knox, Noah Sachs, and Sandra Zellmer, *Reclaiming Global Environmental Leadership: Why the United States Should Ratify Ten Pending Environmental Treaties*, Center for Progressive Reform White Paper #1201 (Jan. 2012), at pp. 2-3, available at: http://www.progressivereform.org/articles/International_Environmental_Treaties_1201.pdf.

¹⁶ See Institute for Trade, Standards and Sustainable Development, *Issues - The Need to Define Sustainable Development ("SD")*, ITSSD website, available at: <https://www.itssd.org/issues---the-need-to-define-sustainable-development.html>; Institute for Trade, Standards and Sustainable Development, *Issues - Negative (Postmodern) SD and the European Union*, ITSSD website, available at: <https://www.itssd.org/issues---negative--postmodern--sd-and-the-european-union.html>; Institute for Trade, Standards and Sustainable Development, *Issues - Negative (Postmodern) SD and the United States*, ITSSD website, available at: <https://www.itssd.org/issues---negative--postmodern--sd-and-the-united-states.html>.

¹⁷ See Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Available Science Mandate*, The Endangered Species Act Turns 30 Symposium Article (2004), at pp. 423-424, available at: <http://cses.washington.edu/cig/outreach/classes/595/files/doremus2004.pdf>. See also Holly Doremus, *Science Plays Defense: Natural Resource Management in the Bush Administration*, 32 Ecology Law Quarterly 249, 286 (2005), available at: <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1768&context=facpubs>.

¹⁸ See Holly Doremus, *Science Plays Defense: Natural Resource Management in the Bush Administration*, 32 Ecology Law Quarterly 249, 253-254 (2005), *supra*.

¹⁹ See Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 Tex. L. Rev. 1601, 1651-52 (2008), available at: <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=3001&context=facpubs>.

²⁰ *Id.*, at p. 1652.

²¹ *Id.*

²² See Holly Doremus and A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resource Regulation*, 26 *Pub. Land & Resources L. Rev.* 1, 32 (2005), available at: <http://scholarship.law.umt.edu/cgi/viewcontent.cgi?article=1282&context=plrlr>.

²³ See, e.g., Institute for Trade, Standards and Sustainable Development, *FOIA Request No. DOC-NOAA-2014-001694* (Sept. 22, 2014), at pp. 13-14, and referenced sources, available at: <https://nebula.wsimg.com/86e0c3d9f0c18e77b33e25d935498bcc?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>. See also Karen T. Liftin, *Framing Science: Precautionary Discourse and the Ozone Treaties*, *Millennium: Journal of International Studies*, Vol. 24, No. 2 (1995), at pp. 251-277 available at: <http://faculty.washington.edu/litfin/research/framing-science.pdf>; Karen T. Liftin, *Ozone Discourse: Science and Politics in Global Environmental Cooperation*, (Columbia University Press 1995), at “Chap. 4 - The Employment of Knowledge in the Montreal Protocol Negotiations”, available at: <http://www.columbia.edu/dlc/cup/litfin/litfin14.html> (“Rather than the science itself, it was Thomas’ interpretation of the science and his own philosophical orientation to the problem of risk that drove his decision”) (emphasis added). *Id.*

²⁴ See, e.g., Martin Führ, Julian Schenten, Andreas Hermann, Dirk Bunke, *Enhancement of the REACH Requirements for (Imported) Articles*, Society for Institutional Analysis (Sofia e.V.) and Institute for Applied Ecology (Öko-Institut e.V.), on Behalf of the Federal Environmental Agency of Germany (Umwelt Bundesamt), Draft Report (Sept. 2014), at Chap. 6, pp. 18, 36, 39, 43, 46 available at: <https://nebula.wsimg.com/b63b17f1d682f951b9634a262ce63c86?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>; Sofia e.V., Öko-Institut e.V. and Umwelt Bundesamt Policy Workshop, *Strengthening REACH Provisions Concerning (Imported) Articles*, (Université Saint-Louis Brussels, Belgium Oct. 9, 2014), available at: <https://nebula.wsimg.com/3fa99b13bb73ce92d68224af08547d57?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>.

²⁵ See Wendy E. Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 *Journal of Law and Policy* 589 (2005), *supra* at fn 1, quoting Sidney A. Shapiro and Robert Glicksman, “Risk Regulation at Risk: Restoring a Pragmatic Approach,” at p. 15 (Stanford Univ. Press 2003), available at: https://www.academia.edu/8842529/Ebook_Risk_Regulation_at_Risk_Restoring_a_Pragmatic_Approach_For_Nook_PC_Kindle_IPAD_Tablets.

²⁶ See Wendy Wagner, *The ‘Bad Science’ Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 *Law and Contemporary Problems* 63, 85 (Aug. 2003), available at: <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1296&context=lcp>.

²⁷ *Id.*, at pp. 589-590.

²⁸ *Id.*, at p. 603.

²⁹ See Wendy E. Wagner, *The Bad ‘Science Fiction’: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 *Law and Contemporary Problems* 63 (Aug. 2003), *supra* at p. 72.

³⁰ *Id.*, at fn. 40.

³¹ *Id.*, at p. 73, citing United States Environmental Protection Agency, *Expert Panel on the Role of Science at EPA – Safeguarding the Future: Credible Science, Credible Decisions* (1992), available at: <http://nepis.epa.gov/Exe/ZyPDF.cgi/30001ZWJ.PDF?Dockey=30001ZWJ.PDF>.

³² See United States Environmental Protection Agency, *Expert Panel on the Role of Science at EPA – Safeguarding the Future: Credible Science, Credible Decisions* (1992), *supra* at p. 24.

³³ See Wendy E. Wagner, *The Bad ‘Science Fiction’: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 *Law and Contemporary Problems* 63 (Aug. 2003), *supra* at p. 74, citing National Academy of Sciences, Committee on Research & Peer Review in EPA, *Strengthening Science at the U.S. Environmental Protection Agency: Research Management and Peer Review Practices* (National Academy Press, Wash., D.C. 2000) at p. 19, available at: http://www.nap.edu/download.php?record_id=9882#.

³⁴ See National Academy of Sciences, Committee on Research & Peer Review in EPA, *Strengthening Science at the U.S. Environmental Protection Agency: Research Management and Peer Review Practices* (National Academy Press, Wash., D.C. 2000), *supra* at p. 145.

³⁵ See U.S. Environmental Protection Agency, *Office of Inspector General Survey Report: EPA’s Selection of Peer Reviewers*, 1999-P-217 (1999), at pp. 7-11, available at: <http://www.epa.gov/oig/reports/1999/9P00217.pdf>.

³⁶ See also Institute for Trade, Standards and Sustainable Development, *FOIA Request No. EPA-HQ-008026* (June 30, 2014), *supra* at Annotated Addendum, pp. 73-78.

- ³⁷ See Stephen M. Johnson, *Junking the 'Junk Science' Law: Reforming the Information Quality Act*, 58 Administrative Law Review 37 (Winter 2006), at 42, available at: <http://www.jstor.org/discover/10.2307/40712004?uid=2134&uid=3739808&uid=2484518903&uid=2&uid=70&uid=3&uid=2484518893&uid=3739256&uid=60&purchase-type=none&accessType=none&searchText=precautionary&sid=21105050973823&showMyJstorPss=false&searchUri=%2Faction%2FdoBasicSearch%3FQuery%3Dprecautionary%2Bprinciple%26amp%3Bfilter%3Ddiid%253A10.2307%252Fi40031497%26amp%3BSearch%3DSearch%26amp%3Bwc%3Don&seq=6&showAccess=false&Search=yes&resultItemClick=true> (quoting Carol Browner, *Environmental Policy: Principles for the Next Generation of Protection*, 30 A. M. J. L. & Med. 115, 115-116 (2004)).
- ³⁸ See Steven Gibb, *Science and Economics Prominent on EPA Agenda*, National Academy of Sciences (Spring 2001), available at: <http://www.issues.org/17.3/gibb.htm>; <http://issues.org/17-3/gibb/>.
- ³⁹ See Stephen M. Johnson, *Junking the 'Junk Science' Law: Reforming the Information Quality Act*, 58 Administrative Law Review 37, 41 (Winter 2006), *supra* at p. 42.
- ⁴⁰ *Id.*, at p. 42, fns 11-12, 42-43, fn 13. See, also e.g., Competitive Enterprise Institute, *CEI Global Warming Lawsuit Draws Ire of Northeast State Attorneys General*, News Release (Aug. 23, 2003), available at: <http://cei.org/news-releases/cei-global-warming-lawsuit-draws-ire-northeast-state-attorneys-general>; Competitive Enterprise Institute, *White House Acknowledges Climate Report Was not Subjected to Sound Science Law: CEI Drops Lawsuit against Bush Administration*, News Release (Nov. 6, 2003), available at: <http://cei.org/gencon/003.03740.cfm>, cited in Wendy E. Wagner *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 Journal of Law and Policy 589 (2005), at pp. 596-597, fn. 32.
- ⁴¹ *Id.*, at p. 43, fn 15.
- ⁴² *Id.*, at p. 43, fn 14.
- ⁴³ *Id.*, at p. 43, fn 16.
- ⁴⁴ *Id.*, at pp. 43-44, fn 17.
- ⁴⁵ *Id.*, at pp. 43-44, fn 18.
- ⁴⁶ *Id.*, at p. 44, fn. 19.
- ⁴⁷ See also Stephen M. Johnson, *Ruminations on Dissemination: Limits on Administrative and Judicial Review under the Information Quality Act*, 55 Cath. U. L. Rev. 59 (2006), at pp. 60-61, available at: <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1188&context=lawreview>; Wendy E. Wagner *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 Journal of Law and Policy 589 (2005), at pp. 596-597 and accompanying footnotes.
- ⁴⁸ *Id.*, at p. 44, fn. 20.
- ⁴⁹ See Office of Management and Budget, *Proposed Risk Assessment Bulletin* (Jan. 9, 2006), at p. 3, available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf.
- ⁵⁰ See Center for Effective Government, *OMB Puts Children's Health at Risk with Data Quality Act* (4/4/2005), available at: <http://dev.ombwatch.org/node/2365>.
- ⁵¹ See Thomas O. McGarity, Sidney A. Shapiro, Rena I. Steinzor, Joanna Goger and Margaret Clune, *Truth and Science Betrayed, The Case Against the Information Quality Act*, Center for Progressive Reform (Feb. 2005), *supra* at p. 7.
- ⁵² *Id.*, at p. 7. See also Sidney A. Shapiro, Rena Steinzor and Margaret Clune, *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, Center for Progressive Policy Reform, CPR White Paper #601 (Feb. 2006), *supra* at pp. 2, 7.
- ⁵³ See Sidney A. Shapiro, Rena Steinzor and Margaret Clune, *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, Center for Progressive Policy Reform, CPR White Paper #601 (Feb. 2006), *supra* at p. 8.
- ⁵⁴ See Thomas O. McGarity, Sidney A. Shapiro, Rena I. Steinzor, Joanna Goger and Margaret Clune, *Truth and Science Betrayed, The Case Against the Information Quality Act*, Center for Progressive Reform (Feb. 2005), *supra* at p. 9.
- ⁵⁵ See Wendy E. Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 Journal of Law and Policy 589 (2005), *supra* at 590.
- ⁵⁶ *Id.*, at pp. 590-591.
- ⁵⁷ See Thomas O. McGarity, *On the Prospect of 'Daubertizing' Judicial Review of Risk Assessment*, 66 Law and Contemporary Problems, 155, 156 (Autumn 2003), available at: <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1298&context=lcp> (discussing the gatekeeper role that

the U.S. Supreme Court had assigned to federal district courts hearing cases involving expert testimony, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)).

⁵⁸ See Wendy E. Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 *Journal of Law and Policy* 589 (2005), *supra* at p. 597.

⁵⁹ See Holly Doremus, *Data Gaps in Natural Resource Management: Sniffing for Leaks along the Information Pipeline*, 83 *Ind. L.J.* 407, 441 (2008), available at: <http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=2601&context=facpubs>.

⁶⁰ See Thomas O. McGarity, *On the Prospect of 'Daubertizing' Judicial Review of Risk Assessment*, 66 *Law and Contemporary Problems*, 155, 156 (Autumn 2003), available at: <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1298&context=lcp>.

⁶¹ Wendy E. Wagner, *The Bad 'Science Fiction': Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 *Law and Contemporary Problems* 63 (Aug. 2003), *supra* at p. 102, citing Thomas O. McGarity, *On the Prospect of 'Daubertizing' Judicial Review of Risk Assessment*, 66 *Law and Contemporary Problems*, 155 (Autumn 2003), *supra*.

⁶² See *Schultz v. Akzo Nobel Paints*, 721 F.3d 426 (7th Cir. 2013).

⁶³ See United States Environmental Protection Agency Office of Research and Development, *Summary Report for the Workshop on Monte Carlo Analysis* EPA/630/R-96/010 (Sept. 1996), at Sec. 2.1.7, pp. 2-17 to 2-21, available at: <http://www.epa.gov/raf/publications/summary-report-workshop-monte-carlo.htm>.

⁶⁴ See United States Environmental Protection Agency, *Guiding Principles for Monte Carlo Analysis*, EPA/630/R-97/001 (March 1997), available at: <http://www.epa.gov/raf/publications/pdfs/montecar.pdf>.

⁶⁵ See United States Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment*, EPA/630/R-00/004 (Sept. 1986), available at: http://www.epa.gov/raf/publications/pdfs/CA%20GUIDELINES_1986.PDF; United States Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment*, NCEA-F-0644 (July 1999) Review Draft, available at: http://www.epa.gov/raf/publications/pdfs/CANCER_GLS.PDF; United States Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment*, EPA/630/P-03/001F (March 2005), available at: http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF (replacing EPA's original cancer risk assessment guidelines (1986) and its interim final guidelines (1999)).

⁶⁶ See United States Environmental Protection Agency, *Toxicological Review of Tetrachloroethylene (Perchloroethylene) (CAS No. 127-18-4) In Support of Summary Information on the Integrated Risk Information System (IRIS) - EPA/635/R-08/011A External Review Draft* (June 2008), available at: http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=475838.

⁶⁷ See, e.g., National Research Council, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Tetrachloroethylene*, (National Academies Press, Wash., D.C. 2010), at p. ix, available at: http://www.nap.edu/download.php?record_id=12863#.

⁶⁸ *Id.*, at p. 4.

⁶⁹ See Stephen Blacklocks and Michael Kruse, *Proof Of Causation In Recent Product Liability Cases*, Law360 (April 30, 2008), available at: http://www.hunton.com/files/Publication/028884d3-fc53-4773-88b8-83c8885e0197/Presentation/PublicationAttachment/2c9a4650-f252-4e1f-8370-3a83771688f1/Proof_Of_Causation.pdf; Cf. Christopher R.J. Pace, *Admitting and Excluding General Causation Expert Testimony: The Eleventh Circuit Construct*, 37 *American Journal of Trial Advocacy* 47, 49-50 (2013), available at: http://www.weil.com/~media/files/pdfs/Admitting_Excluding_General_Causation_Expert_Testimony.pdf

(discussing how the Eleventh Circuit Court of Appeals, in *McClain v. Metabolife International, Inc.*, 401 F.3d 1233, 1239 (11th Cir.), *reh'g denied*, 159 F. App'x 183 (11th Cir. 2005), "and its progeny [] addressed the need for an expert opinion on general causation to be tied closely to the product or chemical compound at issue in a lawsuit. It is not enough for an expert to opine that (1) similar products, related chemicals, or drugs within the same class can cause the injury or illness suffered by a plaintiff, or (2) a defendant's product or chemical compound can cause illnesses or injuries analogous to the injury or illness of the plaintiff. Rather, admissible general causation expert testimony must address whether the agent in question (be it a product or a chemical compound) can cause the specific injury in question.").

⁷⁰ Cf. Richard O. Faulk, *Schultz v. Akzo Nobel Paints: "The Rest of the Story" Reveals Limited Impact of Expert Testimony Decision*, Washington Legal Foundation Legal Backgrounder Vol. 28 No. 15 (Sept. 27, 2013), available at: http://www.wlf.org/publishing/publication_detail.asp?id=2400.

⁷¹ See Wendy E. Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 *Journal of Law and Policy* 589 (2005), *supra* at 613.

⁷² *Id.*, at fn. 93, citing United States Environmental Protection Agency Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, EPA 100/B-03/001 (June 2003), at Foreword, available at: <http://www.epa.gov/stpc/pdfs/assess2.pdf>; United States Environmental Protection Agency, *Notice of Availability - A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, 68 Fed. Reg. 39086 (July 1, 2003), available at: <http://www.gpo.gov/fdsys/pkg/FR-2003-07-01/pdf/03-16328.pdf>; United States Environmental Protection Agency, Memorandum Re: Council for Regulatory Environmental Modeling (“CREM”) (Feb. 7, 2003), available at: http://www.thecre.com/pdf/whitman_memo.pdf.

⁷³ *Id.*, at fn. 93, citing Office of Management and Budget, *Notice of Request for Comments - Proposed Bulletin on Peer Review and Information Quality*, 68 FR 54023 (Sept. 15, 2003), available at: <http://www.gpo.gov/fdsys/pkg/FR-2003-09-15/pdf/03-23367.pdf>.

⁷⁴ See Florida International University, *Foreseeability in Tort Law*, Legal Studies Institute – University College, available at: <http://www2.fiu.edu/~rodrigjm/Torts%20Chapter%204.pdf>. See also Jale Tosun, “Risk Regulation in Europe: Assessing the Application of the Precautionary Principle,” (Springer 2012) at pp.41-42, accessible at: <http://books.google.com/books?id=K6OqfTE7IvgC&pg=PA40&lpg=PA40&dq=prevention+principle+%2B+risk&source=bl&ots=M2r6MoWDAi&sig=whX62bxTpPRjydPlscTIN0pMCRU&hl=en&sa=X&ei=6ZH4UJ72OqWT0QGZy4CwCw&ved=0CEkQ6AEwBDgK#v=onepage&q=prevention%20principle%20%2B%20risk&f=false> (describing the prevention principle and distinguishing it from the precautionary principle); Miriam Haritz, *An Inconvenient Deliberation: The Precautionary Principle’s Contribution to the Uncertainties Surrounding Climate Change Liability*, (Kluwer Law 2011) at p. 77, accessible at: <http://books.google.com/books?id=vGKYkLHWzaoC&pg=PA77&lpg=PA77&dq=prevention+principle+%2B+risk&source=bl&ots=YJ8yqQLclc&sig=0zKKJZffnMn3Z9CCwj04iMsw7YY&hl=en&sa=X&ei=6ZH4UJ72OqWT0QGZy4CwCw&ved=0CF4Q6AEwCDgK#v=onepage&q=prevention%20principle%20%2B%20risk&f=false>; Milieu Ltd, the T.M.C. Asser Institute and Pace, *Considerations on the Application of the Precautionary Principle in the Chemicals Sector*, Final Report prepared for the European Commission (Aug. 2011) at p. 15, accessible at: <http://ec.europa.eu/environment/chemicals/reach/pdf/Final%20report%20PP.pdf>.

⁷⁵ See Lawrence A. Kogan, *Hong Kong’s Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 1 of 3)*, Emerging Issues 7048 (Aug. 2013), at pp. 52-57, available at: <http://nebula.wsimg.com/81880bcab7203d97dc8ec73d4484d79a?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>; Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating Whether a Non-Tariff Measure has Matured into an Actionable Non-Tariff Barrier to Trade*, 28 American University International Law Review 489, 575-582, 611-612, available at: <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1769&context=auilr>; Lawrence A. Kogan, *WTO Ruling on Biotech Foods Addresses, “Precautionary Principle,”* Washington Legal Foundation Legal Backgrounder, Vol. 21 No. 38 (Dec. 8, 2006), available at: <http://www.wlf.org/upload/120806kogan.pdf>; Lawrence A. Kogan, *The Precautionary Principle and WTO Law: Divergent Views Toward the Role of Science in Assessing and Managing Risk*, Seton Hall Journal of Diplomacy and International Relations 77, Vol. 5 No. 1 (2004), available at: <http://www.isn.ethz.ch/Digital-Library/Publications/Detail/?ots591=0c54e3b3-1e9c-be1e-2c24-a6a8c7060233&lng=en&id=29789>; http://blogs.shu.edu/diplomacy/files/archives/6_kogan.pdf.

⁷⁶ See United Nations, *Agenda 21, Chapter 17 – Protection of the Oceans, All Kinds of Seas, Including Enclosed and Semi-Closed Seas, and Coastal Areas and the Protection, Rational Use and Development of Their Living Resources*, United Nations Conference on Environment & Development (Rio de Janeiro, Brazil, 3 to 14 June 1992), available at: <http://sustainabledevelopment.un.org/content/documents/Agenda21.pdf>.

⁷⁷ See Robin Kundis Craig, *Sustaining the Unknown Seas: Changes in U.S. Ocean Policy and Regulation Since Rio ’92*, 32 Environmental Law Reporter 10190, 10206, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=922508 (discussing how, since the Rio Conference, “the United States has only begun to shift away from the paradigm of inexhaustibility to a new paradigm of sustainable use and precautionary thinking”). See also *Id.*, at pp. 10192, 10901.

⁷⁸ See Robin Kundis Craig, *Oceans and Estuaries: The Ocean Commissions’ Unfulfilled Vision*, in *Agenda for Sustainable America*, Chapter 15, Environmental Law Institute, (J. Dernbach, ed. Jan 2009), at pp. 221, 222-237, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=983549; http://www.agendaforasustainableamerica.com/aboutbook_contents.htm (discussing the overall goal of Chapter 17 of Agenda 21 in the context of environmental management of the oceans).

⁷⁹ See Robin Kundis Craig, *Sustaining the Unknown Seas: Changes in U.S. Ocean Policy and Regulation Since Rio ’92*, 32 Environmental Law Reporter 10190, *supra* at 10206, discussed and cited in Lawrence A. Kogan, *What Goes*

Around Comes Around: How UNCLOS Ratification Will Herald Europe's Precautionary Principle as U.S. Law, 7 Santa Clara J. Int'l L. 23 (2009) at p. 94, available at: <http://digitalcommons.law.scu.edu/scujil/vol7/iss1/2/> (arguing that the Clean Water Act's lack of defined water quality standards precludes the EPA from regulating land-based activities that threaten ocean water quality).

⁸⁰ *Id.*, at p. 10196, 10198-10200 (arguing how Agenda 21 obligates coastal state governments to adopt coastal zone management procedures that foster the “sustainable development of coastal areas and the marine environment under their national Jurisdiction,” how such procedures include “applying ‘preventive and precautionary approaches”).

⁸¹ *Id.*, at 10212.

⁸² See Noah Sachs, *Rescuing the Strong Precautionary Principle from its Critics*, 2011 U. Ill. L. Rev. 1285, at p. 1288, available at: <http://scholarship.richmond.edu/cgi/viewcontent.cgi?article=1060&context=law-faculty-publications>. Professor Sachs’ definition of the ‘strong’ precautionary principle “parallels the Wingspread Statement, a document on precaution...directed at emerging toxic risks, such as endocrine-disrupting chemicals.” *Id.*, at p. 1296.

⁸³ *Id.*, at p. 1295.

⁸⁴ *Id.*, at p. 1293.

⁸⁵ *Id.*, at pp. 1289-1290.

⁸⁶ Professor Sachs criticizes this author as being opposed to a precautionary approach/the weak precautionary principle as well as a strong precautionary principle. *Id.*, at pp. 1290, 1294, 1305, 1307, 1315. See, e.g., Lawrence A. Kogan, *Revised U.S. Deep Seabed Mining Policy Reflects UNCLOS and Other International Environmental Law Obligations*, Lexis-Nexis 2013 Emerging Issues 6893 (2013), at p. 14, fn 71, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2216654.

⁸⁷ *Id.*, at p. 1290.

⁸⁸ *Id.*, at pp. 1290-1291.

⁸⁹ See Rebecca M. Bratspies, *Trail Smelter's (Semi)Precautionary Legacy*, in “Transboundary Harms in International Law: Lessons From the Trail Smelter Arbitration,” (Rebecca Bratspies, Russell Miller, eds., Cambridge Univ. Press, 2005-2006), at p. 2, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=893215.

⁹⁰ See Rebecca M. Bratspies, *Sustainability: Can Law Meet the Challenge?*, 34 Suffolk Transnational Law Review 283 (2011), at p. 313, fn. 112, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1993331.

⁹¹ See Rebecca M. Bratspies, *Rethinking Decisionmaking in International Environmental Law: A Process-Oriented Inquiry into Sustainable Development*, 32 Yale Journal of International Law 369 (2007), at p. 387, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=987029, quoting Phillippe H. Martin, *If You Don't Know How To Fix It, Please Stop Breaking It! The Precautionary Principle and Climate Change*, 2 Foundations of Science 263, 264 (1997) (citing “Interpreting the Precautionary Principle”, (Tim O’Riordan et al. eds., 1997)).

⁹² *Id.*, at p. 388.

⁹³ *Id.*, at p. 389.

⁹⁴ *Id.*

⁹⁵ See Rebecca M. Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. Environmental Law Journal 297 (2002), at pp. 304-305, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=353320.

⁹⁶ *Id.*, at pp. 308.

⁹⁷ *Id.*, at pp. 318-319.

⁹⁸ *Id.*, at pp. 320-321.

⁹⁹ *Id.*, at pp. 321-322.

¹⁰⁰ See Rebecca M. Bratspies, *Farming the Genetically Modified Seas—The Perils and Promise of Transgenic Salmon*, American Fisheries Society Symposium 62:xxx (2008), at p. 8, available at: <http://bioeng.fisheries.org/proofs/igfe/bratspies.pdf>.

¹⁰¹ See Holly Doremus, *Precaution, Science, and Learning While Doing in Natural Resource Management*, 82 Washington Law Review 547, 550, 560 (2007), available at: <https://digital.law.washington.edu/dspace-law/bitstream/handle/1773.1/205/82washrev547.pdf?sequence=1> (*inter alia* distinguishing between the roles of science and precaution).

¹⁰² *Id.*, at pp. 552-553.

¹⁰³ *Id.*, at pp. 555-556.

¹⁰⁴ *Id.*, at pp. 556-557.

¹⁰⁵ *Id.*, at p. 557.

¹⁰⁶ See Carl F. Cranor, Toward Understanding Aspects of the Precautionary Principle, 29 Journal of Medicine and Philosophy, No. 3 (2004), at pp. 259-260, available at: <http://www.glerl.noaa.gov/seagrant/ClimateChangeWhiteboard/Resources/Uncertainty/climatech/cranor04PR.pdf>.

¹⁰⁷ *Id.*, at p. 274.

¹⁰⁸ *Id.* Cf. John H. Weisburger, *The 37 Year History of the Delaney Clause*, 48 Experimental and Toxicologic Pathology, Issues 2-3, pp. 183-188 (Elsevier Publ. 1996), at Executive Summary, available at: <http://www.sciencedirect.com/science/article/pii/S0940299396800406>.

¹⁰⁹ See *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 17-18 (1st Cir. 2011), rev'g 664 F. Supp. 2d 137 (D. Mass. 2009), available at: http://scholar.google.com/scholar_case?case=11690110151960979103&q=milward+v.+acuity+specialty+products+group,+inc.&hl=en&as_sdt=6,31&as_vis=1 (explaining the six steps necessary to arrive at an 'inference to the best explanation').

¹¹⁰ See Carl F. Cranor, *Milward v. Acuity Specialty Products: Advances in General Causation Testimony in Toxic Tort Litigation*, 3 Wake Forest Journal of Law & Policy 105, 113-115 (2013), available at: <http://lawpolicyjournal.law.wfu.edu/files/2013/04/Vol.3-1-Article-Cranor.pdf> (discussing the weight-of-the-evidence approach to non-deductive reasoning).

¹¹¹ See Carl Cranor, *Milward v. Acuity Specialty Products: How the First Circuit Opened Courthouse Doors for Wronged Parties to Present Wider Range of Scientific Evidence*, CPR Blog (July 25, 2011), available at: <http://progressivereform.org/CPRBlog.cfm?idBlog=616EE094-D602-ED68-85FD84E7EB0A212E> (discussing how the First Circuit Court recognized a strict line between the role of judge as gatekeeper of reliable testimony and the jury's role as finder of fact on scientific issues).

¹¹² For criticisms of the First Circuit Court's *Milward* decision, see Apryl Underwood, *Rejecting Milward: A "Weight of the Evidence" Methodology is No Methodology At All*, Barnes & Thornburg Toxic Tort Practice Update (2012), available at: <http://www.btlaw.com/files/Uploads/Documents/Publications/Toxic%20Tort%20Update%20-%20A%20Underwood%20July%202012.pdf>; Eric Lasker, "Manning the Daubert Gate: A Defense Primer in Response to *Milward v. Acuity Specialty Products*," Defense Counsel Journal (April 2012), available at: <http://www.hollingsworthllp.com/media/pnc/7/media.787.pdf>; Nathan A. Schachtman, *Milward — Unhinging the Courthouse Door to Dubious Scientific Evidence*, Nathan A. Schachtman, Esq., P.C., (Sept. 2, 2011), available at: <http://schachtmanlaw.com/milward-unhinging-the-courthouse-door-to-dubious-scientific-evidence/>.

¹¹³ "The *Third Edition of the Reference Manual on Scientific Evidence* also endorses the use of such scientific inferences in several articles, and further notes that this procedure is quite appropriate for toxicology and for circumstances in which toxicological, epidemiological, and other scientific evidence must be considered together." See Carl F. Cranor, *Milward v. Acuity Specialty Products: Advances in General Causation Testimony in Toxic Tort Litigation*, 3 Wake Forest Journal of Law & Policy 105 (2013), *supra* at pp. 115-116.

¹¹⁴ See Federal Judicial Center, *Reference Manual on Scientific Evidence Third Edition*, Federal Judicial Center Committee on the Development of the Third Edition of the Reference Manual on Scientific Evidence and the National Research Council Committee on Science, Technology, and Law, (National Academies Press, Wash., D.C. 2011), available at: http://www.nap.edu/catalog.php?record_id=13163; relevant excerpts available at: <https://nebula.wsimg.com/bff4d42fdd9475c94fb48ef0f5d15cce?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>

¹¹⁵ See Federal Judicial Center, FJC website, available at: <http://www.fjc.gov/> ("The Federal Judicial Center is the education and research agency for the federal courts.") *Id.*

¹¹⁶ See Federal Judicial Center, *Reference Manual on Scientific Evidence Second Edition* (2000), available at: [http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/\\$file/sciman00.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/$file/sciman00.pdf); relevant excerpts available at: <https://nebula.wsimg.com/6c8558e6095ce2c1ddd908e45114d696?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1>.

¹¹⁷ See *Milward v. Acuity Specialty Products. Group, Inc.*, 639 F.3d 11, 18-19 (1st Cir. 2011), rev'g 664 F. Supp. 2d 137 (D. Mass. 2009), *supra*. Cf. *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 196 (5th Cir. 1996) (holding that the 'weight of the evidence' methodology used by federal agencies such as IARC, OSHA and EPA "to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure" was not "scientifically acceptable" for establishing a causal link in tort litigation.).

¹¹⁸ See *Mitchell v. Gencorp Inc.*, 165 F. 3d 778, 783 n.3 (10th Cir. 1999) (holding that "The methodology employed by a government agency 'results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances.'") See also Knight S. Anderson, *Government Action Does Not Equal Proximate Causation*, American Bar Association (June 11, 2012), available at:

<http://apps.americanbar.org/litigation/committees/products/articles/spring2012-government-action-not-proximate-causation.html>.

¹¹⁹ See Center for Progressive Reform, *Lisa Heinzerling*, available at: <http://www.progressivereform.org/heinzerlinglisabio.cfm> (“From January 2009 to July 2009, she served as Senior Climate Policy Counsel to the Administrator of the Environmental Protection Agency and then, from July 2009 to December 2010, she served as Associate Administrator of EPA’s Office of Policy. In 2008, she served as a member of President Obama’s EPA transition team.”).

¹²⁰ See Jeremy P. Jacobs, *Lisa Heinzerling Won't Back Down*, Greenwire (May 27, 2014), available at: <http://www.eenews.net/stories/1060000220> (discussing Professor Heinzerling is widely credited with crafting the legal strategy of a coalition of states and environmental groups in *Massachusetts v. EPA*).

¹²¹ See Lisa Heinzerling, *Introduction: Climate Change at EPA*, 64 Fla. L. Rev. 1, 6-7 (2012), available at: <http://scholarship.law.ufl.edu/flr/vol64/iss1/1/> (discussing how EPA has accessed and strengthened the climate-related materials it had prepared during the Bush Administration to arrive at its 2009 GHG Endangerment Findings).

¹²² See Lisa Heinzerling, *Knowing Killing and Environmental Law*, 14 N.Y.U. Env'tl. L.J. 521, 526-527, 533-534 (2006), available at: <http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1323&context=facpub> (likening the use of cost-benefit analysis in the context of life-threatening environmental risks to “pre-killing,” and arguing that addressing environmental risks in statistical terms through use of cost-benefit analysis, which is based on manufactured public consent rather than on people’s “real consent”, reflects that society’s discussion of environmental policy is “impooverished by its lack of attention to our underlying moral commitments.”) *Id.*

¹²³ See Cass Sunstein, *Your Money or Your Life - Book Review of Priceless: On Knowing the Price of Everything and the Value of Nothing*, by Frank Ackerman and Lisa Heinzerling, The New Republic Online (March 11, 2004), available at: http://www.powells.com/review/2004_03_11 (discussing how Professor Heinzerling and colleague Frank Ackerman want to replace cost-benefit analysis with the European-style precautionary principle).

¹²⁴ Professor Heinzerling’s coauthor, Frank Ackerman, is also CPR Member “Scholar.” See Center for Progressive Reform, Frank Ackerman, available at: <http://www.progressivereform.org/AckermanFrankbio.cfm>.

¹²⁵ See Lisa Heinzerling, *Climate Change, Human Health, and the Post-Cautionary Principle*, O’Neill Institute for National and Global Health Law Scholarship Research Paper No. 4 (Sept. 2007), available at: http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1003&context=ois_papers (arguing that the international scientific consensus that climate change is now occurring as the result of anthropogenic greenhouse gas emissions requires humankind to assume a moral obligation to change our behavior immediately).

¹²⁶ See Lisa Heinzerling, *Doubting Daubert*, 14 J. L. & Pol’y 65, 79 (2006), available at: [http://www2.law.columbia.edu/fagan/courses/law_socialscience/documents/Spring_2006/Class%203-Developments%20in%20Federal%20Rules%20of%20Evidence/Heinzerling_Doubting_Daubert\[1\].pdf](http://www2.law.columbia.edu/fagan/courses/law_socialscience/documents/Spring_2006/Class%203-Developments%20in%20Federal%20Rules%20of%20Evidence/Heinzerling_Doubting_Daubert[1].pdf).

¹²⁷ *Id.*, citing Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 Cornell L. Rev. 773, 791-95 (1997).