Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Critical Legal Issues: WORKING PAPER SERIES

REVITALIZING THE INFORMATION QUALITY ACT AS A PROCEDURAL CURE FOR UNSOUND REGULATORY SCIENCE: A GREENHOUSE GAS RULEMAKING CASE STUDY

Lawrence A. Kogan, Esq.

Introduction
Dr. John D. Graham, Indiana University

Foreword
Jim J. Tozzi, Center for Regulatory Effectiveness

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 191
February 2015

TABLE OF CONTENTS

ABOUT WLF'S LEGAL STUDIES DIVISION

Washington Legal Foundation (WLF) established our Legal Studies division in 1986 to address cutting-edge legal issues through producing and distributing substantive, credible publications designed to educate and inform judges, policy makers, the media, and other key legal audiences.

Washington is full of policy centers of one stripe or another. From the outset, WLF's Legal Studies division adopted a unique approach to set itself apart from other organizations in several ways.

First, Legal Studies focuses on legal matters as they relate to sustaining and advancing economic liberty. The articles we solicit tackle legal policy questions related to principles of free enterprise, individual and business civil liberties, limited government, national security, and the rule of law.

Second, WLF's publications target a highly select legal policy-making audience. We aggressively market our publications to federal and state judges and their clerks; Members of Congress and their legal staff; executive branch attorneys and regulators; business leaders and corporate general counsel; law professors; influential legal journalists, such as the Supreme Court press; and major media commentators.

Third, Legal Studies operates as a virtual legal think tank, allowing us to provide expert analysis of emerging issues. Whereas WLF's in-house appellate attorneys draft the overwhelming majority of our briefs, Legal Studies possesses the flexibility to enlist and the credibility to attract authors with the necessary background to bring expert perspective to the articles they write. Our authors include senior partners in major law firms, law professors, sitting federal judges, and other federal appointees.

But perhaps the greatest key to success for WLF's Legal Studies project is the timely production of a wide variety of readily intelligible but penetrating commentaries with practical application and a distinctly commonsense viewpoint rarely found in academic law reviews or specialized legal trade journals. Our eight publication formats are the concise COUNSEL'S ADVISORY, topical LEGAL OPINION LETTER, provocative LEGAL BACKGROUNDER, in-depth WORKING PAPER, useful and practical CONTEMPORARY LEGAL NOTE, informal CONVERSATIONS WITH, balanced ON THE MERITS, and comprehensive MONOGRAPH.

WLF's LEGAL OPINION LETTERS and LEGAL BACKGROUNDERS appear on the LEXIS/NEXIS® online information service under the filename "WLF," and every WLF publication since 2002 appears on our website at www.wlf.org.

To receive information about previous WLF publications, or to obtain permission to republish this publication, please contact Glenn Lammi, Chief Counsel, Legal Studies, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, D.C. 20036, (202) 588-0302, glammi@wlf.org.

ABOUT THE AUTHOR

Lawrence A. Kogan is managing principal of New York City-based The Kogan Law Group, P.C., a multidisciplinary legal services firm assisting U.S. and non-U.S.-based public and private enterprises. He is also chief executive of the nonprofit Institute for Trade, Standards and Sustainable Development based in Princeton Junction, New Jersey. Mr. Kogan has served as an Adjunct Professor of International Trade Law at the John C. Whitehead School of Diplomacy and International Relations at Seton Hall University, South Orange, New Jersey.

INTRODUCTION

By
Dr. John D. Graham[1]

The impetus behind the Information Quality Act ("IQA"), which implements the Paperwork Reduction Act, was to ensure, as a matter of good governance, that the scientific and technical information U.S. federal agencies use is of good quality. The information might be internally developed at the agency or acquired from external sources. The Act's provisions apply when the agency ultimately disseminates the information to the public, especially as the foundation for major agency decisions and rulemakings.

Consistent with Congress's objective, the Office of Management and Budget ("OMB") subsequently developed IQA guidelines and a bulletin that establish a uniform *process* of internal and external peer review modeled largely after procedures employed by the National Research Council of the National Academy of Sciences. OMB guidance subjects highly influential scientific assessments to more rigorous and less discretionary peer-review-process standards than less influential scientific information. The required peer-review process has substantive as well as procedural elements, and imposes identification, disclosure, and resolution obligations upon agency managers. Guidance for addressing peer reviewer independence and conflicts of interest is also provided by OMB.

The IQA and OMB guidance are also intended to fulfill the time-honored public policy objective of ensuring stakeholders due process of law. They require federal agencies to provide affected stakeholders the opportunity to seek correction of poor quality scientific and technical data prior to or after its dissemination. To avoid duplication of administrative processes, agencies are permitted to treat requests for corrections ("RFCs") received during notice-and-comment rulemaking under familiar Administrative Procedure Act ("APA") procedures, if such requests can be adequately addressed as a matter of due process. Given the complex technical nature of much scientific data, computer models, applications, assumptions and extrapolations, however, OMB's guidelines recognize that special administrative review proceedings may be necessary, in certain instances. Stakeholders that are dissatisfied with the disposition of their requests may thereafter appeal them to the agency.

The WORKING PAPER attorney Lawrence Kogan has produced on this subject matter is quite detailed and informative. It clearly conveys the IQA's key concepts and explains how OMB guidance serves the public interest by endeavoring to protect a stakeholder's right not to be burdened by poor quality government-disseminated scientific and technical data. The manuscript also focuses on what IQA opponents have seized upon as its major putative weakness—the statute's failure to expressly provide for judicial review. As Mr. Kogan correctly states, while "[a]gencies and their allies may believe that requests for correction are beyond the scrutiny of courts, … this is not a conviction that OMB—the agency Congress charged with the IQA's implementation—necessarily shares." For this reason, a 2002 OMB memorandum admonished agencies against including within their guidelines any statements that "suggest they are free to disregard their own guidelines," and statements disclaiming

[1] Dr. Graham is Dean of the School of Public and Environmental Affairs at Indiana University. From 2001 to 2006, he was Administrator of the Office of Information and Regulatory Affairs ("OIRA") at OMB.

judicial enforceability, which "might not be controlling in the event of litigation."

It is on this final point that the paper arguably makes the greatest contribution to public understanding of the potential reach of the IQA. Although I am not a lawyer, I can fully appreciate the care he has taken in analyzing the IQA and PRA statutes and the relevant IQA, APA and constitutional jurisprudence to date. I agree with his conclusion that Congress did intend for courts to determine the reviewability of agency denials of RFCs on a case-by-case factual basis.

FOREWORD

By
Jim J. Tozzi[2]

Lawrence Kogan has identified and proposed a solution to the one impediment which has stopped the Information Quality Act ("IQA") from realizing its full potential—judicial review of actions taken pursuant to the statute. In so doing, he has also highlighted the immense reach of the IQA's peer review guidelines. Mr. Kogan also dispels the myth that Congress passed the IQA with no hearings, by providing numerous citations to the public statements of Members and witnesses who appeared before the House Appropriations Committee.

Mr. Kogan's paper is encyclopedic and scholars may differ on some of the points made therein, but it should be noted that the endgame is to demonstrate that Congress enacted a statute which, when implemented in an enthusiastic manner, will ensure that federal agencies provide the American public with reliable and reproducible data. He also gives a detailed description of the plethora of judicial cases involving the IQA, which readily leads the reader to the conclusion that the reviewability of the IQA is unsettled. To this end, Mr. Kogan makes an important point seldom raised by others who have written on the IQA; namely "that a court's 'hard-look' or 'arbitrary and capricious' review of federal agency action … should include a review of the quality of data inputs" *i.e.*, compliance with the IQA.

The challenge is to put Mr. Kogan's recommendations into practice, many of which the United States Department of Justice opposes.[3] Mr. Kogan identifies one candidate for potential legal challenge—EPA's Clean Air Act Endangerment Findings—which could fulfill that purpose. Another possible target of the type of IQA challenge he proposes would be against EPA's failure to conduct a peer review of "highly influential scientific information" in its determination that carbon storage and sequestration is a viable technology—the central component of its proposed rule to control emissions from new gas-fired power plants.[4]

One additional point readers of this WORKING PAPER should consider is the potential use of the Office of Management and Budget ("OMB") as another channel for correcting information disseminated by federal agencies. Nothing in the IQA prevents OMB from becoming directly involved in agency responses to requests for correction. In fact, the statute indicates that OMB is the "lead agency" in the IQA's implementation.

This WORKING PAPER offers a roadmap for precedential action that would establish the IQA's reviewability, and at the same time ensure that costly agency initiatives are science-based. One hopes a regulatory stakeholder will soon utilize Mr. Kogan's ideas in a successful court challenge.

---

[2] Mr. Tozzi is an advisor to the Center for Regulatory Effectiveness. He a former regulatory official of the White House Office of Management and Budget, and was instrumental in the establishment of the Office of Information and Regulatory Affairs in OMB, the Paperwork Reduction Act, and the Information Quality Act.

[3] *See, e.g.*, http://thecre.com/pdf/20100603_Government_DQA_Appeal_to_Court.abrev.pdf.

[4] *See* http://www.thecre.com/forum10/?p=198.

EXECUTIVE SUMMARY

Congress passed the Information Quality Act (IQA) in 2000 to implement and amend the Paperwork Reduction Act. The law requires federal agencies to ensure the quality, objectivity, utility, and integrity of the scientific, technical, and statistical information that federal agencies adopt and disseminate to the public. Although the law is nominally a procedural statute, this WORKING PAPER explains how regulated entities and other stakeholders can successfully seek judicial enforcement of the IQA when agencies rely upon flawed science for federal rules, and those rules impose paperwork, compliance, and other burdens.

The Office of Management and Budget (OMB) is responsible for implementing the IQA. OMB's IQA Guidelines required that each federal agency develop and adhere to their own IQA guidelines, and set out minimum criteria for scientific peer review of agency-drafted and third-party studies and scientific assessments, as well as criteria for the selection of peer reviewers. OMB dictated that these peer-review standards be especially rigorous for "highly influential scientific assessments." Federal agencies must also provide an administrative review mechanism that will allow affected entities to seek correction of agency-disseminated information that was not adequately validated. Agencies routinely carry out this mandate by addressing requests for correction as part of their responses to public comments in a final regulation—an approach, the paper argues, that does not afford sufficient due process to stakeholders.

The Environmental Protection Agency's (EPA) 2009 greenhouse gas Endangerment Findings, and the decision-making process underlying them, offers an instructive IQA case study. A review of the extensive record and the peer review activities underlying the Findings reveals extensive violations of conflict-of-interest and other IQA-related standards. EPA also did not consider stakeholders' challenges regarding these violations in a timely or sufficiently specialized manner. Stakeholders' requests for reconsideration of the Findings were also rejected.

Stakeholders faced with such adverse, final agency actions would traditionally consider legal action against the responsible federal agency. As the WORKING PAPER explains, however, federal courts have been generally skeptical of regulated entities' private causes of action to redress agencies' noncompliance with IQA standards. Those complaints have foundered on plaintiffs' standing to sue, as well as their assertion of a *positive* right to properly peer-reviewed government information.

This paper proposes an alternative approach to judicial enforcement of the IQA, one which addresses past lawsuits' shortcomings. It explains this alternative approach in the context of a challenge to EPA's violation of IQA during its development of the Endangerment Findings. The contemplated cause of action is based on the theory that Congress intended that the IQA, as an implementation of the Paperwork Reduction Act, protect the *negative* right of a designated class of persons not to be burdened, financially or otherwise, by poor quality science that agencies disseminate in support of major regulations. The lawsuit would formally be brought as an action under the Administrative Procedure Act (APA).

Private entities, such as regulated businesses could establish standing to sue based on the particularized economic injuries they have suffered from regulatory burdens. State governments could take advantage of U.S. Supreme Court precedents that convey standing

under the doctrine of *parens patriae* when such public actors are suing in their quasi-sovereign capacity. A narrowly-pled, factually-supported challenge utilizing the APA would not only be consistent with the longstanding presumption that Congress intends judicial review of administrative action, but it would also be sufficient to overcome some federal courts' presumption against implied causes of action.

Fueled by decades of ineffective oversight, federal agencies' respect for science and the scientific process has severely diminished. For that reason, one can easily foresee many potential applications of the enforcement framework offered in this paper. Other actions by EPA where stakeholders have strongly questioned the supporting science could be particularly inviting targets as well. They include: EPA's "Waters of the United States" proposal; its social cost of carbon proposal; its proposed ozone regulations; its NEPA review of the Keystone XL pipeline; its study on the impacts of hydraulic fracturing; and EPA and NOAA disapproval of state coastal nonpoint pollution control programs. Another possible target could be the Fish and Wildlife Service's threatened or endangered species designations.

REVITALIZING THE INFORMATION QUALITY ACT AS A PROCEDURAL CURE FOR UNSOUND REGULATORY SCIENCE: A GREENHOUSE GAS RULEMAKING CASE STUDY

by
Lawrence A. Kogan, Esq.

I. PURPOSE OF PAPER: ENSURING RESPECT FOR REGULATORY SCIENCE

The Information Quality Act ("IQA"), passed by Congress in 2000, is a procedural statute that requires federal agencies to ensure the quality, objectivity, utility, and integrity of the scientific, technical, and statistical information that federal agencies adopt and disseminate to the public. The IQA's peer-review process standards apply to all federal agencies, most critically those focused on protecting public health, safety, and the environment. The law requires agencies to issue information quality guidelines that must include mechanisms for affected entities to seek the correction of information that does not conform to the guidelines.

This WLF WORKING PAPER provides a detailed discussion of the IQA and explains how the public can use the law to ensure that the scientific information and assessments cited as support for federal regulations have been validated through use of the scientific method as required by federal law. Experts have referred to the application of scientific methods and tools from various scientific disciplines to agencies' development of regulations as "regulatory science." [1]

The paper is also meant to inform an ongoing congressional reexamination of federal agencies' use of science in the regulatory process and their compliance with the IQA. It pursues this goal through a case study of the Environmental Protection Agency's ("EPA") peer review of the twenty-eight third-party scientific assessments that supported the EPA Administrator's 2009 Clean Air Act Section 202(a) Greenhouse Gas Endangerment Findings.[2] The case study demonstrates that the Offices of Inspectors General at EPA[3] and the Department of Commerce[4] had previously conducted incomplete investigations of the peer-review processes EPA and the National Oceanic and Atmospheric Administration ("NOAA") employed to validate those climate science assessments, and consequently, that such EPA and NOAA processes had not satisfied either the Office of Management and Budget's ("OMB") IQA Guidelines or the agencies' own IQA guidelines.

Finally, the paper discusses stakeholders' largely unsuccessful effort to legally challenge IQA noncompliance under the Administrative Procedure Act ("APA"). Such challenges have mostly focused on the theory that stakeholders can establish constitutional standing under the APA to advance an implied "positive" right to obtain correct governmental information. An alternative framework for an IQA challenge is proposed in the paper's final section, one based on stakeholders' implied "negative" right to be

unburdened, financially or otherwise, by government regulation supported by improperly peer-reviewed science. Potential plaintiffs for such a cause of action include members of regulated industries and entities in their supply chain suffering particularized economic injuries, as well as State governments acting in their quasi-sovereign capacity pursuant to the doctrine of *parens patriae*.

II. THE RAPID GROWTH OF THE ADMINISTRATIVE STATE WARRANTS PRUDENT AND MEASURED IQA ENFORCEMENT

The administrative state[5] and the "statist" conception of legal rights[6] are rapidly expanding at the national and international levels.

Members of the legal academy, as well, remain engaged in a debate regarding whether the legitimacy of the modern administrative state can be justified on the basis of the following bargain: "we can take away those particular limitations that the Constitution provides so long as we substitute in alternative protections against the concentration of power that work as well as the ones they supplant."[7] Such a bargain "rests on the key assumption" that, in exchange for public deference to federal agency expertise on matters of technical substance, regulators have agreed, *in good faith*, to defer to the public on matters of process and procedure, with the goal of enabling fair and equitable administrative and, ultimately, judicial review of agency actions.[8] Columbia University School of Law Professor Peter Strauss and New York University School of Law Professor Richard Epstein call this bargain a *quid pro quo* of *"constitutional dimensions"* intended "to achieve the protections against the arbitrary application of power which the separation of powers…was designed to preserve."[9] Professor Epstein, however, has observed that this result is far from guaranteed, since "an unthinking administrative state poses unnecessary risk to common-law rights."[10]

University of Houston Law Center professor Jessica Mantel has proceeded to further analyze the sociological underpinnings of administrative law's legitimacy. She has found that its legitimacy depends almost entirely on the public's acceptance that government, including federal executive branch agencies, will actually adhere to the *processes and procedures* that Congress has enacted to hold government accountable to the public. In Professor Mantel's view, "[t]he success of our social contract depends first on those entrusted with governmental powers exercising their discretion for the benefit of 'we the people,' and second on citizens' acceptance of and obedience to the state's rules for organizing societal functioning and its allocation of public resources. Process plays a fundamental role in reinforcing both obligations."[11]

Michigan State University College of Law Professor Adam Candeub has gone even further in evaluating the hidden motivations of government officials who speak in terms of transparency but act in less than a transparent manner. In his estimation, transparency entails more than mere "access to information." Rather, "transparency is about lowering the cost of accessing information, particularly the cost of physical access to information in real-time data,"[12] *and* the cost of analyzing it. In addition to physical transparency, there must be "[c]omputational transparency, which "allows…us…to deduce the facts we want from those that are given to us."[13]

Moreover, U.S. Supreme Court Chief Justice John Roberts observed in *City of Arlington v. Federal Communications Comm'n* how administrative agencies, today, "as a

practical matter…exercise legislative power,…executive power…and judicial power…", and how the "accumulation of these powers in the same hands is not an occasional or isolated exception to the constitutional plan[, but rather] a central feature of modern American government."[14] He added in that *City of Arlington* dissent, joined by Justices Kennedy and Alito, "[t]he administrative state 'wields vast power and touches almost every aspect of daily life[,]"[15] and emphasized how "[t]he Framers could hardly have envisioned today's 'vast and varied federal bureaucracy' and the authority administrative agencies now hold over our economic, social, and political activities."[16]

Protection of an individual's common law rights and liberties in the current era, therefore, precariously depends on government's establishment, maintenance, and oversight of transparent and accountable procedural mechanisms that permit adversely affected citizens to challenge arbitrary and capricious federal agency actions. Such mechanisms include the Administrative Procedure Act ("APA"),[17] the Freedom of Information Act ("FOIA"),[18] the Federal Advisory Committee Act ("FACA"),[19] and the Government in the Sunshine Act.[20]

The IQA, a somewhat lesser-known statute, offers another device intended to promote government transparency and accountability, especially with respect to agency-disseminated "highly influential scientific assessments" ("HISAs") supporting major agency regulations. Congress passed the IQA on December 15, 2000, as part of an amended omnibus consolidated and supplemental appropriations bill for fiscal year 2001.[21] President Clinton signed the bill, including the IQA, into law on December 20, 2000.[22] Congress designed the IQA to affirm, implement, and amend[23] the requirements of the Paperwork Reduction Act ("PRA") of 1995,[24] which had in turn amended the Paperwork Reduction Act of 1980.[25] The OMB has long considered federal agency conformance with IQA standards as a critical element of regulatory impact analysis, a regulatory "best practice," and a complement to economic cost-benefit analysis.[26]

At least one legal commentator has concluded that a court's "hard-look" or "arbitrary and capricious" review of federal agency action should include a review of the quality of data "inputs" agencies consider, "the qualifications and independence of the information's source (particularly where agencies rely on outside studies for their data), whether an agency considered and responded to significant public comments, or whether it employed methodological protections such as peer review in its data acquisition."[27] These are precisely the factors the IQA's peer-review independence, conflict-of-interest, panel-balance, and administrative review standards were intended to address.

III. THE IQA'S INTENT AND PURPOSES

The chief policy objective of the PRA and its 1995 amendments was to "minimize the federal paperwork burden for individuals, small businesses, state and local governments, and other persons."[28] These burdens were both the financial and nonfinancial harms (including those related to regulatory compliance) caused by inaccurate government information, [29] limited contemporary information disclosure laws, and the lack of opportunity for public participation in information disclosure. The legislative history of the IQA and the 1995 PRA amendments reflects that Congress intended federal agencies to achieve this goal by: 1) maximizing and ensuring the quality, utility, integrity, and objectivity of the data agencies collected, created and/or disseminated to the public; *and* 2) improving

public access to agency information.[30]

Executive branch agencies, however, have thwarted regulated entities' efforts to enforce the IQA through court challenges. Those agencies likely feared, in part, that a "right" to accurate, properly peer-reviewed information would undermine their use of third-party studies and scientific assessments as support for precautionary environmental, health, and safety regulations.[31]

The IQA directed OMB to oversee all U.S. federal agencies' development of guidelines that ensure and maximize the quality, objectivity, utility, and integrity of the scientific and technical information they disseminate to the public. OMB interpreted[32] this information quality mandate as requiring federal-agency peer review of all scientific information[33] agencies adopt and publicly disseminate that qualifies as "influential scientific information" (ISI) or highly influential scientific assessments. The guidelines were to provide procedural protections when ISI or HISAs served as the basis for economically significant regulatory action.[34] HISAs are subject to a higher and more robust level of peer review than is ISI.[35] Requiring federal agencies to employ a robust scientific peer-review process to evaluate and validate the scientific information contained in ISI and HISAs is a powerful expression of regulatory transparency and government accountability. It also reduces the likelihood that regulations will be grounded on unsound science and trigger needless, precautionary compliance activity.

In addition, Congress meant to empower affected persons and entities with the right to challenge agencies' improper review of scientific data when those shortcomings imposed unnecessary compliance burdens. Federal agencies must afford stakeholders that present credible evidence a reasonable opportunity to seek correction or reconsideration of flawed ISI and HISAs in specialized administrative proceedings.[36] These proceedings must be capable of addressing complex, technical, and scientific issues, and must take place, in most cases, *prior* to agency enactment of regulations, unless the agency otherwise establishes such proceedings would cause undue delay to the regulatory process. In other words, such proceedings must guarantee affected persons due process of law.

IV. INFORMATION QUALITY REQUIREMENTS

A. Overview of OMB's Four Obligations

The IQA imposed four primary obligations on OMB. First, it required OMB to develop "policy and procedural" guidelines that obliged federal agencies to "ensur[e] and maximize[e] the quality, objectivity, utility and integrity of information" that they disseminate to the public."[37] Second, it required OMB to ensure that its guidelines governed the information shared between and among federal agencies as well as the information that federal agencies disseminated to the public.[38] Third, it required OMB to ensure that each federal agency, within one year of the IQA's enactment, developed its own guidelines or adopt the OMB guidelines[39] Fourth, OMB must require that each federal agency's guidelines, consistent with OMB's guidelines, provided for the establishment of an "administrative review mechanism[] allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with [OMB's] guidelines."[40]

The following discussion elaborates upon the key elements of the third and fourth of these obligations.

B. Information Quality Standards—Generally

OMB's IQA Guidelines define the term "quality" in an all-encompassing fashion. A "state" of information "quality" is achieved with respect to agency-disseminated information only where the "utility," "integrity," and "objectivity" of information are collectively established.[41]

OMB's guidelines provide that the "utility" of publicly disseminated agency information must be assessed with reference to its intended use, as well as from the perspective of its intended users, including both the agency *and* the public.[42] In effect, the disseminated agency information must be comprehensive, informative, and understandable, in both form and presentation.[43] It also must be made readily available and accessible to the public in order to achieve the necessary level of transparency.[44]

In addition, OMB's guidelines require agencies to maintain the "integrity" of publicly disseminated information by taking appropriate steps to protect such "information from unauthorized access or revision, to ensure […it] is not compromised through corruption or falsification."[45] This requirement applies as much to authors of the information as it does to the peer reviewers of such information.

Furthermore, OMB's guidelines establish a rebuttable legal presumption of "objectivity" in favor of formal, independent, external peer reviews of agency-disseminated scientific information or assessments.[46] To qualify for this presumption, agency-sponsored peer-review processes must meet the following *minimum* criteria:

> (a) peer reviewers [must] be selected primarily on the basis of necessary technical expertise[;] (b) peer reviewers [must] be expected to disclose to agencies prior technical/ policy positions they may have taken on the issues at hand[;] (c) peer reviewers [must] be expected to disclose to agencies their sources of personal *and institutional funding* (private or public sector)[;] and (d) peer reviews [must] be conducted in an open and rigorous manner."[47]

Satisfaction of these criteria, in turn, ensures that agencies have disseminated information in a transparent manner.

C. Federal Agency-Disseminated ISI and HISAs Must Satisfy Rigorous Standards of Substantive Peer Review

1. ISI and HISAs Defined

OMB's Peer Review Bulletin[48] explains that the presumption of "objectivity" in favor of peer review constitutes a mandate when federal agencies disseminate "important scientific information." Scientific information includes "factual inputs, data, [computer] models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences […] communicat[ed] or represent[ed] […] in any medium or form."[49]

Scientific information will be deemed "important" if it qualifies as "influential scientific information" or as a "highly influential scientific assessment."

Scientific information will be considered ISI if a federal agency reasonably can determine that it will or does have a clear and substantial impact on important public policies or private sector decisions, especially where it supports or is incorporated into a rulemaking.[50] Scientific information will be categorized as a "scientific assessment" if it evaluates a body of scientific or technical knowledge and synthesizes multiple factual inputs, data, computer models, underlying assumptions and the agency's professional judgment where there are gaps or uncertainties in available information.[51] Assessments include, for example, state-of-science reports, meta-analyses, weight-of-evidence analyses, integrated assessment models, hazard determinations, and exposure assessments.[52] A scientific assessment will be considered "highly influential" (*i.e.*, a HISA) if it "could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest."[53]

The OMB Peer Review Bulletin states, "[I]mportant scientific information *shall* be peer reviewed by qualified specialists *before* it is disseminated by the federal government."[54] While federal "agencies need not have further peer review conducted on [agency-developed or third-party-developed ISI] that has already been subjected to *adequate peer review*," they must conduct a peer review of all HISAs *de novo*, save for those developed by the National Research Council ("NRC") of the National Academy of Sciences ("NAS").[55]

Peer reviews of ISI and HISAs may be conducted either internally or externally—*i.e.*, they may be conducted and managed either by the federal agency itself or by an independent third-party entity the federal agency has commissioned to manage the peer review.[56] Both the NOAA and EPA have exercised their discretion to permit internal as well as external peer reviews of third-party information from both domestic and international sources, depending on the information's importance, consistent with this standard,[57] with EPA imposing relatively stricter standards for HISAs.

EPA's Peer Review Handbook, for example, states that for "economic work products supporting a highly influential scientific assessment [EPA] should conduct an external peer review."[58] It also states that "work products […] with large impacts (*e.g.*, those that support Tier 1 and Tier 2 rulemakings) […] clearly lend themselves to extensive external peer review."[59] In other words, "the more novel or complex the science or technology, the greater the cost implications of the impending decision, and the more controversial the issue, then the stronger the indication is for a more extensive and involved peer review and for external peer review in particular."[60] Consequently, the EPA Peer Review Handbook concludes that "[h]ighly influential scientific assessments *are expected to undergo external peer review*," whereas, for influential scientific information, "external peer review *is the approach of choice*"[61] An external peer review mechanism can consist of individual independent experts or an *ad hoc* panel of independent experts from outside the agency, an agency-sponsored peer review workshop, a "[r]eview by an *established* Federal Advisory Committee Act mechanism such as the Science Advisory Board ("SAB"), FIFRA Scientific Advisory Panel ("SAP"), ORD's Board of Scientific Counselors ("BOSC"), or the Clean Air Scientific Advisory Committee ("CASAC")" (as opposed to an *ad hoc* Federal Advisory Committee), an "Agency-appointed special board or commission," or a review by the NAS.[62]

The OMB Peer Review Bulletin also recognizes that while "the data and models [typically] used in scientific assessments [including HISAs] have already been subject to some form of peer review […scientific] information contain[ing] precedent-setting methods or models [and] conclusions […] likely to change prevailing practices or […] likely to affect policy decisions that have a significant impact […are in] need [of more] rigorous peer review."[63]

NOAA's IQA Guidelines, for example, provide that "interpreted products"[64] may be peer reviewed internally by agency staff or externally by formal, independent third parties, as long as the peer reviews are performed "by technically qualified individuals" who are not otherwise involved in the development of such products.[65]

EPA IQA Guidelines, meanwhile, strongly recommend *external* peer review for information products "support[ing] the most important decisions or hav[ing] special importance in their own right," and accept internal peer review for other information products.[66] EPA's Peer Review Handbook more clearly explains that, in most cases, ISI and HISAs "are expected to undergo external peer review."[67] HISAs should *always* be externally peer reviewed because they: 1) demand the ongoing involvement of the Administrator's office; 2) entail extensive cross-Agency and cross-media involvement; 3) engender highly controversial, precedent-setting issues and rulemaking actions with potentially major economic impacts (i.e., actions that are "economically significant per E.O. 12866"); and 4) "present a significant opportunity for the Agency to advance the Administrator's priorities" (a/k/a "Tier 1 rulemakings" or "Tier 1 actions").[68]

2. Rigorous Peer Review Standards Apply to Agency Disseminations of Internal and Third-Party-Developed ISI and HISAs

As noted above, both agency-developed *and* third-party-developed ISI and HISAs must be peer reviewed before they are publicly "disseminated." OMB's IQA Guidelines and its Peer Review Bulletin define the act of "agency information dissemination" that triggers the application of these IQA peer review standards as an "agency initiated *or* sponsored distribution of information to the public."[69] This means that a federal agency's release of a draft report or other information *solely for purposes of peer review* shall *not* be deemed a public dissemination if accompanied by a clearly and appropriately worded disclaimer.[70] The NOAA and EPA IQA Guidelines generally incorporate this standard.[71]

Federal agencies are *not* ordinarily considered to have publicly disseminated third-party information (*e.g.*, studies) obtained from private consultants, companies, private or non-profit organizations, universities or research institutes incident to their performance of ordinary government operations or activities. However, if a federal agency plans to use such third-party information "as the basis for an agency factual determination" or as the basis for agency regulations, *and* such information is "influential" (*i.e*., as ISI or a HISA), then the agency's use of that information will be treated as a public dissemination that is subject to the most rigorous IQA peer-review standards.[72]

OMB's Peer Review Bulletin further elaborates upon this point. To the extent a federal agency relies on internal agency or third-party-developed ISI or HISAs to support a regulatory action, the agency is required to include in the administrative record a certification explaining how it had satisfied the relevant OMB IQA Guideline and Peer Review

Bulletin peer-review standards.[73]

EPA's IQA Guidelines, for example, provide that the agency will be "deemed" to have initiated a distribution of third-party information to the public where EPA's distribution: 1) "reasonably suggests that EPA endorses or agrees with it;" 2) "indicates […] that the information supports or represents EPA's viewpoint;" or 3) reflects EPA's proposal to use or actual use of "the information to formulate or support a regulation, guidance, policy, or other Agency decision or position."[74] And, although an initial distribution of information by third parties may not be considered a public dissemination by EPA, "a subsequent dissemination of th[at] information in which EPA adopts, endorses, or uses the information to formulate or support a regulation, guidance, or other Agency decision or position" will be so construed.[75]

Similarly, NOAA's IQA Guidelines provide that NOAA's use, distribution, and/or release of third-party-prepared information also can constitute an "agency-initiated dissemination." This will occur, for example, where NOAA distributes third-party information "in a manner that reasonably suggests that the agency agrees with the information," or otherwise gives the appearance that "the information represent[s] agency views."[76]

3. Original and Supporting Data Related to Agency-Disseminated ISI and HISAs Must be Transparently Peer Reviewed and "Reproducible"

OMB's IQA Guidelines provide that a federal agency's dissemination of ISI and HISAs "*shall* include a high degree of transparency about *data and methods* to facilitate the reproducibility of such information by qualified third parties."[77] However, not all data and methods need be reproduced.[78] In other words, the disclosure of data and methods underlying agency-disseminated ISI and HISAs need only be sufficient to ensure that it can be "'substantially reproduced,' subject to an acceptable degree of imprecision."[79] With respect to agency analysis of data and methods, the level of transparency must be enough to enable a qualified member of the public to undertake an independent reanalysis of their original or supporting data and methods to arrive at a similar result[80]

The "reproducibility" standard was intended "to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed."[81] OMB's primary policy goal was to enable the public "to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency."[82]

Under NOAA's IQA Guidelines, for example, disseminations of third-party information used to develop agency regulations is held to a minimum transparency and quality threshold. First, all NOAA-used third-party information "must be of known quality and consistent with [the Agency's] information quality guidelines."[83] Second, "any limitations, assumptions, collection methods, or uncertainties" reflected in such information must "be taken into account and disclosed."[84] These requirements notwithstanding, the discussion in Section IV reflects that NOAA did not have quality control mechanisms in place for the use of external environmental data that would enable it to detect flaws until the third quarter of

2009.[85]

EPA's IQA Guidelines (which supplement existing agency Quality System standards for third-party-derived data and computerized or mathematical models of environmental processes[86]) and Peer Review Handbook require the peer review of all *influential* scientific and technical work products (*i.e.*, ISI and HISAs), including their "analytical methods, scientific database designs [and] technical models."[87] The EPA handbook also provides that environmental regulatory models should be peer reviewed, consistent with agency guidelines promulgated by EPA's Council for Regulatory Environmental Modeling ("CREM") that was established in 2000.[88] The CREM Guidelines, adopted in March 2009, generally call for the transparent peer review of the science underlying model-based decision-making vis-à-vis "comprehensive documentation of all aspects of a modeling project" and "effective communication between modelers, analysts, and decision makers" to "ensure[] that there is a clear rationale for using a model for a specific regulatory application."[89] They also require EPA to engage in "model evaluation" to determine "when a model, despite its uncertainties, can be appropriately used to inform a decision."[90] Indeed, the CREM Guidelines emphasize that, "*[p]eer review* provides the main mechanism for independent evaluation and review of environmental models used by the Agency."[91]

4. Federal Agencies Must Publicly Disclose Peer Review Records, Including Peer Reviewer Identities, on Agency Websites

As noted previously, OMB's Peer Review Bulletin requires public disclosure of various documents relating to the performance of peer reviews of ISI and HISAs.

For ISI, the bulletin calls for the names and identities of all peer reviewers and their organizational affiliations, as well as a verbatim copy of each peer reviewer's comments or a copy of the summarized comments of the group of peer reviewers as a whole without attribution to specific peer reviewers. The summary must include any disparate and dissenting views.[92] In addition, federal agencies must post the entire peer-review report contemporaneously on the agency's website along with *all* materials related to the peer review, including any charge statement to peer reviewers and any agency response(s) to the peer-review report. The peer-review report also must be discussed in the preamble to any related rulemaking and included in the administrative record for any related action.[93]

The OMB bulletin imposes additional records disclosure requirements for HISAs. For example, while the preparation of charge statements and agency responses are optional for ISI, the bulletin requires the preparation of such documents for HISAs. Agency responses must include an explanation of the agency's agreement or disagreement with the views expressed in the report, the actions the agency will undertake or has undertaken in response to the report, and the reasons why the agency believes such actions satisfy the report's key concerns.[94] Peer-review reports for HISAs must also include a short paragraph describing both the credentials and relevant experiences of each peer reviewer, and must be publicly disseminated on each federal agency's website, along with agency responses and all peer review-related materials.[95]

D. Rigorous Standards Apply to the Selection of Peer Reviewers

OMB's IQA Guidelines acknowledge that "the work of fully competent peer-review panels can be undermined by allegations of conflict of interest and bias."[96] Consequently, they direct federal agencies to adopt and maintain effective policies and procedures regarding panel balance, peer reviewer independence, and potential conflicts of interest.

1. Peer Review Panel Balance

OMB's Peer Review Bulletin imposes certain requirements with respect to an agency's (or an agency third-party contractor's) evaluation, selection, and oversight of prospective and current peer reviewers and the establishment of HISA-related peer-review panels. Individual peer reviewers must be selected primarily for their expertise, experience, and skills, as well as their specialized knowledge in one or more disciplines. The selection of peer reviewers as a group must be based on the breadth and diversity of their expertise, experience, skills, and perspectives such that the group or panel is "balanced," *i.e.*, it "fairly represent[s] the relevant scientific and technical perspectives and fields of knowledge."[97]

2. Peer Reviewer Independence

The OMB bulletin "instructs agencies to ensure that reviewers are independent of the agency sponsoring the review."[98] To this end, it requires federal agencies to preclude all scientists who have participated in the development of ISI from serving as peer reviewers of such a work product.[99] It also obliges agencies to avoid using the same peer reviewer in multiple ISI and HISA reviews.[100] Furthermore, the bulletin directly bars, and thus establishes a legal presumption against, the use of "[s]cientists employed by the sponsoring agency […] as reviewers for highly influential scientific assessments."[101] Only one exception to this bar exists. To qualify for it, an agency must establish, consistent with NAS conflict-of-interest criteria,[102] that the reviewer: 1) is a "premier" scientist who is not in any position of management *or* policy responsibility within the sponsoring agency that is, in any way, related to the HISA results that are the subject of peer review;[103] 2) possesses expertise, experience, and skills that are essential but cannot be obtained elsewhere; *and* 3) is "employed by a different agency of the Cabinet-level department than the agency that is disseminating the scientific assessment."[104] In other words, this exception is available *only if* the government scientist did "*not* have had *any* part in the development *or* prior review of the scientific information and [does] *not* hold a position of managerial or policy responsibility."[105] If any one of these requirements is not satisfied, the exception will not be available.

In effect, an agency sponsoring the peer review of a HISA may use only "special government employees" the agency employed temporarily, with or without compensation, for the exclusive purpose of conducting the peer review,[106] "such as academics appointed to advisory committees,"[107] barring other irregularities. An irregularity would arise, for example, where the agency charge to the advisory committee on which the academic served was to assist in the development of the same HISA that person has been asked to peer review.

EPA's Peer Review Handbook states that an "independent" peer reviewer is "an expert who was *not associated with* the generation of the specific work product *either*

directly by substantial contribution to its development *or indirectly* by significant consultation during the development of the specific product."[108]

Furthermore, the OMB Peer Review Bulletin highlights the independence or conflict-of-interest concerns that can arise when the selection of reviewers "receiv[ing] a substantial amount of research funding from the agency sponsoring the review," is based on something *other than* "investigator-initiated, competitive, peer reviewed proposals."[109] The National Institutes of Health ("NIH"), whose approach to conflicts of interest are instructive to federal agencies,[110] defines the term "investigator-initiated research" as "[r]esearch funded as a result of an investigator, on his or her own, submitting a research application[; a]lso known as *unsolicited* research."[111] Thus, OMB recognized that substantial research grants awarded to recipients on the basis of federal-agency-solicited research proposals that were not necessarily subject to competitive bidding (such as broad agency announcements),[112] have the potential to adversely affect the independence of peer reviewers and to trigger individual, if not institutional, conflicts of interest.

3. Peer Reviewer Conflicts of Interest

OMB's Peer Review Bulletin imposes a general prohibition against agency (and agency-commissioned third-party contractors') use of prospective and current peer reviewers harboring apparent or actual conflicts of interest.[113] It also imposes standards upon selected peer reviewers employed by federal agencies that are distinct from those imposed on third-party scientists.

Federal agencies, for example, must ensure that permanent and temporarily-employed government scientists selected as peer reviewers "comply with applicable federal ethics requirements," namely, the applicable standards issued by the Office of Government Ethics ("OGE")[114] and related "[c]riminal conflict-of-interest statutes of general applicability to all employees."[115] Such OGE standards preclude government employees from "hold[ing] financial interests that conflict with the conscientious performance of duty,"[116] and require government employees "to act impartially and not give preferential treatment to any private organization or individual."[117] Such standards define the term "financial interest" as entailing the rendering of "service, *with or without compensation*, as an […] employee of any person, including a non-profit entity [i.e., a public or private university or nonprofit institute], whose financial interests are imputed to the employee…"[118] Thus, pursuant to such OGE standards, the financial interests of an organization or entity for which a government employee serves will be imputed to that employee.[119]

OGE standards prohibit government employees from "hold[ing] any financial interest" that a statute, agency regulation, or agency determination of "substantial conflict" precludes such employee from holding.[120] An agency may deem a substantial conflict to arise where the matter at hand is so critical or central to the employee's performance of his/her official duties that the employee's holding of the financial interest would materially impair his/her ability to perform those duties in connection with such matter, thereby requiring the employee's disqualification.[121] Alternatively, a substantial conflict may to arise where the employee's holding of the financial interest would adversely affect the efficient accomplishment of the agency's mission and no other qualified agency employee could be readily assigned to replace the conflicted employee if disqualified.[122] OGE standards also preclude the appearance of partiality.[123]

The OMB Peer Review Bulletin requires third-party scientists who peer review scientific assessments done in support of regulations to meet the NAS conflict-of-interest policy.[124] This policy, which broadly examines a *peer reviewer's* financial ties to regulated entities, other stakeholders, *and the peer review-sponsoring agency*, covers conflicts arising from: 1) investments; 2) agency, employer, and business affiliations; 3) grants; 4) contracts; and 5) consulting income.[125] Consequently, where current research funding is received "from a party that would be directly affected by the regulatory process," a conflict of interest would arise if: 1) "the research funding could be directly affected by the outcome of the regulatory process[;]" *or* 2) "the research is directly related to the subject matter of the regulatory process and the investigator's right to independently conduct and publish the results of the research is *limited or controlled by the sponsor*."[126]

The NAS conflict-of-interest rules for peer reviewers may be sufficiently broad to encompass real and apparent individual as well as *institutional* conflicts of interest. Consequently, that policy should raise red flags where the following affiliations arise: 1) the scientist or academician who peer reviewed an agency-developed HISA was selected by an external contractor that derives significant ongoing revenues from the agency for which it managed the peer review; 2) the reviewer was employed by the same institution as the scientist or academician who prepared the research and derived the data that the agency incorporated into the assessment it developed and was going peer reviewed; 3) the research and data were prepared pursuant to an agency contract or grant award to that investigator or institution under an ongoing agency-overseen research program; and 4) the agency relied upon the assessment as scientific support for a rulemaking.

Under these circumstances, the parties' interests appear to be aligned. The peer-review contractor has an interest in delivering an overall peer review of the agency assessment that is favorable to the agency. The financial and nonfinancial interests of the science contributor, reviewer, and institution that employs them are interdependent, coterminous with, and mutually reinforcing of one other and subservient to the same grantor-agency interests. In the end, each indirect recipient of federal funds is similarly motivated to fulfill the client agency's ultimate objective: to ensure the agency can use the assessment as scientific support for a rulemaking. And, this is without regard to the additional conflicts that would arguably arise if the university or non-profit institute, or its employees, also received a "milestone" cash payment, technology commercialization right, or corporate equity stake as an added incentive to secure the initial or ongoing agency contract or grant award leading to the scientific contribution to and subsequent favorable peer review of the assessment incorporating it.[127]

This interpretation of the NAS conflict-of-interest policy, furthermore, would be consistent with NIH's conflict rules, which incorporate the NAS policy.[128] Those rules ensure that research performed for NIH by third-party grantees is "free from any intended or unintended bias."[129] The NIH conflicts policy similarly defines an institutional conflict of interest broadly as arising "when *an institution's own financial interests* (*e.g.*, royalties, equity, stockholdings, and gifts) or those of its senior officials *pose a risk of undue influence on decisions involving the institution's research*."[130] It precludes peer reviewer participation in such instances, unless an exception or agency waiver is secured.[131] And, if a conflict cannot be avoided, the agency must identify and publicly disclose it.[132]

Similar to NIH's conflicts-of-interest policy for peer reviewers, NOAA's Policy on Conflicts of Interest for Peer Review, which "has adapted the NAS conflict of interest policy," precludes the appointment of individuals to review ISI or HISAs "subject to the OMB Bulletin if that individual has a conflict of interest that is relevant to the functions to be performed," *unless* "NOAA determines that such conflict is unavoidable and promptly and publicly discloses the conflict of interest."[133] A conflict of interest is defined under NOAA's policy as "any [current] financial or other interest *which conflicts with the service of the individual on the review panel* because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization."[134] In assessing whether an individual's service as a peer reviewer will engender a potential conflict of interest, the individual's interests, as well as, the interests of the individual's employer and others with whom the individual has substantial common financial interests must be considered.[135] Thus, employment interests, honorariums, travel expense reimbursements, *research funding and other forms of research support*, financial ties to NOAA-regulated entities, other stakeholders, *and NOAA itself*, are to be considered if they are relevant to the functions to be performed.[136] Furthermore, peer reviewers are precluded from critically reviewing their own work and that of their immediate employers.[137]

NOAA's conflict-of-interest policy, moreover, charges NOAA and NOAA-commissioned peer-review managers with the responsibility of securing background and updated information from prospective and selected peer reviewers to ensure against conflicts of interest.[138] To this end, NOAA's policy, like the analogous NIH policy, imposes an *ongoing* obligation upon peer reviewers to submit this information by completing the agency's "Background Information and Confidential Conflict of Interest Disclosure" form, and to report new or changed information promptly.[139]

EPA's Peer Review Handbook, meanwhile, provides that where the peer review of a third-party-developed assessment gives rise to an actual or apparent conflict that has been identified and disclosed, but not resolved, the agency is directed to peer review the assessment again.[140]

E. Adequate Administrative Review Mechanism Required for Correction of Improperly Peer-Reviewed Data

The IQA directed OMB to require that federal agencies "establish" administrative mechanisms that affected persons could utilize to seek correction of information the agency disseminated in violation of OMB's IQA Guidelines and Peer Review Bulletin.[141] OMB's IQA Guidelines also require that agencies extend those mechanisms to situations where agencies violated their own IQA guidelines. In addition, such mechanisms must be "flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices."[142]

OMB's IQA Guidelines further clarify that stakeholders' right to IQA administrative review includes the ability to appeal agency determinations of their initial requests for correction.[143] The guidelines require each federal agency to establish an objective administrative appeal process permitting stakeholders to seek reconsideration of agency adverse denials, nonresponses, and unsubstantiated corrections.[144] Federal agencies must respond to requests for correction and appeals of agency decisions within sixty calendar-days.[145]

Under the IQA, OMB must impose both the law's substantive requirements[146] (*i.e.* guidance that insures the quality and objectivity of agency information) *and* its procedural requirements (*i.e.* establishment of administrative mechanisms) on federal agencies in the context of rulemaking. Agencies must provide a process for stakeholders to seek correction of studies and other information not only when that data is posted online or otherwise published, but also when proposed rules cite that data as support for a regulation. Academic skeptics of the IQA take issue with this conclusion,[147] but the argument favoring IQA procedural mandates in rulemaking is a compelling one.

OMB's IQA Guidelines provide that the procedures it requires agencies to establish must afford stakeholders, "the degree of correction that [agencies] conclude is appropriate for the nature and timeliness of the information involved […and which] addresses the genuine and valid needs of the agency and its constituents without disrupting agency processes."[148] In drafting their IQA guidelines, federal agencies have leaned heavily on the "without disrupting agency processes" language of this OMB mandate. EPA's and NOAA's respective IQA Guidelines, for instance, indicate that these agencies "expect to treat" requests for correction, including for HISAs supporting a proposed rulemaking, "like a comment to the rulemaking, addressing it in response to comments rather than through a separate response mechanism."[149]

Situations will arise in the context of a rulemaking, however, where the procedural safeguards of the ordinary notice-and-comment process, such as agencies' need to address comments in the final rule, are insufficient or not "appropriate for the *nature* and *timeliness* of the information involved." Consider, for example, a situation where a stakeholder does not becomes aware that an agency has *changed* how it intends to use a HISA in a rulemaking until reading the notice of proposed rulemaking. That stakeholder may have learned prior to the formal notice being issued that the agency had *not* intended to use that HISA for regulatory purposes, and thus the stakeholder may have discounted that study. Under the IQA and OMB's implementation of it, the stakeholder should have a *timely* opportunity to request a correction of what it believes is flawed agency information.

The highly technical *nature* of such a stakeholder's request for correction also dictates that an agency cannot comport with the IQA's procedural requirements simply by addressing that request as part of its APA-mandated response to public comments in the final published rule. In order to afford stakeholders a fair, equitable, and truly informed administrative review of their more specialized submissions, agencies must *establish* procedures separate from what the APA requires.

OMB's implementation of the IQA shows it understood the occasional need for a separate, additional process when requests for correction are made during a rulemaking. For instance, OMB requires agencies to respond to information quality complaints sooner than would otherwise be required under such APA-mandated procedures "where needed to avoid the potential for actual harm or undue delay"[150] that would arise if an agency's response to a request for correction was postponed until closer to the time of (or following) the planned issuance of a final agency action or the planned dissemination of an agency scientific study. Thus, an agency must consider a stakeholder's information quality complaint *prior to* such planned issuance or dissemination if: 1) the agency has determined that an earlier response would *not unduly* delay that issuance or dissemination; *and* 2) the complainant has shown a reasonable likelihood it would suffer actual harm from the

agency's information product dissemination if its complaint is not resolved prior to such planned *final* issuance or dissemination.[151]

V. A CASE STUDY OF THE IQA'S APPLICATION: EPA'S CLEAN AIR ACT ENDANGERMENT FINDINGS

The EPA's 2009 Greenhouse Gas ("GHG") Endangerment Findings offer an instructive case study for how the IQA applies to agencies' use and dissemination of highly influential scientific information ("HISA"s) for two reasons. First, the agency developed a rich factual record and relied upon many HISA-level documents to support its Endangerment Findings. Second, IQA standards with regard to HISAs are clear and rigorous. The non-profit Institute for Trade, Standards and Sustainable Development ("ITSSD") filed Freedom of Information Act requests with EPA and NOAA to learn whether its peer reviews of the supporting studies had satisfied the IQA's most rigorous and least discretionary standards. While neither EPA nor NOAA have complied with the FOIA requests,[152] independent research supporting the requests confirms that these agencies have failed to follow IQA peer-review independence, conflict-of-interest, panel-balance and administrative review standards applicable to HISAs.

A. Relevant Facts Underlying EPA's Use of Science for its Endangerment Findings

In *Massachusetts v. EPA*, the United States Supreme Court held that Congress delegated to EPA, pursuant to Section 202(a)(1) of the Clean Air Act (CAA), "the statutory authority to regulate the emission of…[GHGs] from new motor vehicles." [153] The EPA Administrator, before exercising such authority, must undertake an endangerment analysis and form a "judgment" "relate[d] to whether an air pollutant cause[s], or contribute[s] to, air pollution which may reasonably be anticipated to endanger public health or welfare."[154] On December 15, 2009, the EPA Administrator issued Endangerment Findings, concluding that "six greenhouse gases taken in combination endanger both the public health and the public welfare of current and future generations."[155]

Section III.A of these findings, entitled, *The Science on Which the Decisions Are Based*,[156] referred to a Technical Summary Document ("EPA-TSD") that explained how the Administrator's findings had been reached.[157] Table 1.1 of the EPA-TSD listed twenty-eight "core reference" documents that the Administrator had "relied upon most heavily" as scientific support.[158] These twenty-eight "core reference" documents consisted of:

- Three reports from the 2007 Fourth Assessment Report of the Intergovernmental Panel on Climate Change ("IPCC");
- Sixteen of twenty-one Synthesis and Assessment Products ("SAPs")[159]developed by federal agencies participating in the interagency United States Global Research Change Program /U.S. Climate Change Science Program ("USGCRP/CCSP");[160]
- The 2009 NOAA-developed USGCRP second national climate assessment ("NCA2") containing a synthesis of twenty-one SAPs;
- Four National Research Council ("NRC")/National Academy of Sciences ("NAS") reports;
- NOAA's State of the Climate in 2008 report;
- The 2009 EPA annual U.S. Inventory of Greenhouse Gas Emissions and Sinks;

- The 2009 EPA assessment of the impacts of global change on regional U.S. air quality; and
- The Arctic Council's 2004 climate impact assessment.[161]

Section III.A of the Endangerment Findings also emphasized how these USGCRP/CCSP, NRC/NAS, and IPCC assessments "essentially represent the U.S. government's view of the state of knowledge on greenhouse gases and climate change. […] It is the Administrator's view that such review and acceptance by the U.S. Government lends further support for placing primary weight on these major assessments."[162]

The EPA-TSD emphasized that the twenty-eight documents had "undergone their own peer-review processes, including review by the U.S. government."[163] It also emphasized how, "[g]iven the comprehensiveness of these assessments and their [peer-]review processes, these assessment reports provide EPA with assurances that this material has been well vetted by both the climate change research community and by the U.S. government."[164] The EPA-TSD stated in a footnote that, "Volume 1 of EPA's *Response to Comments* document [in Appendices A-C] on the Administrator's Endangerment and Cause or Contribute Findings [website], provides more detailed information on these review processes."[165] However, as discussed, below, EPA has provided no substantiation that these USGCRP/CCSP, NRC/NAS, and IPCC peer review procedures had in fact been followed.

Moreover, the EPA-TSD proclaimed that, "*use of these assessments complies with EPA's information quality guidelines*, as this document relies on information that is objective, technically sound and vetted, and of high integrity."[166] Another footnote stated how EPA responses to stakeholder APA comments (rather than stakeholder IQA requests for correction) regarding EPA's use of these assessments and its compliance with IQA standards had been addressed in EPA's *Response to Comments* document accompanying the agency's final Endangerment Findings.[167]

Finally, EPA emphasized how the EPA-TSD, as well as the documents it summarized and synthesized, had been prepared consistent with EPA's guidelines: "In addition to its reliance on existing and recent synthesis reports, which have each gone through extensive peer-review procedures, this document also underwent a technical review by twelve federal climate change experts, internal EPA review, interagency review, and a public comment period."[168] Nevertheless, as discussed below, the third-party peer-review procedures employed to review these assessments did not conform with IQA statutory and administrative guidelines.

B. EPA's Legal Obligations under the IQA

Information Quality Act standards applicable to HISAs and ISI subject EPA to four distinct legal obligations for agency and third-party peer reviews of EPA and third party-developed climate science assessments the Administrator relied upon for the Endangerment Findings.[169]

1. Peer Reviews of EPA-Developed HISAs Used to Support the Endangerment Findings

EPA bore "lead agency" development responsibilities for three USGCRP/CCSP

synthetic assessment products ("SAPs").[170] The EPA-TSD had designated two such SAPs as "core reference" documents: SAP4.1/CCSP(2009b) and SAP4.6/CCSP(2008b).[171] Although the third EPA-developed SAP (SAP4.4/CCSP(2008)) had not been expressly listed in the EPA-TSD as a "core reference" document, the EPA Administrator nevertheless relied upon it to the extent it was incorporated by reference within the NOAA-developed "core reference" document—the *Global Climate Change Impacts in the United States* (a/k/a Second National Climate Assessment).[172]

EPA certified that the SAPs met all applicable IQA guideline requirements.[173] This certification also stated that each SAP is an "interpreted product" as that term is used in EPA guidelines and is classified as "highly influential."[174] The classification of such assessments as HISAs triggered the application of the IQA's most rigorous peer-review standards. However, EPA failed to demonstrate how it had substantiated its IQA certification of HISA compliance to the CCSP Committee, as required by Article VII of OMB's Peer Review Handbook.[175]

The peer reviewers of SAP4.1 included three scientists from USGS, EPA, and NOAA who had peer reviewed a portion of the HISA that had been prepared by other USGS, EPA, and NOAA scientists (including the particular chapter 2 in question). These institutional interrelationships presented the clear appearance of, if not an actual, conflict of interest that EPA failed to explain, disclose, or resolve.[176] In addition, an official of the U.S. Army Corps of Engineers served on the peer-review panel even though a colleague of his had served on the EPA-established *ad hoc* federal advisory committee—the Coastal Elevations and Sea-Level Rise Advisory Committee ("CESLAC")—that advised the SAP4.1 authors on subject matter content development and report accuracy.[177] Furthermore, a member of the Maryland Department of Natural Resources served on the peer-review panel even though a colleague of his had prepared author contributions to SAP4.1, and although another colleague served on the EPA-established CESLAC.[178]

The peer reviewers of SAP4.6 were members of the EPA-established *ad hoc* federal advisory committee—the Human Impacts of Climate Change Advisory Committee ("HICCAC") "convened to provide an independent expert review of the SAP 4.6."[179] The peer-review panel included a scientist from the Centers for Disease Control and Prevention ("CDC") and a professor affiliated with the University of North Carolina even though their professional colleagues (*i.e.*, employees of) at CDC and UNC had made author-contributions to the relevant assessment.[180] In addition, the University of North Carolina professor had been selected as a peer reviewer notwithstanding that the university had then been participating in EPA climate-science research-related grant programs.[181] Other professors who had served on this peer-review panel also had been affiliated with universities that had participated in EPA climate science research-related programs.[182] These institutional interrelationships presented the clear appearance of, if not an actual, conflict of interest.

The peer reviewers of SAP4.4 were members of another EPA-established *ad hoc* federal advisory committee—the Adaptation for Climate-Sensitive Ecosystems and Resources Advisory Committee ("ACSERAC"). EPA convened ASCERAC to conduct a peer review of SAP4.4.[183] The peer-review panel included a professor affiliated with the University of Maryland's Joint Global Research Institute even though two University of Maryland professional colleagues had made author-contributions to SAP4.4.[184] These institutional interrelationships presented the clear appearance of, if not an actual, conflict of interest.

In sum, EPA has failed to substantiate that the peer reviews performed of these three EPA-developed HISAs constituted "external peer reviews" and otherwise satisfied IQA standards applicable to HISAs.

2. EPA Validation of the IQA Compliance of Third-Party Peer Reviews of Third-Party-Developed HISAs

EPA was also legally obligated to validate the IQA compliance of the third-party peer reviews performed for the scientific assessments of the IPCC, the federal agencies participating in the USGCRP (e.g., NOAA), and the NRC that the agency had utilized and relied upon ("disseminated") to support the Endangerment Findings.[185] According to the EPA, these HISAs had "essentially represent[ed] the U.S. government's view of the state of knowledge on greenhouse gases and climate change," and were "the best reference materials for determining the general state of knowledge on the scientific and technical issues before the agency in making an endangerment decision."[186] In addition, these assessments also served as the scientific basis for various GHG emissions control regulations EPA's Endangerment Findings had triggered, including: 1) GHG tailpipe emissions rules;[187] 2) prevention of significant deterioration and Title V GHG tailoring rules for stationary source facilities;[188] 3) proposed new source performance standards for CO_2 emissions potentially applicable to new "fossil fuel-fired electric utility generating units;"[189] and 4) proposed carbon pollution emission guidelines for existing electric utility general units.[190] EPA, however, failed to substantiate how it had satisfied this legal obligation.

Indeed, a third-party examination of the procedures employed to peer review the IPCC assessment found those processes to be systemically flawed. The InterAcademy Council ("IAC"), a United Nations Secretary General and IPCC Chair-commissioned body,[191] issued a report in 2010 finding that the Third and Fourth IPCC Assessment Reports ("AR3," "AR4") suffered from numerous systemic process and procedural failures.[192] These failures occurred in the critical areas of peer review, reviewer independence, lead author selection, assessment scoping, and assessment communication transparency.[193] Notwithstanding these findings, the IAC Board-appointed Review Committee still managed to conclude that the IPCC-AR3 and IPCC-AR4 "assessment process[es] ha[d] been successful overall."[194] Apparently, EPA was similarly unfazed by the IAC's findings and concurred with the IAC Review Committee's conclusions and recommendations.[195]

The IPCC peer-review procedural flaws were significant considering that NOAA—the U.S. government's lead climate science agency[196]—had adopted and incorporated the substantive information contained in IPCC-AR3 and IPCC-AR4 within the ten NOAA-developed HISAs, and that four of twelve IAC Review Committee members had been affiliated with institutions participating at that time in NOAA grant funded climate research.[197] The U.S. government directed several hundred scientists to make author contributions to and/or review these IPCC reports.[198] In fact, nearly half of those scientists worked for NOAA.[199] Additionally, many other professors affiliated with universities and non-profit institutes then participating in NOAA grant-funded climate-science research programs also made author contributions to and/or reviewed the IPCC-AR3 and IPCC-AR4.[200] Those relationships should have raised red flags concerning the risk that their institutional affiliations had impaired their financial and intellectual independence and triggered apparent, if not actual, conflicts of interest.[201]

Notwithstanding the extent of NOAA-employed and NOAA grant-funded scientist involvement in the development of those IPCC reports, NOAA did *not* then have in place formal agency-wide policy covering the use of third-party environmental data that approached the level of a data quality management system such as the ISO 9001 Quality Management System.[202] Nor did NOAA have in place, as a supplement to peer review, a data-quality control mechanism such as EPA's Council for Regulatory Environmental Modeling ("CREM") guidelines.[203] In other words, NOAA accepted as valid the IPCC-developed AR3 and AR4 that NOAA incorporated into its own climate assessments, on the basis of a simple *pro forma* paper review; it did not *validate* the peer review processes the IPCC had actually employed to ensure the quality, objectivity, utility, and integrity of these assessments.

EPA, likewise, accepted as valid the NOAA-developed assessments on the basis of simple *pro forma* reviews. It did not *validate* whether the peer-review procedures NOAA, USGCRP/CCSP, and NRC/NAC actually employed were in conformance with IQA standards. Reports prepared by various EPA offices reveal internal agency weaknesses that arguably precluded EPA from competently undertaking and validating the peer reviews of the scientific assessments underlying the Endangerment Findings.

For example, reports have demonstrated that: 1) "the Agency d[id] not have the resources, nor is it EPA's mission…to fully address the data and research needs for public health protection;"[204] 2) EPA had experienced difficulties (during 2005-2011) ensuring the collection, retention, and dissemination of useful climate science research information for the benefit of EPA's regional and local offices;[205] 3) since 2008, the EPA-ORD-Global Change Research Program ("ORD-GCRP") has increasingly directed its focus and proportionately committed more of its limited local and regional budgets and other resources to federal interagency and international climate science initiatives;[206] 4) EPA-ORD (between 2005-2011) "*d[id] not test* its policies and procedures…to address internal control standards, such as:...*Principles of Scientific Integrity* [and] *Peer Review Handbook*…[and consequently,] ORD *c[ould] not assert with certainty the effectiveness of [its] controls*…";[207] 5) EPA-NCEA suffered from shortcomings in its documentation and handling of conflicts-of-interest decisions and in ensuring consistency between third party contractor panel selection procedures; [208] and 6) with respect to EPA's Endangerment Findings, "EPA's TSD [p]eer [r]eview [m]ethodology [d]id [n]ot [m]eet OMB [r]equirements for [h]ighly [i]nfluential [s]cientific [a]ssessments."[209] In fact, it was not until 2012-2013 that EPA had finally begun to address agency weaknesses in identifying, disclosing, and resolving conflict-of-interest[210] and scientific-integrity lapses,[211] and in ensuring the quality of agency and third-party-developed and reviewed scientific information the agency uses.[212]

EPA's validation lapses were most significant in connection with the IPCC computer models and related datasets that NOAA, EPA, and other federal agencies incorporated into the USGCRP/CCSP HISAs they developed. The EPA-TSD later summarized and synthesized these models and datasets. As previously discussed, OMB's Peer Review Bulletin requires federal agencies to rigorously peer review scientific information which contains "precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact."[213] Yet, EPA dismissed stakeholder comments arguing that it had failed to "make publicly available the data, models, and other relevant information used in the studies upon which the endangerment determination was made."[214] EPA responded that these models and

applications could be accessed in the existing assessment literature, studies, and reports the sources of which it had disclosed.[215] EPA also dismissed numerous other stakeholder comments arguing that it had failed to validate the accuracy, validity, and reliability of such third-party-generated observational and future projection-based modeling, datasets, and applications, as the IQA required.[216]

In further defense of its position, EPA cited *Appalachian Power Co. v. EPA*, a *Clean Air Act* case decided by the D.C. Circuit, which held that federal agencies are entitled to "an 'extreme degree of deference' when they are 'evaluating scientific data.'" [217] Focusing on an agency's *use* of computer models, the court concluded that "the agency's use of models would only be arbitrary and capricious 'when the model bears no rational relationship to the characteristics of the data to which it is applied.'"[218] *Appalachian Power Co.*, however, does not relieve EPA of its disclosure and peer-review responsibilities under the IQA with regards to EPA-disseminated HISAs supporting the Endangerment Findings.

NOAA, as "lead" development agency,[219] developed ten climate science assessments, one of which it certified as ISI (*State of the Climate in 2008* ("SOC-2008")) and nine of which were certified as HISAs.[220] The EPA-TSD then designated the one ISI report and six of the HISAs as "core reference" documents.[221] NOAA also developed three other SAPs that EPA did not designate as "core reference" documents, but which EPA, nevertheless, indirectly referenced in one such "core reference" document[222] the *Global Climate Change Impacts in the United States* report. That report had synthesized and was "largely based on the results of all twenty-one SAPs of the U.S. Global Change Research Program."[223]

Seven NOAA-developed HISAs[224] were peer reviewed pursuant to contracts entered into with the NRC/NAS. An examination of the NAS's peer reviewer selection processes for each HISA exposes consistent failures to detect, identify, disclose, and resolve apparent, if not actual, *institutional* conflicts of interest.[225] A number of participants in NRC/NAS's peer-review process, including both NAS-selected panel members and report committee members, either had professional colleagues from the same federal agencies[226] that had made author contributions to the HISAs under review, or had been professionally affiliated with contributors to such HISAs and/or affiliated with institutions that participated in at least nine different NOAA-funded, climate research programs.[227] In addition, several members of the NAS boards and committees responsible for oversight of these processes also had been affiliated with those third parties.[228] Furthermore, two HISAs peer reviewed by the USGCRP and NOAA suffered from institutional conflicts.[229] Moreover, NOAA failed to disclose the names or organizational affiliations of any of the "many anonymous reviewers" who had performed the NOAA-managed peer review of the SOC-2008.[230]

During fiscal years 2004-2010, at least five NOAA office lines[231] had solicited (individually and together) the participation of universities and non-profit institutes in such programs through the issuance of numerous announcements for federal-funding opportunities. These grant solicitations appear on their face to facilitate broad, open bidding for the contracts. The geographic proximity to NOAA laboratories and research specialization the contract specifications required, however, betray that only a few preselected candidates could bid successfully.[232] NOAA doled out more than $750 million in grants to just sixteen universities and non-profit institutes participating in only one of NOAA's many programs—the Cooperative Institutes Program—during this period.[233] These sixteen entities then solicited the participation of other institutions in the Cooperative

Institute Programs they founded and maintained.[234] Although the OMB Peer Review Bulletin flags the conflict risks that arise from "the receipt of substantial amounts of research funding from the agency sponsoring the review," based on factors other than "investigator-initiated, competitive, peer reviewed proposals," the administrative record does not indicate that the NAS, NOAA, or EPA respected that warning.[235]

3. Validation of the Interagency Panel's Peer Review of EPA-TSD Summaries and Syntheses of "Core Reference" HISAs

As discussed above, EPA was obligated to validate the synthesized and summarized HISAs referenced in the Technical Support Document–EPA-TSD—accompanying the Endangerment Findings.[236] The EPA-TSD designated twenty-eight major assessments as "core reference" documents, sixteen of which were USGCRP/CCSP-"synthesized assessment products" ("SAPs").[237] EPA claimed that the federal agency-developed SAPs, which incorporated the major IPCC and NRC assessments, had been previously peer reviewed and characterized as HISAs within the meaning of the IQA,[238] and OMB agreed.[239] Such a designation subjected each of these assessments to the IQA's most rigorous peer-review standards. EPA indicated that an interagency panel comprised of "12 federal climate experts" had peer reviewed the EPA-TSD.[240] EPA thereafter relied upon these peer-reviewed, synthesized assessments, *and* the peer-reviewed EPA-TSD-synthesized summaries of them, as primary support for the Endangerment Findings.[241]

The EPA-TSD synthesized and "summarized the scientific findings from the major assessments of the USGCRP, the IPCC and the NRC"[242] which, themselves, were "synthesis reports of climate science and potential impacts."[243] The IPCC defines "synthesis reports" as reports that "synthesize and integrate materials contained within the Assessment Reports and Special Reports and are written in a non-technical style suitable for policymakers…"[244] According to OMB's Peer Review Bulletin, scientific assessments (which are a form of scientific information) "typically synthesize multiple factual inputs, data, models, assumptions, and/or appl[y] best professional judgment to bridge uncertainties in the available information."[245]

The EPA-TSD asserts that it "does not convey any judgment or conclusion regarding the two steps of the endangerment finding[s]," which the CAA had reserved to the Administrator.[246] However, the Administrator had actually exercised her judgment, based on these assessments *and* the EPA-TSD synthesized summaries of them, to determine that "the cause or contribute criterion [of CAA Section 202(a) ha[d] been met."[247]

The EPA-TSD is *itself* a HISA, and thus subject to the IQA's most rigorous standards. The EPA-TSD's synthesis and summary of HISAs was not an identical, word-for-word reproduction of any one or more of the assessments discussed, and thus, could not, by its very nature, convey precisely the same scientific information in precisely the same manner.

EPA's Office of Inspector General ("EPA-OIG") drew the same legal conclusion following its investigation of whether the agency's peer review of the EPA-TSD had satisfied IQA requirements.[248] EPA officials insisted, in response, that the EPA-TSD merely constituted ISI that was subject to lower IQA peer-review standards.[249] They reasoned that the EPA-TSD's scientific findings were mere *summaries* rather than *syntheses* of the findings of the major assessments that did not reflect any selection or judgment regarding scientific data,

and consequently, that the EPA-TSD did *not* constitute a "scientific assessment."[250]

The EPA-OIG report found four instances where the twelve-member interagency panel's peer review of the EPA-TSD had violated IQA standards.[251] The most serious violation concerned EPA's failure, as the peer-review-sponsoring agency, to address the lack of "independence" of one interagency peer reviewer who was not "external" to EPA.[252] In particular, the EPA-OIG concluded that "this panel did not fully meet the independence requirements for reviews of highly influential scientific assessments because one of the panelists was an EPA employee."[253]

If the EPA-OIG had investigated the interagency panel's peer review of the EPA-TSD more broadly, as had been warranted based on EPA officials' statements, it would have detected more IQA violations. EPA admitted that "[t]he federal experts [who served on the interagency peer review panel] were ideal candidates because they ha[d] contributed significantly to the body of climate change literature and played active roles in the IPCC and CCSP."[254] Arguably, these admissions are an implicit, if not explicit, acknowledgement that the peer review of the EPA-TSD's synthesized summaries of the twenty-eight major "core reference" assessments had required a "look-through" to the original assessments for purposes of ensuring accurate summarization of selected portions of their data, models, and conclusions that EPA had then synthesized into a logical and cohesive technical support document.[255] Since this synthesis could have taken place only after each of these twenty-eight assessments had already been summarized, it is quite apparent that at least seven of the twelve interagency panel members had effectively peer reviewed new, condensed versions of selected portions of HISAs they had previously coauthored.[256] Those HISAs served as the scientific foundation for EPA's Endangerment Findings and the regulations they subsequently triggered.[257] Therefore, EPA's assertion that "the [12] federal experts were *not* involved with developing the TSD or Findings *in any way other than their review roles*" was simply not true.[258]

4. Review of Requests for Correction of HISAs Supporting EPA's Endangerment Finding

EPA was required but failed to ensure that the administrative review mechanisms EPA and other federal agencies employed to address stakeholders' requests for correction ("RFC") of HISAs satisfied the IQA.[259] Stakeholders had not only been misinformed about the agency's intended use of the USGCRP/CCSP assessments during agency pre-dissemination review, but those "affected persons" also had been denied a genuine opportunity to have their RFCs seriously considered and factored into EPA's final Endangerment Findings during such the post-dissemination review of those HISAs.

a. Pre-Dissemination Review Did Not Provide Adequate Opportunity or Information for Public Comment

NOAA solicited public comments on behalf of itself, EPA, and the Department of Interior on *pre*-dissemination drafts of fourteen "lead" agency-developed SAPs and one NOAA-developed synthesis covering all twenty-one SAPs (each of which had been categorized as a HISA).[260]

Notwithstanding this ostensible nod to due process, stakeholders complained, on at least one occasion, that the underlying studies that had served as the tentative foundation for the scientific assessment under public review (the NOAA-developed "unified synthesis product," *i.e.* the second national climate assessment (NCA2-2009)) had not been made available to stakeholders in a timely manner.[261] On other occasions, it was quite apparent that few members of the public, *aside from employees of federal government agencies including NOAA*, had submitted public comments on drafts of NOAA-developed SAPs that generated author responses.[262] Arguably, the dearth of comments received from public stakeholders other than federal agency personnel, particularly comments of a scientific or technical nature, can be attributed to NOAA's failure to adequately apprise the public of the true purpose for which these draft SAPs were then being developed.

Public stakeholders were apparently uncertain of whether EPA, NOAA, and other federal agency decision-makers would use these SAPs and the NCA2-2009 for purely internal or interagency science development and administrative purposes, or for regulatory purposes. That uncertainty was justified considering the written assurances contained in early prospectuses for each SAP NOAA was to develop, as well as the in the Federal Register notices NOAA had subsequently issued during 2007-2009 that solicited public comment on draft versions of those NOAA-developed assessments and the NCA2-2009.[263] These declarations stated that the SAPs would *not* be used for regulatory purposes,[264] and/or that they did not reflect an agency regulatory policy or determination. [265] Thus, at the *pre*-dissemination stage, public stakeholders had remained largely unaware of, and had arguably been deceived regarding, the true purposes for which these assessments had been intended and would ultimately be used.

b. Post-Dissemination Review Did Not Provide Adequate Opportunity to Address Stakeholder Requests for Correction

It was not until EPA published a July 2008 Advance Notice of Proposed Rulemaking[266] that the public first became aware that the initial five agency-developed USGCRP/CCSP assessments[267] that had been referenced in a supporting draft EPA-TSD[268] *could* be used for regulatory purposes.[269] And, it was not until EPA's April 2009 Notice of Proposed Rulemaking,[270] supported by an updated EPA-TSD referencing eleven additional SAPs, that the public finally understood such assessments *would* be used for regulatory purposes.[271]

As explained above, EPA and NOAA treat requests for correction of scientific and technical information supporting a proposed or final rule "procedurally like a comment to the rulemaking." The agencies would thus "address [such requests…] in the response to comments in the final rule rather than through a separate response mechanism,"[272] and "comments filed as 'requests for correction' (RFCs) […would] not be assigned an RFC number by EPA."[273] According to EPA, the public comment process surrounding the Endangerment Findings benefitted from a thorough consideration of stakeholder concerns consistent with "the purposes of the [IQA] Guidelines."[274] In addition, EPA argued that such a process "provide[d] an opportunity for correction of any information that complies with the Guidelines, and d[id] not duplicate or interfere with the orderly conduct of the action."[275] Despite its assurances, EPA's post-dissemination review and procedures did not comport with the IQA.

For example, numerous comments argued that the peer-review processes the IPCC and USGCRP/CCSP had employed to validate the science contained in IPCC-developed HISAs and federal agency-developed HISAs did not satisfy IQA standards.[276] Yet, EPA chose not to specifically demonstrate how the IPCC and USGCRP/CCSP procedures it employed had ensured IQA compliance. EPA responded by generally reciting the IPCC and USGCRP/CCSP peer-review procedures and asserting that they were consistent with the IQA and EPA's IQA guidelines.[277] In effect, EPA only addressed how the "peer-review approach [it had employed] *for the TSD* [had been] consistent with EPA's Guidelines."[278] However, EPA's peer review of the TSD had *not* satisfied the IQA's most rigorous peer-review standards applicable to HISAs.

Several commenters also specifically "argue[d] that EPA [had] failed to describe how the [USGCRP/]CCSP ensured that the 21 synthesis and assessment products" and the NOAA-developed NCA2-2009 that synthesized them had "satisfied EPA's IQA guidelines."[279] EPA responded by merely referencing *pro forma* USGCRP/CCSP product development and peer-review procedures.[280]

Eleven commenters argued that, "EPA's external peer-review process [had been] inadequate because *the federal expert reviewers [of the EPA-TSD] were involved with developing the IPCC and CCSP reports upon which the endangerment finding is based* and therefore not objective."[281] Additionally, five stakeholders argued that the EPA-TSD had failed to meet EPA IQA guidelines because the agency did not demonstrate how it had validated the "baseline assumptions" it used to draw conclusions about the impacts of "climate change pressures" on physical and biological systems.[282]

EPA issued "canned" responses to all such comments. It claimed that it had "fully complied with the requirements of the IQA," had "acted consistently" with its own "applicable information quality guidelines," and that commenters should refer to "EPA's general response to the information quality concerns submitted during the public comment process."[283] In addition, it referred stakeholders to the ranges of uncertainty in the "assumptions about future concentrations of GHGs and aerosols in the various scenarios considered by the IPCC and the differing climate sensitivities of the various climate models used in the simulations."[284] However, EPA has yet to disclose specific records revealing how it had actually validated the reproducibility of the assumptions, theories, and extrapolations underlying the computer models and datasets supporting such HISAs.[285]

Numerous commenters claimed that "EPA did not following IQA guidelines when it decided not to conduct a new analysis of the best available scientific information and instead relied upon IPCC and [USGCRP/]CCSP assessments."[286] EPA responded that its "approach [had been] consistent with these guidelines because [it had] thoroughly *reviewed and evaluated* [but not *validated*] the author selection, report preparation, expert review, public review, information quality, and approval procedures of IPCC, USGCRP/CCSP, and NRC to ensure the information adhered 'to a basic standard of quality, including objectivity, utility, and integrity.'"[287]

Furthermore, numerous commenters alleged that EPA failed to "make publically available the data, models, and other relevant information used in the studies upon which the endangerment determination was made,"[288] that would enable third parties to ensure their "reproducibility." EPA responded with a reference to the D.C. Circuit's *American*

Trucking Association v. EPA,[289] ruling: "EPA [was] not required to obtain and publicize the data underlying all the studies on which they rely."[290] That holding, however, is limited to the disclosure requirements under the Clean Air Act, and consequently, has no bearing upon the agency's legal obligations under the IQA. EPA also cited copyright restrictions that had prevented it from publicizing such data, and directed stakeholders to the EPA reading room where they could view particular studies if available.[291]

Throughout the entire rulemaking process for the Endangerment Findings, including two scheduled (May 2009) public hearings,[292] EPA relied on standard APA notice-and-comment procedures, which were entirely inadequate given the nature of IQA stakeholders' requests, the timing sensitivities, and EPA's nonresponses and hand-selected conflicted speakers.[293] The agency subsequently refused to grant stakeholders' requests for reconsideration of the Findings.[294] EPA should have considered stakeholders' HISA RFCs in separate specialized proceedings *prior* to issuing the findings. The agency failed to formally determine that such separate proceedings would *unduly* delay issuance of the Endangerment Findings, and stakeholders had shown a reasonable likelihood they would suffer actual harm from the uncorrected HISAs' dissemination.

EPA's actions effectively denied "affected persons" a reasonable opportunity for an adequate public hearing of their concerns, and thus, their right to due process of law. As a result, IQA stakeholders have exhausted their administrative remedies and have no alternative means of securing redress of their claims. Consequently, private counsel for regulated parties and public State Attorneys General should seriously consider challenging EPA's pervasive IQA noncompliance before the general six-year statute of limitations applicable to APA actions expires.[295]

VI. UNDERSTANDING JUDICIAL REVIEW OF AGENCY IQA NONCOMPLIANCE

A. Skepticism Regarding Judicial Review of IQA Noncompliance

Information Quality Act opponents have long asserted that stakeholders' filing of IQA requests for correction and reconsiderations have had little impact on agency policy,[296] and that IQA stakeholders have nearly no success persuading federal courts to review allegations of agency IQA noncompliance. Three factors have led to this sense of security: 1) The statute's lack of an express provision granting judicial review;[297] 2) courts' reluctance to construe OMB and agency IQA-implementing guidelines as having the force of law *and* enabling an implied cause and/or right of action;[298] and 3) the shortcomings of past plaintiffs' IQA pleadings. Agencies and their allies may believe that requests for correction are beyond the scrutiny of courts,[299] though this is not a conviction that OMB—the agency Congress charged with the IQA's implementation—necessarily shares.[300]

The Administrative Conference of the United States[301] and the U.S. Department of Justice ("DOJ") also appear to acknowledge the potential justiciability of IQA. DOJ's IQA Guidelines, for instance, provide that, although such guidelines are "not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on the agency or the public [, n]othing in [said] guidelines affects any otherwise available judicial review of agency action."[302] IQA opponents and proponents in academia recognize

that, despite the IQA's silence on the issue of judicial review, "whether an agency's action under the Information Quality Act is judicially reviewable will likely depend on the action that is being challenged, the context in which the agency made the decision, and the person that is challenging the action."[303] As the U.S. Supreme Court has held, there is a "strong presumption that Congress intends judicial review of administrative action." This presumption can be overcome "[o]nly upon 'a showing of clear and convincing evidence of a contrary legislative intent."[304]

B. The Federal Question Statute Can Potentially Provide Federal Jurisdiction for an APA Action Challenging an Agency's IQA Noncompliance

The APA itself does not provide courts with the jurisdictional authority to hear a case seeking review of agency administrative actions.[305] Therefore, a party filing an IQA action exclusively under the APA without reference to a specific substantive law statute conferring jurisdiction[306] must rely upon 28 U.S.C. § 1331[307] (the federal question statute).[308] Parties claiming jurisdiction under this provision must establish that the cause of action engenders "a substantial federal element" that is "part of the plaintiff's 'well-pleaded complaint.'" [309]

At least one legal commentator, Professor Lumen Mulligan, has argued that, "even under the [federal element] test, §1331 doctrine seldom requires plaintiffs to actually establish a federal cause of action in order to vest the court with jurisdiction. Rather, plaintiffs most often establish § 1331 jurisdiction by merely asserting a federal cause of action."[310]

C. Efforts to Establish an Implied IQA "Cause of Action" under the APA

According to Professor Mulligan, the distinction between rights of action and causes of action is often overlooked: "A statute creates a right when, by clear language, it fashions mandatory, judicially enforceable obligations. A cause of action, by contrast, is the further determination that a person falls into a class of litigants empowered to vindicate a specified right in court." While "persons may hold federal rights without being authorized to enforce those rights in a federal court […] Congress often couples explicit statutory causes of action with federal statutory rights."[311]

The APA could afford stakeholders an independent basis ("cause of action") to legally challenge[312] federal agency IQA noncompliance where Congress did not expressly provide for such a basis in the IQA law: "The APA provides specifically not only for review of '[a]gency action made reviewable by statute', but also for review of 'final agency action for which there is no other adequate remedy in a court,' 5 U.S.C. §704."[313] In other words, pursuant to the APA, "the legality of an agency action is presumptively subject to judicial review unless a statute 'preclude[s] judicial review,' 5 U.S.C. §701(a)(1), the 'action is committed to agency discretion by law,' 5 U.S.C. §701(a)(2), or the action is not final. 5 U.S.C. §704."[314]

One IQA opponent has acknowledged "the possibility that courts could otherwise potentially grant judicial review to an IQA claim pursuant to APA §702,[315] and interpret an

agency's rejection of or failure to respond to an IQA request for correction/reconsideration as an 'order', and thus, as a 'final agency action', under APA §704.[316] To secure jurisdiction under APA §702, which is akin to a "prudential standing requirement," a plaintiff must establish that it has "suffered a sufficient injury in fact" *and* that "'the interest sought to be protected by the complainant [is] arguably within the zone of interests to be protected or regulated by the statute . . . in question.'"[317]

For example, one federal court has held that IQA causes of action may exist under the APA despite the IQA's failure to explicitly provide for a right to judicial review of agency rejections of RFCs. In the separate cases of *Family Farm Alliance v. Salazar*,[318] and *San Luis & Delta-Mendota Water Auth. v. Salazar*,[319] a California federal district court held that while "it is undisputed that the IQA provides no private right of action [,…] the lack of 'rights-creating' language in the IQA is not fatal to [plaintiff's] claims."[320] As the court explained, "[t]he APA authorizes suit by a plaintiff 'suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute.' 5 U.S.C. §702. There is a presumption of reviewability under the APA…"[321] Nevertheless, the court also emphasized how such a presumption is circumscribed by APA § 701's limitation, which "precludes judicial review where…'agency action is committed to agency discretion by law,'" and by APA § 704's limitation which provides that "[w]here a statute lacks an internal judicial review provision […there must be a] final agency action for which there is no other adequate remedy in a court."[322]

1. Final Agency Action

The U.S. Supreme Court had held,

> As a general matter, two conditions must be satisfied for agency action to be 'final': [323] First, the action must mark the 'consummation' of the agency's decision making process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'[324]

The Court also has held, for example, that the Fish and Wildlife Service's ("FWS") release of a Biological Opinion and accompanying Incidental Take Statement [that had] alter[ed] the legal regime [i.e., the Endangered Species Act] to which the action agency [was] subject, authorizing it to take the endangered species if (but only if) it complie[d] with the prescribed conditions […constituted a 'final' agency action because it] ha[d] *direct and appreciable legal consequences*."[325] By comparison, the Court had previously held that the Secretary of Commerce's "presentation to the President of a report tabulating the results of the decennial census" did *not* constitute a "final" agency action because it "*carried 'no direct consequences*' and served 'more like a tentative recommendation than a final and binding determination.'"[326]

Prior to the IQA's enactment, courts recognized that an agency's disclosure of information could have an indirect economic effect on consumer purchasing habits, but had been unwilling to hold that agency action to be "final."[327] For this reason, Professor Stephen Johnson has argued that "*[o]utside of the rulemaking context*, it will be difficult to prove that an agency's response to an information correction request constitutes final agency action,

since the agency's response will not likely have a *direct and immediate effect* on potential challengers."[328]

Furthermore, courts in the D.C., Fourth, and Ninth Circuits have held that agency "disclosure of information […] does not constitute final agency action *unless* the disclosure is intertwined with another reviewable agency action *or* the disclosure *triggers other regulatory effects*."[329]

a. *Salt Institute v. Thompson*

In this seminal IQA case, a Virginia federal district court heard a challenge to the National Institute of Health's National Heart, Lung and Blood Institute's ("NHLBI") denial of a stakeholder request for disclosure of the data and methods underlying the reported results of a salt consumption trial conducted by an NHLBI grant recipient and whose results were reported on NHLBI's website. The court held that the denial of the stakeholder's request for reconsideration did *not* constitute a "final" agency action that was reviewable under the APA.[330] Consistent with pre-IQA law, the court reasoned that "NHLBI's mere[] descri[ption of…] the results of the DASH-Sodium trials, the findings of research scientists, and ma[king of] recommendations to limit sodium intake to moderate levels [constituted a] dissemination of advisory information that ha[d] no legal impact."[331]

b. *Single Stick v. Johanns*

In *Single Stick*, plaintiff, a manufacturer and seller of small cigars, brought suit to challenge the U.S. Department of Agriculture's ("USDA") methods for calculating monetary assessments levied against it under the Fair and Equitable Tobacco Reform Act ("FETRA"), and to challenge the USDA's IQA noncompliance.[332] In particular, plaintiff had alleged that the USDA "refus[ed] to respond or otherwise acknowledge [its] IQA Petition and Request for Reconsideration," and that it also had "fail[ed] to correct influential information [publicly] disseminated...and/or to make available data and data sources Single Stick needed and requested to test and reproduce the [USDA's] estimate of market share."[333]

In reviewing plaintiff's IQA claims, a D.C. district court concluded that "there was no final agency action."[334] The court reasoned that, since "the IQA does not vest any party with a right to information or to correction of information [,…] the USDA's actions under the IQA did not determine Single Stick's rights or cause any legal consequence,"[335] consistent with the "final agency action" requirement of the APA.[336]

c. *Americans for Safe Access ("ASA") v. HHS*

In *ASA*, plaintiff filed an RFC on October 4, 2004 with HHS, seeking correction of information the agency had disseminated about the medical use of marijuana. Specifically, "plaintiff [had] disagree[d] with defendants' statements that marijuana 'has no currently accepted medical use in treatment in the United States'"[337] HHS initially responded by "stating that it needed to consult with the Drug Enforcement Administration, which was contemporaneously reviewing a petition to reschedule marijuana […, and consequently,] needed more time to coordinate agency review."[338] During the ensuing twenty months, "HHS made a series of interim responses noting that the process was still ongoing, and on July 12, 2006, noted that it anticipated providing a response by September 2006 in

connection with a marijuana rescheduling petition pending before the DEA."[339]

Plaintiff filed initial and amended complaints in February 2007 and August 2007, respectively, seeking declaratory and injunctive relief under the APA and the IQA. Plaintiff had alleged that "defendants [had] unlawfully withheld or delayed agency action by not providing a substantive response to plaintiff's information-correction petition."[340] A California district court dismissed the complaint. It held that plaintiff had "failed to show that defendants ha[d] unreasonably delayed the performance of a legally required duty [, because…] the IQA and OMB guidelines do not create a duty to perform legally required actions that are judicially reviewable.[341] In other words, since "the HHS guidelines do not impose a strict deadline" of sixty calendar days within which agencies must respond to requests for correction or appeals, HHS's interim responses could not be considered a "final agency action" within the meaning of the APA.[342]

ASA appealed to the Ninth Circuit, which affirmed the lower court's finding that no final agency action had occurred. [343] The court held that since "HHS's response to the organization's IQA petition did not constitute final agency action, the district court had no jurisdiction under the Administrative Procedure Act."[344] The court reasoned that "the first *Bennett* [*v. Spears*] criteria—that 'the action must mark the 'consummation' of the agency's decision making process'—[had] not [been] met," because HHS had withheld its response to plaintiff's petition pending the completion of its comprehensive review of "whether or not marijuana has a currently accepted medical use in the United States."[345] In effect, the court concluded that "HHS [had] made an 'interlocutory' decision to defer its determination of whether marijuana has a currently accepted medical use to an existing administrative procedure […] in conjunction with a petition for rescheduling filed with the DEA […] under the Controlled Substances Act."[346]

2. Committed to Agency Discretion

APA § 701(a) is "a very narrow exception" to the general presumption in favor of judicial review, which "is applicable in those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.'"[347] Judicial "review is not to be had if the statute is drawn so that a court would have *n*o meaningful standard against which to judge the agency's exercise of discretion. In such a case, the statute ('law') can be taken to have 'committed' the decisionmaking to the agency's judgment absolutely."[348] "If *no* 'judicially manageable standard' exists by which to judge the agency's action, meaningful judicial review is impossible and the courts are without jurisdiction to review that action."[349]

The Supreme Court has held "the mere fact that a statute contains discretionary language does not make agency action unreviewable."[350] The Court also has emphasized in several decisions that "§701(a)(2) requires careful examination of the statute on which the claim of agency illegality is based."[351] The D.C. Circuit, furthermore, "has noted that judicially manageable standards may be found in formal and informal policy statements and regulations as well as in statutes,"[352] and that "[t]he use of the phrase 'should be' rather than 'shall' suggests but does not necessarily mean [agency peer review] Guidelines are not binding."[353]

- ***Family Farm Alliance v. Salazar; San Luis & Delta-Mendota Water Auth. v. Salazar***

In *Family Farm Alliance* and *San Luis & Delta-Mendota Water Auth.*, the same California federal district court held that, "[n]one of the [IQA] guidelines cited by Plaintiffs set forth any 'judicially manageable standards' against which the presentation, use, or analysis of data can be measured,"[354] within the meaning of the APA. These cases involved simultaneous challenges brought by private and public parties against the FWS. The Service had denied Family Farm Alliance's requests for correction concerning the FWS's alleged IQA noncompliance "in connection with FWS's issuance of a 2008 Biological Opinion under the Endangered Species Act ('ESA'), addressing the impact of the coordinated operations of the federal Central Valley Project ('CVP') and State Water Project ('SWP') on the threatened Delta smelt (hypomesus transpacificus) ('2008 Smelt BiOp')."[355]

Family Farm Alliance argued that "FWS failed 'to timely respond to [FFA's] appeal and/or make corrections to the 2008 Biological Opinion.'"[356] In addition, Family Farm Alliance argued that "the peer review FWS commissioned to review the 2008 Smelt BiO violated National Academy of Sciences standards governing peer reviewer conflicts of interest, incorporated by reference into FWS's IQA Guidelines." [357] In particular, the *Family Farm Alliance*'s July 2009 complaint alleged *inter alia* that, "the FWS failed to follow the requirements of their own adopted peer review policy [because t]he peer reviewers of the 2008 Biological Opinion [selected by an 'independent' peer review contractor,] consisted of authors of the papers upon which it was based, their graduate students, recipients of CALFED (a consortium of federal and state agency decision-makers) funding, and participants in working groups examining delta smelt whose work formed the basis of the 2008 Biological Opinion."[358]

With respect to the first IQA claim, the *Family Farms Alliance* court held that "neither the IQA nor the OMB Guidelines contain substantive standards with respect to response deadlines,"[359] and that, in any event, the challenge of "the timing of FWS's failure to respond to FFA's IQA Appeal […was] moot" because "FWS [had since] responded."[360] Plaintiff's pleadings, however, had neglected to cite a 2002 OMB policy memorandum clearly interpreting its IQA Guidelines as imposing a sixty calendar-day response time to RFCs as official federal policy.

With respect to the second claim, the court held that "[t]he IQA itself contains no standards concerning peer review, committing such matters to agency discretion."[361] In particular, the court found that, the "OMB-OIRA criteria do not create enforceable rules of conduct. Nothing in the statute or the [OMB or FWS IQA] Guidelines address the use of peer reviewers with the potential sources of conflict."[362] The court appears to have been persuaded by the guidelines' omission of criteria calling for disqualification of peer reviewers in the event of a conflict of interest. The court also generally referenced how the FWS had adopted the OMB Peer Review Bulletin, which "requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS) when selecting peer reviewers who are not government employees," and how the "NAS Policy referenced in the OMB IQA Bulletin […] contains guidance on the subject of conflicts of interest." However, the court appears to have not examined the NAS conflict-of-interest standards. In addition, plaintiff's pleadings failed to reference significant applicable portions of the OMB Peer Review Bulletin and the NAS Conflict of Interest Policy, both of

which would arguably have demonstrated "enforceable rules of conduct" concerning peer review of highly influential scientific assessments.

3. Standing under the APA

a. Standing Generally

The U.S. Supreme Court has held, "[t]he question of standing 'involves both constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise.'"[363] Article III imposes on plaintiffs a three-part requirement of "standing" to show they are individually "entitled to an adjudication of the particular claims asserted."[364] Each "plaintiff must show: (1) it suffered an "injury-in-fact" that is (a) concrete and particularized, (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision."[365] In other words, "[p]laintiffs must demonstrate that they are not merely asserting a 'generally available grievance' about the government, unconnected with a threatened concrete interest of their own."[366] The determination of whether a concrete injury-in-fact has been established "requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted."[367] "Standing is evaluated on a claim-by-claim basis. A plaintiff must demonstrate standing 'for each claim he seeks to press' and for 'each form of relief sought.'"[368]

Furthermore, the suffering of a procedural injury (*e.g.*, the denial of an ability to respond to a federal agency's statutory notice, comment, and appeal process), "even if the procedural right has been accorded by Congress,"[369] is insufficient *alone* to establish Article III standing.[370] Standing "'requires...a factual showing of perceptible harm.'"[371] "The procedural injury must 'impair a separate concrete interest.'"[372]

The concept of "informational standing" has arisen in the context of regulated entities challenging agencies' failure to comply with statutory duties to disclose information to the public.[373] In such situations where standing is not conferred by a statutory citizen suit provision, courts must draw inferences from legislative history and carefully construe the APA and other statutes to discern whether they permit suits in the public interest to require disclosure.[374] Courts in these cases take into consideration "a range of empirical issues—the likely performance, without lawsuits, of the agency and the private sector; the cost of any lawsuits; the effects of lawsuits on the agency's capacity for priority-setting; and the effects of lawsuits on the agency's substantive regulation."[375] The D.C. Circuit has generally been less inclined to grant informational standing,[376] while other circuit courts, such as the Sixth Circuit, have been more open to the concept.[377] The Ninth Circuit, meanwhile, has "concluded that general notice and appeal provisions in a statute that are designed to promote public participation, *but do not establish an explicit public right to information from the government*, are insufficient to establish informational standing."[378] In doing so, it effectively "restricted procedural[/informational] standing to only those *plaintiffs who can demonstrate a concrete injury*."[379]

The U.S. Supreme Court also has held that, "[i]n addition to the immutable requirements of Article III, 'the federal judiciary has also adhered to a set of prudential principles that bear on the question of standing.' […] that can be modified or abrogated by

Congress."[380] Such "'judicially self-imposed limits on the exercise of federal jurisdiction, […] are 'founded in concern about the proper—and properly limited—role of the courts in a democratic society.'"[381] One key prudential principle requires that "a plaintiff's grievance must arguably fall within the zone of interests protected or regulated by the statutory provision or constitutional guarantee invoked in the suit."[382] The Court has recently held, for example, that, "[e]ven when Article III permits the exercise of federal jurisdiction, prudential considerations demand that the Court insist upon 'that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult constitutional questions.'"[383] In other words, prudential standing principles come into play as an additional factor to limit judicial review where Article III standing requirements have been satisfied.

Moreover, the APA imposes its own standing requirement set forth in 5 U.S.C. § 702. The Supreme Court has interpreted this provision as requiring not only a demonstration of an injury-in-fact, *but also* a showing that "the interests sought to be protected by the [plaintiff are] arguably within the zone of interests to be protected or regulated by the statute […] in question."[384] "In determining whether the petitioners have standing under the zone-of-interests test to bring their APA claims, [courts must] look […] to the substantive provisions of the [statute] the alleged violations of which serve as the gravamen of the complaint."[385] "Whether a plaintiff's interest is 'arguably. . .protected. . .by the statute' within the meaning of the zone-of-interests test is to be determined not by reference to the overall purpose of the Act in question, but *by reference to the particular provision of law upon which the plaintiff relies*."[386] In effect, the "zone-of-interest" test has two prongs. "First, the court must determine what interests the [substantive] statute arguably was intended to protect, and second, the court must determine whether the 'plaintiff's interests affected by the agency action in question are among them.'"[387] It is generally understood that the Court's prior interpretation of the language of 5 U.S.C. § 702—"[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action"—"creat[ed] a right to appeal as a 'private attorney general.'"[388]

b. Relevant Federal Court Cases

i. *Salt Institute v. Thompson*

In this ruling, a Virginia federal district court noted two possible avenues for securing judicial review of federal agency actions. First, a plaintiff can show that "a substantive statute [expressly] provide[s] a private right of action for judicial review of an agency action."[389] Second, a plaintiff can employ "the provisions of the Administrative Procedure Act [to] provide for judicial review."[390] The APA can be invoked "[w]hen Congress in a substantive statute has not explicitly created a private right of action for review of an agency action."[391] In such a case, "an implied [right of action] may exist in favor of a particular plaintiff, *but only if Congress 'intended to create the private remedy sought by the plaintiff*[ ]'"[392] Therefore, "*[t]he burden is on the plaintiff to demonstrate such an intent*, and the requirement in order for a plaintiff to succeed is 'a stringent one…particularly given the Court's generally 'restrictive attitude […] toward creating implied rights of action."[393]

The district court thereafter examined whether the plaintiffs had sufficiently demonstrated an injury-in-fact. It found not only that plaintiffs had "ma[de] no specific assertions of injury caused by NHLBI's recommendations regarding dietary intake or NHLBI's

inability to provide them with the DASH-Sodium data,"[394] but also that plaintiffs had not even asserted an indirect economic or other injury as the result of NHLBI's information dissemination.[395] The court further found that "[p]laintiffs [had] fail[ed] to allege that their purported injury [was] fairly traceable to the challenged conduct of NHLBI and not attributable to some independent third party not before the Court."[396] In the absence of such evidence, the district court conceived that plaintiffs' injuries could have been as easily caused by the "published results of the DASH-Sodium Trial" and/or "numerous other studies" as by the NHLBI's recommendations, the U.S. Dietary Guidelines, and the Recommended Dietary Allowances report, each of which had "reached the conclusion that reducing sodium intake reduce[d] blood pressure."[397] The court then held that "none of the [p]laintiffs' alleged harms [was] sufficiently concrete and particularized to confer standing."[398]

Moreover, the court held that "[p]laintiffs' purported injuries would not be redressed even if they [had] received their desired remedies of access to the DASH-Sodium Trial data and amendment of NHLBI's statements and recommendations regarding salt intake."[399] It had reasoned that the desired remedies would not have made a difference because "numerous other scientific studies, the DASH-Sodium Trial results [,…] the U.S. Dietary Guidelines, and the NAS Recommended Dietary Allowances' recommendations […] would [have] all remain[ed] unchanged, in circulation, and potentially influencing the public to reduce its consumption of salt."[400]

In sum, the *Salt* court concluded that plaintiffs were unable to show that Congress had expressly intended for the IQA to provide them with a right of action that had been invaded. Instead, the district court held that "[t]he language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts,"[401] and consequently, dismissed the case.

As support for this conclusion, the *Salt* court cited *Alexander v. Sandoval*.[402] In *Sandoval*, the Supreme Court "declined to imply a private right of action to enforce the disparate impact regulations of Title VI of the 1964 Civil Rights Act," where the statute did not expressly provide such a right. The Court held that the determination of whether a statute created an *implied* right *and* an *implied* judicial remedy to enforce it should be focused principally on Congress's intent as gleaned from the text of the substantive statute.[403] The Court also held that § 602 did not create a new implied right of action because the regulations agencies adopted pursuant to § 602 went beyond the statutory schema established by § 601 (*i.e.*, rather than focusing only on purposeful discrimination, they also prohibited practices that had a discriminatory effect). [404]

ii. *Salt Institute v. Leavitt*

The Fourth Circuit, in *Salt Institute v. Leavitt*, reviewed the district court's dismissal of *Salt Institute v. Thompson* for lack of standing *de novo*.[405] It held that since the IQA "creates no legal rights in any third parties [,…particularly,] a legal right to access to information or to correctness, appellants ha[d] not alleged an invasion of a legal right and, thus, ha[d] failed to establish an injury in fact sufficient to satisfy Article III."[406]

It analyzed the claim of *positive* rights raised in terms of common law rights. The court found that "[t]he injuries alleged by appellants [had been] the deprivation of the raw data from the studies and the asserted incorrectness in NHLBI's public statements [, a]lthough there is no general common law right to information from agencies or to informational correctness."[407] It also found that the IQA, "by its terms [, only…] orders the Office of Management and Budget to draft guidelines concerning information quality and specifies what those guidelines should contain."[408] The court held that because the IQA "does not create a legal right to access to information or to correctness,"[409] and "appellants ha[d] not [otherwise] alleged an invasion of a legal right," they "failed to establish an injury in fact sufficient to satisfy Article III."[410] The court reasoned that the IQA was unlike the Federal Election Campaign Act of 1971 that had been the subject of dispute in *Federal Election Commission v. Akins*,[411] which "clearly created a right to information by requiring the Federal Election Commission to make certain information available to the public."[412] Federal district courts in the Ninth and D.C. Circuits thereafter adopted this reasoning in *Family Farm Alliance v. Salazar* and in *Single Stick v. Johanns*

iii. *Family Farm Alliance v. Salazar*

The court in *Family Farm Alliance* found that "*Salt Institute's* reasoning [was] sound."[413] It noted that the Salt Institute had made two IQA claims: "that information was withheld in violation of the IQA and another alleging that erroneous information was released in violation of the IQA."[414] It also noted how Family Farm Alliance's "contention that assertion of an informational injury [was] sufficient [had been] specifically rejected."[415] The district court held that because the showing of injury required to establish Article III standing presupposes a statute's creation of legal rights that have been invaded, and "the IQA creates no enforceable legal rights at all [*i.e.*, rights to information or correction information], and the OMB and FWS Guidelines contain no judicially manageable standards relevant to [p]laintiff's claims," there can be "no standing" with respect to these claims.[416]

The district court also addressed plaintiff's claim that peer reviewers of the October 2008 draft Biological Opinion had violated OMB and FWS IQA guidelines because they had not been sufficiently independent from the agency whose report had been subject to peer review.[417] It held that "the OMB's IQA Bulletin for Peer Review, which incorporates the NAS Peer Review Policy, and which is in turn incorporated by reference into FWS's IQA Guidelines, specifically disclaims creating any rights enforceable against the United States."[418]

4. *Prime Time Int'l Co. v. Vilsack*: A Potential Breakthrough

The D.C. Circuit's decision in *Prime Time Int'l Co. v. Vilsack*[419] arose from an appeal of *Single Stick v. Johanns*, a ruling discussed above. Single Stick had changed its name to Prime Time International Co. during the lower court proceedings. In its motion for summary judgment, Single Stick had argued that the denial of an IQA RFC is reviewable under the APA because the IQA establishes a right to correct information, the IQA doesn't preclude judicial review, and the APA manifests "the strong presumption that Congress intends judicial review" of agency action.[420] In its opposition, USDA argued that the IQA does not create a right to information "because the IQA does not contain any rights-creating language [,…] but […r]ather focuses on regulating the conduct of federal agencies," citing *Sandoval*.[421] In addition, USDA argued that "[e]ven if the IQA did create rights to seek the production and

correction of information maintained and disseminated by an agency, those rights would not be actionable here under the APA […] because the APA does not permit judicial review of matters committed to agency discretion by law."[422] Furthermore, plaintiff's reply to USDA's opposition motion argued that, despite the IQA's lack of express rights-creating language, *Sandoval* and APA jurisprudence and the IQA's text indicate that Congress had intended to provide an implied right and cause of action.[423]

On appeal, Prime Time argued that USDA's IQA guidelines set out defined, non-discretionary standards with which the agency was required to comply. In support of that point, appellant explained that the resulting release of data USDA utilized in a publicly disclosed FETRA assessment that Prime Time had sought in its FOIA request and its IQA request for correction, constituted an agency "dissemination" within the meaning of the IQA and USDA's guidelines.[424] In response, USDA argued for the first time in the litigation that such assessments constituted an "adjudication" that qualified as an exemption from the definition of "dissemination," thereby removing it from IQA review.[425]

The D.C. Circuit's resulting opinion reflected the court's disinterest in deciding whether the IQA and the APA authorized an implied right of action for standing purposes. Yet, in order to ascertain whether "USDA's determination of Prime Time's assessments for three quarters of FY 2005 was an adjudication" within the meaning of the statute and guidelines, the court was all but compelled to examine Prime Time's appeal on the merits. The court reviewed the OMB IQA guidelines, the APA, and the FETRA definitional standards, and concluded that USDA's FETRA assessments qualified for the IQA "dissemination" exemption.[426]

This conclusion thus denied Prime Time the information it was seeking. However, IQA proponents were encouraged by the reasoning underlying the D.C. Circuit's holding. The court essentially determined that that the IQA (as well as OMB's IQA Guidelines) and the APA authorized an implied cause of action. In so deciding, the court had to conclude that USDA's failure to respond to Prime Time's IQA request for correction constituted a "final agency action" *and* that the particular definitional provisions of the USDA IQA guidelines provided a "meaningful" standard for judicial review under APA § 704.

Significantly, in reviewing the USDA IQA Guidelines' definition of "dissemination" as "exclud[ing] distribution limited to…adjudicative processes," (which in turn implemented the OMB guidelines' definition of "dissemination")[427] the court held that it would "defer to OMB's reasonable construction of the statute…because Congress [had] delegated authority to OMB to develop *binding* guidelines implementing the IQA."[428] In granting OMB such broad deference, the court did not mention, but likely recognized, that OMB had complied with Congress's intent that it develop guidelines "*with public* and Federal agency *involvement*" by seeking public comments on proposed guidelines[429] that were subsequently incorporated into the final IQA guidelines.[430] Consequently, the court also held that, since "[t]he IQA was silent on the meaning of 'dissemination,' and…OMB…in defining the term…exercised its discretion to exclude documents prepared and distributed in the context of adjudicative proceedings" OMB's exercise of discretion was "a permissible interpretation of the statute."[431] Moreover, the D.C. Circuit's holding in *Prime Time Int'l Co.* also confirmed, consistent with the Supreme Court's holding in *United States v Mead*,[432] that even non-legally binding OMB and agency IQA guidelines are entitled to judicial deference under *Chevron* as if they were legally binding, to the extent of their "reasonableness,"

"consistency," and "power to persuade."[433]

The D.C. Circuit's holding that specific OMB IQA Guidelines and Peer Review Bulletin provisions are entitled to judicial deference will enable prospective IQA claimants to challenge flawed IQA peer-review and administrative-review procedures that resulted in agency dissemination of flawed third-party-developed HISAs as support for major rulemakings. Since, as noted in Section I, information quality is an important component of a court's hard-look review of agency regulations (*e.g.*, the Endangerment Findings and the GHG emissions control regulations they have spawned), an IQA litigant may, based on the evidence it is able to adduce, overcome the presumption that EPA is entitled to judicial deference regarding the judgment it exercised.

Therefore, it is no surprise that the D.C. Circuit's ruling and its underlying rationale instigated forcefully skeptical reactions from DOJ and some in the federal judiciary. DOJ immediately petitioned the D.C. Circuit for a rehearing of *Prime Time Int'l Co.* to clarify that the court "did not reach the question whether the IQA creates judicially enforceable rights,"[434] which the court promptly denied. DOJ's reaction was curious, considering its prior suggestion in *Salt Institute v. Thompson* that "a different question might be presented in a case in which a plaintiff challenges an agency's dissemination of information in connection with its formal rules or regulations. In that context, the IQA might conceivably be relevant to 'arbitrary and capricious' and 'substantial evidence' reviews under the APA."[435]

Federal district court judges in California also sought to minimize *Prime Time Int'l Co.*'s significance. In *Family Farm Alliance,* and *San Luis & Delta-Mendota Water Auth*, Judge Oliver Wanger asserted that *Prime Time Int'l Co.* did "[n]ot [s]upport [a]ssertion of [j]udicial [r]eview in [that] [c]ase."[436] Arguably, the plaintiffs in those cases did not sufficiently plead their cases before Judge Wanger, as discussed above. They should have emphasized the distinction between a court's granting judicial review in a case involving "informal agency statements, recommendations or opinions […made] *outside* the context of formal rulemaking or adjudication," and a court's granting judicial review to assess *in the context of an agency rulemaking* of an agency's noncompliant "rel[iance on scientific data that has not been generated using 'sound statistical and research methods.'"[437]

5. Anticipating and Addressing Judges' Prudential Concerns over IQA Stakeholders' Standing to Sue

Some judges' ideological predisposition against private causes of action[438] will animate their consideration of APA-based suits alleging harm from violations of the IQA. For this reason, stakeholders must understand the prudential and other factors federal judges have considered when analyzing standing and tailor their arguments accordingly.

As discussed above, the Supreme Court's standing doctrine is rooted in the Constitution's "case or controversy" requirement in Article III. The Court has demanded "concrete adversity" to ensure that courts will resolve disputes based on actual, particularized injuries, which will in turn conserve the judiciary's scarce resources.[439] Concrete adversity also "is used to show that the Court's power is properly invoked."[440]

Beginning with Justice Powell's *Cannon v. University of Chicago*[441] dissent, the Rehnquist Court narrowed Article III standing *inter alia* by emphasizing the importance of

congressional clarity in creating private causes of action.[442] In his dissent, Justice Powell "argued that because federal power is limited—that is, each branch of government can exercise only the power that is specifically and affirmatively granted to it—judicial recognition of causes of action risked distorting the constitutional process."[443] The Rehnquist Court's approach, which sought to avoid distortion of the constitutional process, served to "reverse the presumption found in the first implication cases and to place the burden on plaintiffs to show that Congress clearly intended to grant a private right of action in the statute."[444]

Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.[445] reflects this presumption. It held that a court's inference of an implied right of action "runs contrary to the established principle that '[t]he jurisdiction of the federal courts is carefully guarded against expansion by judicial interpretation …' and conflicts with the authority of Congress under Art. III to set the limits of federal jurisdiction."[446]

The Court has also found that the redress of alleged harm in some cases is "better suited to the political [democratic] process."[447] Under this prudential justification, "if a plaintiff suffers an injury that is 'undifferentiated and common to all members of the public,' the plaintiff has a 'generalized grievance' that must be pursued by political, rather than judicial, means."[448]

Consistent with this view, the Court "has rejected a general federal concept of a pure 'private attorney general,' who pursues lawbreakers through the courts solely from an interest in seeing the law obeyed,"[449] which Congress has encouraged through the authorization of attorneys' fees in environmental and safety laws.[450] In the Court's view, "[s]uch a person is indistinguishable from any of thousands or millions of other people who wish to see the law obeyed; rather than sue, those people should band together and ensure that their democratically elected representatives see that the law is enforced."[451] The federal courts' decisions rendered in *Family Farm Alliance* and *Salt Institute*, respectively, possibly reflected the judge's concern that the grant of standing in IQA-focused APA cases could open the floodgates to litigation of disputes that could arguably be resolved by Congress or the executive branch.

The Court's decision in *FEC v. Akins*,[452] however, provides plaintiffs' an opportunity to show particularized injuries even where they are part of a group of aggrieved persons. There, the Court found that "an injury held in common with all voters could nonetheless give rise to standing because the plaintiff suffered that injury concretely *and in a way particular to her*."[453] The Court's decision in *Massachusetts v. EPA* also could help plaintiffs show "particularized harm […] even though global warming arguably affects every person on the planet."[454]

Stakeholders and other entities operating in their supply chains may cite *Akins* and *Massachusetts* in IQA noncompliance suits. They will need to distinguish their particularized economic harm from the general harm alleged by all other downstream third parties. If such stakeholders can demonstrate sustained, particularized injuries, "it is irrelevant […] whether many others share that same injury."[455]

A third prudential factor some judges have considered in their standing analysis is the promotion of a strong executive. Justice Scalia is a proponent of this view, which "protect[s]

the executive branch against an unholy alliance between Congress and the courts,"[456] and "serves as a brake on Congress' efforts to conscript the courts to oversee executive action."[457] One legal commentator has found that various Court decisions reveal how Justice Scalia's aversion to Congress "turn[ing] the courts into 'virtually continuing monitors of the wisdom and soundness of Executive action.'"[458]

This third prudential standing factor is in direct tension with the concerns Chief Justice Roberts evidenced in his *City of Arlington* dissent, which is referenced in Section II "[t]he administrative state 'wields vast power and touches almost every aspect of daily life."[459] Decisions motivated by this factor run the risk of expanding the power of administrative agencies at the expense of Congress, which among other checks on that power, explicitly or implicitly encourage stakeholders to file suit for redress of harm from regulations. As the Court stated in the 2010 case *Kucana v. Holder*, "[s]eparation concerns […] caution us against reading legislation, absent clear statement, to place in executive hands authority to remove cases from the Judiciary's domain."[460]

IQA stakeholders must contemplate each of these prudential factors that may influence judges' perspectives on standing.[461] They must carefully craft their arguments to avoid the impression that they are acting as "private attorney generals." Aggrieved parties will have to show that they fall within the zone of interests of a protected class (*e.g.*, a regulated party or supplier thereof, or a state government); 2) they suffered a particularized injury-in-fact (*e.g.*, economic injury arising from GHG emissions regulations triggered by the Endangerment Findings supported by improperly peer reviewed HISAs), irrespective of whether others share the same injury; and 3) the injury-in-fact will be eliminated or substantially reduced if the relief sought is granted (*e.g.*, an injunction precluding EPA's use of all improperly peer reviewed EPA and NOAA-developed HISAs supporting the Endangerment Findings *and* the regulations they have spawned until they have been peer reviewed again).

6. States as APA/IQA Plaintiffs: The Doctrine of *Parens Patriae*

The Supreme Court recently "recognized a special standing doctrine of *parens patriae* [meaning literally 'parent of the country'] to allow states to protect certain quasi-sovereign interests including the health, welfare, or natural resources of their citizens."[462] In *Massachusetts v. EPA*, the Court held that "the Commonwealth of Massachusetts [was] entitled to 'special solicitude' in [the Court's] standing analysis,"[463] in light of the State's statutory procedural right to challenge the EPA's administrative execution of the CAA and its "'stake in protecting its quasi-sovereign interests.'"[464]

The majority relied on the Supreme Court's decision in *Snapp v. Puerto Rico*[465] to sort out the different interests a State may invoke in an action. In *Snapp*, the Court generally explained what State quasi-sovereign interests included and distinguished them from a State's sovereign and proprietary interests.

The Court described State *sovereign* interests as including "the exercise of sovereign power over individuals and entities within the relevant jurisdiction [which…] involves the power to create and enforce a legal code, both civil and criminal," and the power to "demand recognition from other sovereigns […which] involves the maintenance and recognition of borders."[466] It described State *proprietary* interests as including ownership of

land or participation in a business venture, in which the State asserts an interest similar to that of private parties.[467]

The *Snapp* Court described State *quasi-sovereign* interests, which are to be determined on a case-by-case basis,[468] as generally "consist[ing] of a set of interests that the State has in the well-being of its populace."[469] According to the Court, "a State has a *quasi-sovereign* interest in the health and well-being—both physical *and economic*—of its residents in general."[470] A State also "has a quasi-sovereign interest in not being discriminatorily denied its rightful place within the federal system,"[471] which would occur where its residents are denied benefits assured to them by federal law.[472]

Legal commentators have concluded that a State's *quasi-sovereign* interests include an interest in defending "the health and well-being of its citizens in a public nuisance suit for transboundary pollution."[473] Another commentator has explained that State quasi-sovereign interests, like sovereign interests, are best understood in economists' terms—*i.e.*, as "public goods."[474]

Professor Bradford Mank, has written that the *Massachusetts* Court "appropriately relied on the Court's *parens patriae* decisions as the grounds for giving states greater standing rights when they sue on behalf of quasi-sovereign interests, although none of those earlier cases had explicitly applied a different standing test for states."[475] Since quasi-sovereign interests "normally involve generalized grievances applicable to large numbers of people or to extensive natural resources," a State plaintiff will not likely be required "to show that it had an individual injury."[476] Accordingly, the Court found that the computer model projections the Commonwealth had proffered as evidence about the effects of global warming on its coastline through 2100 were sufficient to satisfy more generalized requirements of injury-in-fact standing.[477] In other words, the Court did not require Massachusetts "to prove how much the EPA's regulation of new vehicle emissions would reduce future harms to its coastline, as long as it [was] likely that such regulation would reduce the harm to the state."[478] Professor Daniel Weinstock, who is in accord with this view, notes that the "predominant" or "prevailing scholarly interpretation" is that *Massachusetts* "dilut[es] the *Lujan* standing requirements when state plaintiffs assert injuries to sovereign or quasi-sovereign rights alongside proprietary interests in the context of a statutory cause of action."[479]

These commentators have provided the following reasons for this conclusion. First, the Commonwealth had been "positioned" to assert each of these three types of interests, recognizing that while the "preservation of a state's coastline [was] superficially a proprietary interest, [it] ha[d] been classified as a [natural resource, and thus, as a] quasi-sovereign interest by many lower courts and commentators"[480] because it affected the welfare of a large number of its citizens.[481]

Second, the Court integrated into its standing analysis "the principle of relaxed standing in statutory procedural rights cases rooted in […] 'footnote seven' of Justice Scalia's *Lujan* opinion."[482] It had justified such relaxed standing on the grounds that Massachusetts's exercise of its "procedural right" via the Clean Air Act's citizen suit provision and the Commonwealth's "stake in protecting its quasi-sovereign interests entitled it to "special solicitude in our [traditional *Lujan*] standing analysis."[483] The Court's justification did not necessitate the existence of an express statutory citizen suit provision *per se* in order for

Massachusetts to exercise its procedural rights. The Court had based the "special solicitude" granted to Massachusetts on the Court's prior reasoning in *Georgia v. Tennessee Copper Co.*[484] and Justice Brennan's concurring opinion in *Snapp v. Puerto Rico*.[485] Although *Tennessee Copper* had not been a standing case, it articulated "the broad[] principle that states are entitled to broader rights than individuals because of the quasi-sovereign rights they retain as a limited substitute for their former full sovereign rights."[486] In *Snapp*, "Justice Brennan [had] call[ed] for deference to a state's assessment of its sovereignty-related interests."[487]

Third, the Court held in *Massachusetts* that the traditional bar prohibiting States from bringing suit against the federal government in their capacity as *parens patriae*, as it had previously decided in *Massachusetts v. Mellon*,[488] did not apply.[489] It reasoned that there is a "critical difference between allowing a State 'to protect her citizens from the operation of federal statutes' (which is what *Mellon* prohibits) and allowing a State to assert its rights under federal law (which it has standing to do). Massachusetts does not here dispute that the Clean Air Act applies to its citizens; it rather seeks to assert its rights under the Act."[490] Consequently, "states should be able to file *parens patriae* suits on behalf of its citizens against the federal government if the federal government has allegedly failed to perform a statutory or constitutional duty."[491]

VII. A FRAMEWORK FOR AN IQA ACTION UNDER THE APA

This section sets forth a framework for a potential cause of action under the APA focusing on the facts set forth in the case study outlined in Section V, and based on the jurisprudential analyses discussed in Section VI.

A. Securing Judicial Review of APA Actions Challenging Breaches of the IQA

1. Advancing a "Negative" Right to be Unburdened by Improperly Peer-Reviewed Scientific Information

As described in Section VII, none of the courts to consider APA/IQA suits have found as a matter of law that Congress intended to provide an explicit or implied right to obtain correct government information. Such a lack of success is due in part to plaintiffs' framing of the IQA issues in their complaints. A careful review of IQA statutory language reveals that Congress expressly intended for that statute to implement the purposes and objectives of the Paperwork Reduction Act. While access to government information was among those purposes and objectives, it was neither the PRA's nor the IQA's *primary* purpose. Rather, the language and legislative history of these statutes show that Congress was concerned *primarily* with relieving special classes of legal "persons" from the direct and indirect *burdens* federal agencies had increasingly imposed through collection and dissemination mandates which, in certain instances, had converged.

a. Courts Have Largely Rejected an Implied "Positive" Right to Correct Information under the IQA

Federal courts have largely rebuffed stakeholders' arguments that the IQA grants

informational standing. Those courts have followed the Supreme Court's decisions in *Federal Election Commission v. Akins*,[492] *Sandoval*, and *Gonzaga University v. Doe*.[493] In *Akins*, the Court expressly contrasted the generalized grievance language of APA "5 U.S.C. § 702 (stating that those 'suffering legal wrong' or 'adversely affected or aggrieved . . . within the meaning of a relevant statute' may seek judicial review of agency action)" with what it considered the more explicit grant-of-standing language in the Federal Election Campaign Act of 1971.[494] *Akins* narrowed informational standing even further than the Court had in *Sandoval* and *Gonzaga*, holding that "where the text and structure of a statute provide no indication that Congress intends to create *new* individual rights, there is no basis for a private suit."[495] In order to confirm whether Congress had intended (explicitly or implicitly) to establish such rights, the Court required an affirmative evidentiary showing that the statutes in question were "phrased 'with an unmistakable focus on the benefited class.'"[496]

Professor Cass Sunstein has offered several reasons why courts have been reluctant to grant a broad positive right to obtain correct government information: it would engender significant legal costs, divert administrative resources, and ossify executive branch rulemaking.[497] Such a right may be conceived of as a *positive* right "entitling a person to have another do some act for the *benefit* of the person entitled," as opposed to a relatively less imposing *negative* right "entitling a person to have another refrain from doing an act that might harm the person entitled."[498] Since "[c]laims to *positive* rights can take various forms,"[499] and the Supreme Court has generally continued to deny "claims for government services" without a clear showing of congressional intent,[500] federal courts in the past arguably perceived IQA plaintiffs' claims for correct government information as simply another request for "government services" that warranted a more measured standing assessment.[501]

b. The IQA Provides an Implied "Negative" Right to be Unburdened by Improperly Peer-Reviewed Information

IQA § 515(a) expressly instructed OMB to "issue guidelines under [PRA] sections 3504(d)(1) and 3516 […] that ensure "the quality, objectivity, utility, and integrity" of agency-*disseminated* information, *in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act*."[502] PRA § 3504(d)(1) in turn required OMB to "develop and oversee the implementation of policies, principles, standards, and guidelines [applicable] to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated."[503] PRA § 3516 mandated OMB to "promulgate rules, regulations, or procedures necessary to exercise the authority provided by this chapter."[504]

Sections 3501(1)-(2) set forth what are arguably the primary purposes of the PRA. Those goals are to "minimize the paperwork *burden* […] resulting from the *collection of information* by or for the Federal government [and to...] ensure the greatest possible public benefit from and maximize the utility of information created, *collected*, maintained, *used*, shared and *disseminated* by or for the Federal government."[505] PRA § 3501(4) sets forth the additional purpose of "improv[ing] the *quality* and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society."[506] PRA § 3501(8)(C) dictates one further purpose of the statute to be "ensur[ing] that the [Federal Government's] creation, *collection*, maintenance, use [and] *dissemination* […] is consistent with applicable laws, including laws relating to […] *access to information*, including section

552 of title 5 [of the Freedom of Information Act]."[507]

The reports of the House Committee on Government Reform and Oversight and the Senate Committee on Government Affairs accompanying the 1995 amendments to the PRA support and clarify this textual reading. They provide that "Section 3501 maintains *the Act's primary focus on minimizing paperwork burdens on the public*."[508] In addition, they provide that the 1995 amendments:

> add[ ] several additional purposes and revise[] and realign[] other purposes […] [They] promote[] the theme of improving the quality and use of information *to strengthen agency* decisionmaking and *accountability* and to maximize *the benefit* and utility of information created, *collected*, maintained, *used, shared, disseminated*, and retained by or for the Federal Government.[509]

These reports also state that the amendments:

> provide[ ] a detailed framework to guide Federal Government *dissemination* of public information. […] OMB has an obligation to promote public *access* to Government information *through* the development and oversight of government-wide information *dissemination* policies. Likewise, agencies have an obligation to conduct their *dissemination* activities to ensure that the public has timely and equitable *access* to public information.[510]

Information access, however, arguably does *not* appear to constitute the IQA's primary purpose. Notably, IQA § 515(a) did not direct OMB to issue guidelines under § 3504(d)(2) to "*promote public access to public information*," which Congress presumably recognized was covered by other laws such as FOIA.[511]

PRA §§ 3501(1) and 3502(10) identify the class of intended beneficiaries of the protections the statute affords, consistent with these statutory purposes as "individuals, small businesses, state and local governments, and other persons."[512] Furthermore, PRA §§ 3502(2) and 3502(2)(C) define the term "burden." It includes the financial and nonfinancial (time, effort, etc.) resources such persons expend to "generate, maintain or provide information to or for a federal agency"[513] provoked by regulatory compliance obligations resulting from poor quality federal agency information disseminations that lead to new requirements.[514] PRA §§ 3502(2)(D)-(F) indicate that the term "burden" also includes the use of financial and nonfinancial resources necessary to search, collect, and review data sources and then transmit or disclose the collected information to federal agencies and the public.[515] PRA § 3502(3)(i) defines "collection of information" as including "the obtaining [or] causing to be obtained […] of facts or opinions by or for an agency, regardless of form or format, calling for […] identical reporting or recordkeeping requirements imposed on, ten or more persons"[516] other than U.S. agencies, instrumentalities or employees.[517] Congress envisioned that poor quality HISAs that support major regulations could impose harmful new compliance burdens on industry and state and local government entities that qualify as members of the "protected class" under the PRA. Congress also considered that the prospect of bearing such burdens would prompt stakeholder requests for correction under IQA § 515(b)(2)(B), which requires such actors to review, collect, and publicly disclose data

sources and other information.[518] Hence, the statutory scheme Congress created reflects how federal agency information dissemination burdens can indirectly beget additional agency information collection burdens.

In sum, the statutory text and legislative history of the PRA explicitly identify Congress's primary policy objective as reducing the burdens imposed by poor quality federal agency information dissemination and collection activities. The PRA was to achieve this objective through mandated information quality improvements and increased information access and federal agency transparency and accountability. The failure of the Clinton Administration OMB to promulgate data quality guidelines compliant with the PRA compelled Congress to enact the IQA. Consequently, to the extent Congress intended the IQA primarily as a *procedural* device to implement the PRA and to minimize such burdens, the IQA provides protection, vis-à-vis assured federal agency adherence to uniform peer-review standards, of a person's *negative* right not to be burdened by poor quality federal agency scientific and other information disseminations and collections.

The assertion of a negative right in the context of the IQA is analogous to the raising of a claim invoking the constitutional right to government inaction. The right to government inaction is the right to freely pursue one's aims without governmental intrusion, which arguably calls for the application of a relatively lower Article III standing threshold. Legal scholars recognize that natural rights theory, the common law undergirding U.S. constitutional rights, and U.S. constitutional rights themselves are largely *negative* rights[519] "which convey no affirmative entitlement but simply confer protection against prohibited governmental action."[520] Judge Posner's holding in the Seventh Circuit case *Jackson v. City of Joliet*[521] explained that "the Constitution is a charter of *negative* rather than *positive* liberties":

> The men who wrote the Bill of Rights were not concerned that Government might do too little for the people but that it might do too much to them. The Fourteenth Amendment, adopted in 1868 at the height of laissez-faire thinking, sought to protect Americans from oppression by state government, not to secure them basic governmental services. [522]

Thus, it is clear that the PRA, like the U.S. Constitution and the Bill of Rights, essentially embodies the protection of the negative "right to be left alone." Approximately one century ago, Justice Louis Brandeis recognized in his dissent in *Olmstead v. United States*, that "[t]he right to be left alone [was] the most comprehensive of rights, and the right most valued by a free people."[523]

2. The APA Empowers Stakeholders to Challenge EPA and NOAA Violations of "Negative" Rights

Plaintiffs advancing an implied cause of action case under the APA must show that the statute being challenged does not explicitly preclude judicial review, the action is not committed to agency discretion by law, *and* the agency action in dispute constitutes final agency action.[524]

The PRA expressly precludes judicial review of OMB Director determinations regarding certification (through control number assignment) of agency information

collection demands.[525] In addition, various federal courts have held that the protection provision of the PRA,[526] which prevents a person from being penalized for not providing information to an agency where the agency's information collection request fails to display an OMB Director-assigned control number, does *not* provide a private right of action for an alleged violation of the Act.[527] Rather, courts have held this only provides a right to limited judicial review—*i.e.*, to a "*defense* to [agency] enforcement actions."[528] In one such case, *Tozzi v. EPA*,[529] the D.C. District Court also held that an implied cause of action to challenge an agency's violation of the PRA does not exist under the APA,[530] because PRA § 3507(d)(6), by its explicit terms, states that OMB information *collection* request approval decisions "*shall not* be subject to judicial review."[531] The court reasoned that the APA's general waiver of sovereign immunity was unavailable because the text of the applicable statute in question (44 U.S.C. § 3507(d)(6)) precluded judicial review[532] and, consequently, failed to satisfy both of the requirements of APA § 701(a)[533] as explained by applicable case law.[534]

By contrast, the statutory text of the IQA, which focuses exclusively on agency information *disseminations*, does *not* preclude judicial review of agencies' failure to conform with OMB, EPA, or NOAA IQA peer-review or administrative-review standards applicable to HISAs. Congress directed OMB to promulgate these standards, which include a $500 million threshold that must be reached before an external peer review of agency-disseminated HISAs will be mandated, which is significantly higher than the threshold triggering an OIRA review of a related proposed agency regulation ($100 million). Taken together, these two factors strongly suggest that Congress intended for the courts to decide, on a case-by-case basis, whether judicial review of alleged agency nonconformance with such standards is warranted. Therefore, the IQA meets the requirement of APA § 701(a)(1).

In addition, the previously discussed OMB, EPA, and NOAA IQA HISA-related standards are also sufficiently well-defined, and thus, justiciable. These standards consist of HISA-specific peer-review independence, conflict-of-interest, and panel-balance standards set forth in OMB's IQA Guidelines and Peer Review Bulletin, EPA's IQA Guidelines and Peer Review Handbook, and NOAA's IQA Guidelines and Conflict of Interest Policy. They establish a minimal identifiable standard of data quality, usability and reproducibility for purposes of protecting affected persons' negative right not to be burdened by poor quality agency scientific information disseminations. This minimum standard strongly suggests that a court reviewing an APA implied-cause-of-action case pled by stakeholders challenging EPA and NOAA nonconformance will *not* find that Congress had committed such standards entirely to agency discretion by law, within the meaning of APA § 701(a)(2).

Because the OMB standards, in particular, were also promulgated pursuant to APA public notice-and-comment procedures, they may be construed as imposing legally binding obligations on federal agencies deserving of *Chevron* deference, for purposes of assessing agency conformance with them. To the extent that EPA and NOAA can show they had applied their respective IQA standards consistently with OMB standards, as required by IQA § 515(b)(2)(A), a court may rule that such EPA and NOAA standards are entitled, based on their persuasiveness, to the relatively lower level of *Skidmore* deference.

Furthermore, IQA § 515(b)(2)(B) directed OMB to establish an administrative-review mechanism that agencies should emulate enabling "affected persons" to exercise their negative right to protect themselves from the burdens imposed by agencies' using of improperly peer-reviewed scientific information, especially HISAs used as the basis for major

regulations. The legislative history regarding the enactment of IQA § 515(b)(2)(B) suggests that Congress did not trust federal agencies to self-police their data quality activities and sought to limit their discretion to impose economic and regulatory compliance burdens upon affected persons. Congress did so by restricting agencies' discretion to deny the requests for correction that affected persons file. OMB's standards, promulgated consistent with this authority, and also pursuant to APA notice-and-comment procedures, arguably afford stakeholders with the opportunity to seek and secure *special* administrative review of agency IQA nonconformance. To such extent, they are both justiciable and entitled to *Chevron* deference. Equally well-defined EPA and NOAA administrative review procedures, however, do not closely adhere to OMB standards because they most always treat specialized IQA requests for correction relating to HISAs supporting major rulemakings as general APA notice-and-comment submissions. This practice engenders the use of standards that are justiciable; thus, courts arguably will be able to adjudicate whether EPA's and NOAA's application of their respective standards diminish affected persons' ability to protect their negative rights in violation of IQA § 515(b)(2)(B).

Moreover, the disputed EPA actions arguably constitute final agency actions within the meaning of APA § 704. Applicable case law defines a final agency action as one by which "rights or obligations have been determined," or from which "legal consequences will flow."[535] On August 13, 2010, EPA denied IQA stakeholder petitions to reconsider the Endangerment Findings. These Findings had primarily relied upon the improperly peer-reviewed HISAs of the IPCC, USGCRP/CCSP, and NRC/NAS summarized and synthesized in EPA's accompanying Technical Support Document. EPA's denial of reconsideration reflected the consummation of the APA notice-and-comment review processes, and the stakeholders had exhausted all administrative remedies available.

One may also argue that the Endangerment Findings and EPA's August 2010 denial of reconsideration petitions implicated more considerable legal obligations for certain regulated IQA stakeholders and members of their supply chains from which quite significant legal consequences thereafter flowed. For example, the Endangerment Findings triggered GHG tailpipe emissions rules, prevention of significant deterioration and Title V GHG tailoring rules for stationary source facilities, and other burdensome proposals.

Consequently, it may be argued that the EPA's August 2010 denial constituted the "final agency action" that triggered legal consequences, which in turn determined the rights of these parties within the meaning of APA § 704.

3. Stakeholder Standing to Sue under Article III and Prudential Standing Requirements

EPA's and NOAA's violations of the IQA in the context of the Endangerment Finding have imposed significant economic burdens and injuries upon a number of different entities the PRA protects. Those protected class members include individuals, small businesses, state and local governments, and other persons.[536] Each prospective plaintiff must provide particularized evidence of economic harm caused by the Endangerment Findings, the related GHG emissions control regulations they triggered, and EPA's subsequent refusal to reconsider the Endangerment Findings.

Furthermore, prospective APA plaintiffs must also show that their economic injuries resulted from EPA's denial of their IQA-protected procedural rights. In other words, they must show that their injuries arose from: 1) EPA's failure to provide a special administrative review mechanism to evaluate their requests for correction arising from improper third-party peer reviews of HISAs supporting EPA's Endangerment Findings separately from the general APA notice-and-comment procedure; 2) EPA's failure to adequately respond to such requests; 3) EPA's failure to accord such stakeholders an opportunity to participate in scheduled APA public hearings; and 4) NOAA's prior misrepresentations about the intended use for NOAA-developed HISAs during the pre-dissemination review stage.

Moreover, but for EPA's reliance on deficiently peer-reviewed HISAs in violation of OMB, EPA, and NOAA IQA standards, it would not have been possible to issue those Findings, and consequently, it would have been neither necessary nor possible to promulgate the GHG emissions-control regulations they subsequently triggered.

As previously discussed, a number of HISAs disseminated by EPA and NOAA failed to satisfy applicable OMB, EPA, and NOAA IQA standards related to peer-review independence, conflict of interest, and panel balance. These standards are intended to protect the negative right of affected persons from the burdens imposed by improperly peer-reviewed, agency-developed HISAs supporting major regulations. In addition, EPA failed to accord affected persons their procedural right to seek and obtain correction of such improperly peer-reviewed assessments. Arguably, had this procedural right been provided, these persons would have been protected against such burdens. Given NOAA's recognized role as the lead federal climate science agency and its responsibility for the development of many HISAs that failed to follow IQA standards, IQA plaintiffs should be able to establish that an injunction curtailing EPA's use of those studies until they are peer reviewed again under the watchful eyes of the public in conformance with HISA-applicable IQA peer review procedural standards would redress their economic injuries.

The U.S. Supreme Court in *Summers v. Earth Island Institute* held that "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing. Only a 'person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy.'"[537] If prospective APA/IQA plaintiffs are able to show particularized economic injuries-in-fact caused by EPA's violation of these procedural rights, they would arguably qualify for relaxed standing.[538]

B. States May File IQA Suits Pursuant to the Doctrine of *Parens Patriae*

1. States Have Already Challenged EPA's Endangerment Findings to Protect Their Sovereign Interests

On May 23, 2011, the State of Texas, "[a]cting on behalf of 14 other states" brought suit under § 307 of the Clean Air Act, in its *sovereign* and *proprietary* capacity, against EPA in an effort to overturn the Endangerment Findings.[539] State Petitioners "challeng[ed] the endangerment finding on the grounds that the EPA's decision was 'arbitrary and capricious.'"[540] Having brought this action in their *sovereign* and *proprietary* capacity, these

states were treated as though they were private parties and were thus obliged to fulfill each of the three elements of Article III standing.

To successfully establish injury-in-fact, State Petitioners alleged that, although "the endangerment finding d[id] not itself regulate […] it is an essential component of EPA's GHG regulations […which] harm the State Petitioners [by…] impos[ing] [] a duty on the State Petitioners to spend resources implementing and enforcing [them, and consequently,…] various financial and resources burdens […] to administer the regulations."[541] State Petitioners also alleged, that since they "purchase, own, and operate vehicles and facilities that are subject to the GHG regulations [—*i.e*… EPA's Tailoring Rule…] stationary sources owned by State Petitioners will be subject to GHG permitting [and…] the GHG regulations will increase the purchase price of vehicles by an average of nearly $1,000 each by 2016."[542]

To establish causation, they alleged that the "Endangerment Finding is a necessary and indispensable component of the GHG regulations that directly harm State Petitioners," referencing 42 U.S.C. § 7521(a)(1) as "predicating regulation of air pollutants on a finding of endangerment."[543] And, to establish redressability, State Petitioners alleged that, since "EPA's GHG regulations hinge[d] on the validity of the Endangerment Finding [,…] if th[e] Court sets aside the Endangerment Finding […] the remaining GHG regulations w[ould] be rendered invalid, thereby redressing the harm to the State Petitioners."[544]

2. State Challenge of IQA Noncompliance under the APA

Because the D.C. Circuit's decision in *Coalition for Responsible Regulation v. EPA* did not address the IQA,[545] and the Supreme Court did not grant certiorari on that issue, no *res judicata* concerns arise.

In situations where private stakeholders cannot establish standing to bring IQA challenges, States may find more success invoking *parens patriae* authority to protect their citizens' collective rights and interests. States could bring an APA action for EPA and NOAA noncompliance with IQA standards during their development of the Endangerment Findings. States can show that the APA provides an implied cause of action under the IQA to protect a negative right not to be burdened by poor quality agency disseminations, and that a final agency action had triggered concrete legal consequences that caused economic injuries to the interests of the State and its residents. In addition, States can show that the implementation of the well-defined IQA peer-review independence, conflict-of-interest, and panel-balance standards applicable to HISAs that had been violated are not left to the discretion of the agencies, and thus, are justiciable.

Furthermore, States bringing suit in their quasi-sovereign capacity on behalf of their citizens will arguably be subject to a less rigorous test for standing that requires injury-in-fact to collective, rather than individual, state, and citizen interests. To this end, States should be able to utilize collective statistical and other data, including computer projections of current and future economic harm, to prove injury-in-fact, along with a lesser standard of general causation. A showing of general causation should not present too great of an obstacle considering that the EPA had primarily relied upon the improperly peer-reviewed HISAs as scientific support for its Endangerment Findings which automatically triggered, as a matter of law, the promulgation of various broadly applicable costly carbon-emissions control regulations. Moreover, States should be able to meet a relaxed standard of redressability

consistent with a proper pleading of their *parens patriae* interests without concern of federal preemption.

VIII. CONCLUSION

This WORKING PAPER explains in detail how the Information Quality Act and implementing guidelines from the Office of Management and Budget provide a procedural-law mechanism to ensure the objectivity, quality, utility, integrity *and* reproducibility of highly influential scientific assessments developed by federal agencies and third parties, which agencies in turn "disseminate" as support for major agency regulations.

OMB's guidelines, which bind all federal agencies, impose rigorous, uniform, peer-review-process standards that govern agency peer reviewer selection and retention practices. The guidelines also govern agencies' public disclosure obligations with respect to the data, computational and computer program inputs, assumptions, and applications that are incorporated into the assessments. In addition, OMB's guidelines require federal agencies to provide an administrative review mechanism that will allow affected persons to seek correction of agency-disseminated HISAs that were not adequately validated. Given the highly technical and specialized nature and characteristics of HISAs and the data on which they are based, the IQA and OMB's IQA guidelines anticipate that specialized review procedures, separate and apart from ordinary APA notice-and-comment procedures, must be utilized under certain circumstances.

EPA's 2009 GHG Endangerment Findings and the decision-making process that led to those Findings, offer an ideal case study in how the IQA applies in the rulemaking context and how agencies contravene the law. EPA's review of climate-science assessments disseminated in support of the Endangerment Findings were subject to four distinct IQA legal obligations, none of which EPA satisfied. These obligations related to: EPA-developed and peer-reviewed HISAs; third-party-developed and peer-reviewed HISAs; EPA's peer review of the Technical Support Document accompanying the Endangerment Findings that summarized and synthesized the numerous HISAs supporting them into a new HISA; and EPA's improper treatment of IQA stakeholder requests for correction. EPA and NOAA failed to ensure that the peer reviews of the HISAs satisfied the IQA's most rigorous peer reviewer independence, conflict-of-interest, and panel-balance standards.

As the WORKING PAPER explains, businesses and other stakeholders unsuccessfully sought correction of the faulty peer-review processes employed to validate the scientific assessments supporting the Endangerment Findings, and reconsideration of the Findings themselves. Such final agency action potentially gives rise to legal challenges of EPA's failure to comply with the IQA's peer-review standards and its denial of specialized review of technical correction requests outside of the routine rulemaking process. A review of similar past legal actions filed by aggrieved regulatory stakeholders reflects that federal courts have been generally skeptical of IQA private causes of action. Those complaints foundered on plaintiffs' standing to sue, as well as their assertion of a "positive" right to properly peer-reviewed government information.

The paper proposes an alternative approach to judicial enforcement of the IQA, one which addresses past lawsuits' shortcomings. It explains this alternative approach in the context of a challenge to EPA's and NOAA's noncompliance with the IQA in its actions

leading up to EPA's GHG Endangerment Findings. The suit would seek to enjoin EPA's use of all EPA, NOAA, and other agency-developed, improperly peer-reviewed HISAs supporting the Findings, as well as the regulations they have spawned, until those HISAs have been peer reviewed once again in conformance with such IQA standards.

The contemplated cause of action is based on the theory that Congress intended that the IQA, as an implementation of the Paperwork Reduction Act, protect the *negative* right of a designated class of persons not to be burdened, financially or otherwise, by poor quality science that agencies disseminate in support of major regulations. Private entities, such as regulated businesses and those in their supply chains, can establish standing to sue based on the particularized economic injuries they have suffered from regulatory burdens. State governments can take advantage of U.S. Supreme Court precedents that convey standing under the doctrine of *parens patriae* when such public actors are suing in their quasi-sovereign capacity to protect the collective economic interests of state citizens and residents unable themselves to legally substantiate particularized injuries.

The analysis concludes that a narrowly-pled, factually-supported challenge utilizing the APA would not only be consistent with the longstanding presumption that Congress intends judicial review of administrative action, but also sufficient to overcome some federal courts' presumption against implied rights of action. It also concludes that, in an IQA-focused cause of action brought under the APA, rather than under the Clean Air Act, courts would defer to OMB, rather than EPA, for purposes of ascertaining the definition of the terms contained in applicable OMB IQA Guidelines and measuring the conformance of EPA IQA standards with such OMB standards, given Congress' delegation of authority to OMB to develop binding IQA guidelines. Since, as noted above, information quality is an important component of a court's hard-look review of agency regulations, an IQA litigant may be able to overcome the presumption that EPA's judgment in evaluating and selecting the science to support the Endangerment Findings is entitled to judicial deference. Such a stakeholder would need to present evidence that flawed IQA peer-review procedures resulted in EPA's dissemination of poor quality data in support of its Endangerment Findings, which in turn inspired burdensome regulations.

This WORKING PAPER has utilized the development of EPA's GHG Endangerment Findings as a vehicle to explain the IQA's requirements, facilitate ongoing debate over the use of science in the regulatory process, and craft a roadmap to successful judicial enforcement of the law. One can easily foresee, however, many potential applications of the enforcement framework offered here. Fueled by decades of ineffective oversight, federal agencies' respect for science and the scientific process has severely diminished. Other actions by EPA where stakeholders have strongly questioned the supporting science could be particularly inviting targets as well. They include: EPA's "Waters of the United States" proposal;[546] its social cost of carbon proposal;[547] its proposed ozone regulations;[548] its NEPA review of the Keystone XL pipeline;[549] its study on the impacts of hydraulic fracturing;[550] and EPA and NOAA disapproval of state coastal nonpoint pollution control programs.[551] Another possible target could be the Fish and Wildlife Service's threatened or endangered species designations.[552]

Finally, although the IQA is a U.S. federal procedural statute, the Administration should insist that OMB's rigorous peer-review independence, conflict-of-interest, and panel-balance standards be incorporated in international agreements that advance regulatory

cooperation, such as the Transatlantic Trade and Investment Partnership and the Trans-Pacific Partnership Agreement.[553]

In a 1996 Seventh Circuit opinion, Judge Posner observed that "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."[554] The same principle applies with equal, if not greater, force in the context of regulation. Effective judicial enforcement of the Information Quality Act would be a significant step toward ensuring that regulation does not lead science.

ENDNOTES

[1] *See* A. Alan Moghissi, Betty R. Love, and Sorin R. Straja, *Peer Review and Scientific Assessment: A Handbook for Funding Organizations, Regulatory Agencies, and Editors* (Institute for Regulatory Science) (2013), available at: https://nebula.wsimg.com/571cc7cacba816f0c69c60dea905cb36?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1. *See also* A. Alan Moghissi, Sorin R. Straja, Betty R. Love, Dennis K. Bride and Roger R. Stough, *Innovation in Regulatory Science: Evolution of a New Scientific Discipline*, 16 TECH. AND INNOVATION 155, 161 (Cognizant Comm. Corp. © 2014), available at: https://nebula.wsimg.com/b1265cf5bed345007aa5ea1246efa108?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1 ("Regulatory science is a scientific discipline consisting of the development and application of scientific methods, tools, approaches, and other relevant processes derived from various scientific disciplines used in regulatory and other policy decisions.").

[2] United States Environmental Protection Agency, *Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202(a) of the Clean Air Act—Final Rule* [Hereinafter "Endangerment Findings"], 74 Fed. Reg. 66,496 (Dec. 15, 2009), available at: http://www.epa.gov/climatechange/Downloads/endangerment/Federal_Register-EPA-HQ-OAR-2009-0171-Dec.15-09.pdf.

[3] *See* United States Environmental Protection Agency Office of Inspector General, *Procedural Review of EPA's Greenhouse Gases Endangerment Finding Data Quality Processes* [Hereinafter "EPA-OIG Procedural Review"], Report No. 11-P-0702 (Sept. 26, 2011), available at: http://www.epa.gov/oig/reports/2011/20110926-11-P-0702.pdf.

[4] *See* United States Department of Commerce Office of the Inspector General, *Correspondence to United States Senator James Inhofe Regarding the Examination of Issues Related to the Internet Positing of Email Exchanges Taken from the Climatic Research Unit (CRU) of the University of East Anglia in the United Kingdom* (Feb. 18, 2011), available at: http://www.oig.doc.gov/OIGPublications/2011.02.18-IG-to-Inhofe.pdf; United States Department of Commerce, National Oceanic and Atmospheric Administration, *Inspector General's Review of Stolen Emails Confirms No Evidence of Wrong-Doing by NOAA Climate Scientists*, Press Release (Feb. 24, 2011), available at: http://www.noaanews.noaa.gov/stories2011/20110224_clstimate.html.

[5] *See* Richard Epstein, *Why the Modern Administrative State is Inconsistent with the Rule of Law*, 1 NYU J. OF LAW & LIBERTY 491 (2008), available at: http://www.law.nyu.edu/sites/default/files/ECM_PRO_060974.pdf.

[6] *See* Jerry L. Mashaw, *"Rights" in the Federal Administrative State*, Faculty Scholarship Series. Paper 1149, 1129-1173 (1983), available at: http://digitalcommons.law.yale.edu/fss_papers/1149/?utm_source=digitalcommons.law.yale.edu%2Ffss_papers%2F1149&utm_medium=PDF&utm_campaign=PDFCoverPages.

[7] Epstein, *supra* note 5 at 492.

[8] *Id.*

[9] *Id*.

[10] Richard Epstein, *The Perilous Position of the Rule of Law*, 36 HARV. J. OF LAW & PUB. POL'Y 5, 18 (2013), available at: http://www.harvard-jlpp.com/wp-content/uploads/2013/01/36_1_005_Epstein.pdf.

[11] Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 ADMIN. L. REV. 343, 347 (2009), available at: http://www.law.uh.edu/faculty/jmantel/health-law/MantelProceduralSafeguards.pdf.

[12] Adam Candeub, *Transparency in the Administrative State*, 51 HOUS. L. REV. 385 (2013), available at: http://digitalcommons.law.msu.edu/cgi/viewcontent.cgi?article=1505&context=facpubs.

[13] *Id*. at 403.

[14] 133 S. Ct. 1863, 1877 (2013), (Roberts, CJ, dissenting).

[15] *Id*., quoting *Free Enterprise Fund v. Public Company Accounting Oversight Bd.*, 130 S. Ct. 3138, 3156 (2010).

[16] *Id*., quoting *Alden v. Maine*, 527 U.S. 706, 807 (1999) (Souter, J., dissenting).

[17] Pub. L. 79–404, 60 Stat. 237 (June 11, 1946), as amended, codified at 5 U.S.C. § 551 et seq.

[18] Pub. L. No. 89-487, 80 Stat. 250 (1966), as amended, codified at 5 U.S.C. § 552.

[19] Pub. L. No. 92-463, 86 Stat. 770 (1972), as amended, codified at 5 U.S.C. App. 2, §§ 1-16.

[20] Pub. L. No. 94-409, 90 Stat. 1241 (1976), as amended, codified at 5 U.S.C. § 552b.

[21] The House bill covering OMB appropriations was subsequently incorporated into the Consolidated Appropriations Act for Fiscal Year 2001 that was enacted into law on December 21, 2000. *See* U.S. House of Representatives, *Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001–Conference Report [To accompany H.R. 4577]*, 106th Cong. 2d Sess., Rept. 106–1033 (Dec. 15, 2000), at Title V, § 515, p. 362.

[22] Pub. L. No. 106-554, 114 Stat. 2763, 2763A-153-154 (2000), § 515, codified at 44 U.S.C. § 3516 note.

[23] *See* U.S. Department of Justice, Justice Information Sharing–Privacy and Civil Liberties, *Paperwork Reduction Act (PRA), 44 U.S.C. § 3501 et seq.*, available at: https://it.ojp.gov/default.aspx?page=1289.

[24] Publ. L. 104-13, 109 Stat. 163, 104th Cong. (May 22, 1995).

[25] Pub. L. 96-511, 94 STAT. 2812, as amended, codified at 44 U.S.C. §§ 3501-3520.

[26] *See* The White House, Office of Management and Budget, *Circular A-4* (Sept. 17, 2003), at 17, 39, 43-44, available at: http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf. http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf.

[27] Louis J. Virelli, III, *Deconstructing Arbitrary and Capricious Review*, 92 N.C. L. REV. 721, 738-739, 745-749 (2014), available at: http://nclawreview.org/documents/92/3/Virelli.pdf. *See also* Edward Rubin, *Viewing the Arbitrary and Capricious Test as a Set of Function-Specific Criteria*, JOTWELL (Mar. 17, 2014) (reviewing *Deconstructing Arbitrary and Capricious Review*), available at: http://adlaw.jotwell.com/viewing-the-arbitrary-and-capricious-test-as-a-set-of-function-specific-criteria/.

[28] Publ. L. 104-13, 109 Stat 166.

[29] The 1995 amendments to the 1980 PRA (H.R. 830), in part, fleshed out the specific types of paperwork burdens the 1980 PRA was intended to regulate. *See* U.S. House of Representatives, *Paperwork Reduction Act of 1995–Committee on Government Reform and Oversight Report Together With Additional Views [To accompany H.R. 830]*, 104th Cong. 1st Sess., Rept. 104–37 (Feb. 15, 1995), available at: http://www.gpo.gov/fdsys/pkg/CRPT-104hrpt37/pdf/CRPT-104hrpt37.pdf.

[30] *Id*. at 27, 35. *See also* Institute for Trade, Standards and Sustainable Development, *A Brief Overview Of The Legislative History Surrounding The Information Quality Act and the Paperwork Reduction Act of 1995*, "ITSSD Programs—Theme #4 (2006-2013)—International Regulatory Transparency: Information Quality Act," available at: https://nebula.wsimg.com/9855faa15e51b4706327c46360013bc1?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[31] *See* Institute for Trade, Standards and Sustainable Development, *The Information Quality Act and the Post-Modern Precautionary Principle*, "ITSSD Programs—Theme #4 (2006-2013)—International Regulatory

Transparency: Information Quality Act," available at: https://nebula.wsimg.com/79d22b24f3e1149d2b0465789de113b0?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1; Institute for Trade, Standards and Sustainable Development, *Information Quality Act Opponents Are Post-Modern Precautionary Principle Proponents*, "ITSSD Programs—Theme #4 (2006-2013)—International Regulatory Transparency: Information Quality Act," available at: https://nebula.wsimg.com/46093c80df10130c677000d47b9fb3d7?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[32] *See* Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* [Hereinafter "OMB IQA Guidelines"], 67 Fed. Reg. 8,452 (Feb. 22, 2002), available at: http://www.whitehouse.gov/sites/default/files/omb/fedreg/reproducible2.pdf. *See also* Office of Management and Budget, *Final Information Quality Bulletin for Peer Review* [Hereinafter "OMB-PRB"] (Dec. 16, 2004), available at: http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf.

[33] "[T]he term 'scientific information' means factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms." *See* OMB-PRB, *supra* note 32 at Sec. I.5.

[34] "A scientific assessment is considered 'highly influential' if the agency or the OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. One of the ways information can exert economic impact is through the costs or benefits of a regulation based on the disseminated information. The qualitative aspect of this definition may be most useful in cases where it is difficult for an agency to predict the potential economic effect of dissemination." *Id*., at Preamble, Sec. III, p. 23. HISAs are defined as "influential scientific information that the agency or the Administrator determines to be a scientific assessment that…(i) could have a potential impact of more than $500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest"… *Id*., at § III.1, p. 39.

[35] "To the extent permitted by law, each agency *shall* conduct peer reviews on all information subject to this Section. The peer reviews shall satisfy the requirements of Section II of this Bulletin, *as well as the additional requirements found in this Section*" (emphasis added). *Id.* at § III.2, p. 39.

[36] *See* Public Law 106-554, § 515(b)(2)(B), codified in 44 U.S.C. § 3516, note.

[37] *See* Pub. L. 106-544, 114 Stat. 2763 ("IQA"), § 515(a), codified at 44 U.S.C. § 3516, note (implementing 44 U.S.C. §§ 3504(d)(1) and 3516 of the PRA).

[38] *Id*. at § 515(b)(1).

[39] *Id*. at § 515(b)(2)(A).

[40] *Id*. at § 515(b)(2)(B).

[41] OMB IQA Guidelines, *supra* note 32 at 8,453 and §. V.1, p. 8,459.

[42] *Id.* at § V.2, p. 8,459.

[43] *Id*. at 8,457.

[44] *Id*. at § V.2, p. 8,459.

[45] *Id*. at Sec. V.4, pp. 8,453, 8,460.

[46] *Id.* at 8,454.

[47] *Id*. (emphasis added).

[48] *See* OMB-PRB, *supra* note 32 at Preamble, p. 2.

[49] *Id*. at § I.5.

[50] *Id*. at Preamble, §§ I, p. 11, II, p. 12; § I.6.

[51] *Id*. at § 1.7, pp. 36-37.

[52] *Id*.

[53] *Id.* at § III.1, p. 39. The $500 million threshold amount before which external peer review of agency-disseminated HISAs will be required, accompanied by heightened independence, conflict of interest and panel balance standards, reflects an executive branch (OMB) compromise to prevent an anticipated deluge of HISA challenges; it is significantly higher than the $100 million threshold needed to trigger an OMB Office of Information & Regulatory Affairs review of a proposed agency regulation under E.O. 12866. *See* White House, Executive Order 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993), at Sec. 3(f), available at: http://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf/.

[54] *Id.* at Preamble, p. 2 (emphasis added).

[55] *Id*. at § III.2 (emphasis added).

[56] *Id*. at § II.6, § III.7.

[57] United States Department of Commerce, National Oceanic and Atmospheric Administration, Office of the Chief Information Officer & High Performance Computing and Communications, *National Oceanic and Atmospheric Administration Information Quality Guidelines* [Hereinafter "NOAA IQA Guidelines"], at "Part II: Information Quality Standards and Pre-Dissemination Review–Third Party Information," available at: http://www.cio.noaa.gov/services_programs/IQ_Guidelines_011812.html; United States Environmental Protection Agency, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008 [Hereinafter "EPA IQA Guidelines"] (Oct. 2002) at § 4.2, p.11 available at: http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

[58] *See* United States Environmental Protection Agency, *Peer Review Handbook* (3rd ed.), EPA/100/B-06/002 (2006) [Hereinafter "EPA-PRH (2006)"], at §2.2.5, p. 35, available at: http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf.

[59] *Id*. at § 2.4.1, p. 45.

[60] *Id*.

[61]*Id*. (emphasis added).

[62] *Id*. at § 2.4.3, p. 46.

[63] OMB-PRB, *supra* note 32, at Preamble, pp. 11-12, 23.

[64] NOAA IQA Guidelines, *supra* note 57 at "Part I: Background, NOAA Information, Definitions, and Scope—Definitions—Information Disseminated by NOAA and Covered by these Guidelines." Interpreted products includes those information products that have been developed through interpretation of original data and synthesized products developed through analysis of original data using well documented and routine methods of analysis, such as statistical methods, model interpolations, extrapolations, and simulations, and combinations of multiple sets of original data.

[65] *Id*.

[66] EPA IQA Guidelines, *supra* note 57 at § 4.2, p.11.

[67] EPA-PRH (2006), *supra* note 58 at § 1.2.11 p. 15.

[68] *Id.*

[69] OMB IQA Guidelines, *supra* note 32 at §§ III.2, V.8 (emphasis added).

[70] OMB-PRB, *supra* note 32 at § I.3, p.10

[71] NOAA IQA Guidelines, *supra* note 57 at "Part II: Information Quality Standards and Pre-Dissemination Review." *See also* EPA-PRH (2006), *supra* note 58 at § 1.3.4, p. 18. ("Products that are undergoing peer review are not considered to be disseminated under EPA's Information Quality Guidelines because they are dynamic documents that are subject to change and therefore, do not represent EPA's final decision or position.").

[72] OMB IQA Guidelines, *supra* note 32 at 8,454; OMB-PRB, *supra* note 32 at Preamble, p. 9.

[73] *Id*. at Preamble, p. 31 and § VII, p. 43.

[74] EPA IQA Guidelines, *supra* note 57 at § 5.3, pp. 15-16.

[75] *Id*. at § 5.8, p. 18.

[76] *See* NOAA IQA Guidelines, *supra* note 57 at "Part I: Background, NOAA Information, Definitions, and Scope—Definitions—Agency Initiated Distribution of Information to the Public."

[77] OMB IQA Guidelines, *supra* note 32 at Sec. V.3.b.ii, p. 8,460 (emphasis added).

[78] *Id*. at § V.3.b.ii.A, p. 8,460.

[79] *Id.* at § V.10, p. 8,460 and p. 8,456.

[80] *Id*. at § V.3.b.ii.B, p. 8,460 and p. 8,456 (emphasis added).

[81] *Id*.

[82] *Id*.

[83] NOAA IQA Guidelines, *supra* note 57 at "Part II: Information Quality Standards and Pre-Dissemination Review—Third Party Information.

[84] *Id*.

[85] *See* Institute for Trade, Standards and Sustainable Development, *FOIA Request No. DOC-NOAA-2014-001694* (Sept. 22, 2014) [Hereinafter "ITSSD September FOIA"], at Addendum, pp. 41-42, available at: https://nebula.wsimg.com/86e0c3d9f0c18e77b33e25d935498bcc?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[86] *See* EPA IQA Guidelines, *supra* note 57 at § 6.5 and n. 31, p. 28, citing *EPA Quality Manual for Environmental Programs* 5360-A1 (May 2000), at Sec. 1.3.1, available at: http://www.epa.gov/quality/qs-docs/5360.pdf; United States Environmental Protection Agency, Office of Environmental Information Quality Staff, *EPA Quality Manual for Environmental Programs*—CIO 2105-P-01-0 (formerly 5360-A1) (May 5, 2000), at § 1.1, Appendix A—Glossary, p. A-6, available at: http://www.epa.gov/irmpoli8/policies/2105P010.pdf (*These data and program quality guidelines inter alia distinguish between the validation and verification of a product or process*). *See also* United States Environmental Protection Agency Office of Information, *Final Guidance for Quality Assurance Project Plans*—EPA QA/G-5, EPA/240/R-02/009 (Dec. 2002), at Introduction, p. 1, at available at: http://www.epa.gov/QUALITY/qs-docs/g5-final.pdf; United States Environmental Protection Agency Office of Information, *Guidance for Quality Assurance Project Plans for Modeling* - EPA QA/G-5M, EPA/240/R-02/007 (Dec. 2002), § 1.3, p. 2, § 1.7, pp. 6-7, § 4.3.1, pp. 63-66, at available at: http://www.epa.gov/QUALITY/qs-docs/g5m-final.pdf (These quality control guidelines, which relate to Quality Assurance Project Plans, apply to third-party-developed computer models and programs of environmental processes, and data used therein, emphasize the peer review of all inputs, assumptions, extrapolations and applications).

[87] *See* EPA-PRH (2006), *supra* note 58 at §§ 2.2.1-2.2.2.

[88] *Id.* at § 2.2.16; United States Environmental Protection Agency Council for Regulatory Environmental Modeling, *History*, available at: http://www.epa.gov/crem/history.html; United States Environmental Protection Agency Council for Regulatory Environmental Modeling, *Information about the Council for Regulatory Environmental Modeling for the Science Advisory Board*, available at: http://www.epa.gov/crem/crem_sab.html.

[89] *See* United States Environmental Protection Agency Office of the Science Adviser, Council for Regulatory Environmental Modeling, *Guidance on the Development, Evaluation, and Application of Environmental Models*, EPA/100/K-09/003 (Mar. 2009), available at: http://epa.gov/crem/library/cred_guidance_0309.pdf.

[90] *Id*. at § 4, pp. 20-21.

[91] *Id*. at § 4.2.1 (emphasis added).

[92] *See* OMB-PRB, *supra* note 32 at § II.5.

[93] *Id*.

[94] *Id*. at § III.6.

[95] *Id*.

[96] OMB IQA Guidelines, *supra* note 32 at 8,454-55, quoting *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance*, GAO–01– 536, General Accounting Office, Washington, D.C. (June 2001), at 19.

[97] OMB-PRB, *supra* note 32 at § III.3.a, p. 39.

[98] *Id*. at § III.3.c.

[99] *Id.* § II.3.c.

[100] *Id*. at § II.3.c and III.3.d.

[101] *Id*. at § III.3.c.

[102] *See* The National Academies, *Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports* (May 12, 2003), at 6, available at: http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

[103] *Id*. This NAS criterion explicitly requires that the science "not be involved *in any way within the agency in any* deliberative or decision-making process *or any* policy-making or similar process *relating to the study or other activity or the expected or intended results of the study or other activity*" (emphasis added).

[104] *Id*. (emphasis added)

[105] OMB-PRB, *supra* note 32 at §. III.3.c.

[106] *See, e.g.*, 18 U.S.C. § 202, available at: http://www.gpo.gov/fdsys/pkg/USCODE-2012-title18/html/USCODE-2012-title18-partI-chap11-sec202.htm. It defines a "special government employee" as "an officer or employee who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days."

[107] OMB-PRB, *supra* note 32 at Preamble, p. 24.

[108] *Id.* at § 1.5.8, p. 26 (emphasis added). "Independence is freedom from institutional or ideological bias regarding the issues under review and is necessary for objective, fair, and responsible evaluation of the work product."

[109] OMB-PRB, *supra* note 32 at Preamble, p. 25 ("We also considered whether a reviewer can be independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. Research grants that were awarded to the scientist based on investigator-initiated, competitive, peer-reviewed proposals do not generally raise issues of independence. *However, significant* consulting and *contractual relationships with the agency* may raise issues of independence or conflict, depending upon the situation.") (emphasis added).

[110] NIH is the "the primary Federal agency responsible for conducting and supporting medical research." *See* Daniel R. Levinson, *Institutional Conflicts of Interest at NIH Grantees* (OEI-03-09-00480), Department of Health and Human Services Office of Inspector General [Hereinafter "Levinson"] (Jan. 2011), at 17, available at: http://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf.

[111] *See* U.S. Department of Health and Human Services, National Institutes of Health Office of Extramural Research, *Grants and Funding—NIH Grants Policy Statement, Part I: NIH Grants—General Information, Section I.2—Glossary, Definition of Terms* (10/1/13), available at: http://grants.nih.gov/grants/policy/nihgps_2013/; http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch1.htm#definitions_of_terms; *Glossary & Acronym List*, available at: http://grants.nih.gov/grants/glossary.htm (emphasis added). *See also* U.S. Department of Health and Human Services, National Institutes of Health Offices of Extramural Research, NIH Grants Policy Statement (12/03) (archived), available at: http://grants.nih.gov/archive/grants/policy/nihgps_2003/index.htm (applicable during the period examined for purposes of the case study included in this working paper).

[112] *See* Federal Acquisition Regulation 35.016(a), 48 C.F.R. § 35.016(a), *Broad Agency Announcement*, available at: http://www.gpo.gov/fdsys/pkg/CFR-2002-title48-vol1/pdf/CFR-2002-title48-vol1-sec35-016.pdf; http://www.acquisition.gov/far/html/Subpart%2035_0.html. A Broad Agency Announcement is essentially a general solicitation from a federal agency identifying specific areas of research interest and includes criteria for selecting proposals to which prospective applicants are directed to respond.

[113] OMB-PRB, *supra* note 32 at Preamble describing § III.3b, p. 24.

[114] *Id*. at Preamble, p. 24 and § III.b.i.

[115] 5 C.F.R. § 2635.101(c), available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=06f812f26e7ed9f364bb87944757b912&rgn=div5&view=text&node=5:3.0.10.10.9&idno=5#sp5.3.2635.d.

[116] 5 C.F.R. § 2635.101(b)(2).

[117] 5 C.F.R. § 2635.101(b)(8).

[118] 5 C.F.R. § 2635.403(c)(2) (emphasis added).

[119] *Id.*

[120] *See* 5 C.F.R. § 2635.403.

[121] *See* 5 C.F.R. § 2635.403(b)(1).

[122] *See* 5 C.F.R. § 2635.403(b)(2).

[123] *See* 5 C.F.R. § 2635.501(a); § 2635.502(a), (d); 5 C.F.R. § 2635.502(a)(iv).

[124] OMB-PRB, *supra* note 32 at § II.3.b.ii.

[125] *Id*. at § III.b.ii.

[126] National Academy of Sciences, National Academy of Engineering, Institute of Medicine and National Research Council, *Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports* (May 12, 2003), at "APPENDIX A—Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports" at 9-10, available at http://www.nationalacademies.org/coi/bi-coi_form-0.pdf (italicized emphasis in original; underlined emphasis added) (emphasis added).

[127] *See, e.g.*, Bernard Lo and Marilyn J. Field, *Conflict of Interest in Medical Research, Education, and Practice*, National Academy of Sciences Institute of Medicine, (National Academies Press, Wash., D.C. ©2009), at 218-229, available at: http://www.nap.edu/catalog/12598/conflict-of-interest-in-medical-research-education-and-practice.

[128] *Id*.

[129] *See* Levinson, *supra* note 110 at Executive Summary, pp. i and iii, p.1.

[130] *Id.* at Executive Summary at p. i (emphasis added). *See also* Institute for Trade, Standards and Sustainable Development, *OMB's Peer Review Bulletin Establishes Uniform IQA Conflict of Interest Standards to Ensure Validity of Agency-Disseminated Third-Party-Developed HISAs Supporting Major Regulations*, "ITSSD Programs—Theme #4 (2006-2013)—International Regulatory Transparency: Information Quality Act," available at: https://nebula.wsimg.com/fc42b37c687e33a81670e4344c5e0a1e?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[131] *See, e.g.,* U.S. Department of Health and Human Services, National Institutes of Health Office of Extramural Research, *Grants and Funding—Managing Conflict of Interest in NIH Peer Review of Grants and Contracts – When Does COI Arise?*, available at: http://grants.nih.gov/grants/peer/peer_coi.htm; U.S. Department of Health and Human Services, National Institutes of Health, *NIH Conflict of Interest Rules: Information for Reviewers of NIH Applications and R&D Contracts*, NIH/OER/OEP (Approved 9/20/2011 for implementation by January 25, 2012), at Sec. 5, pp. 2-3, available at: http://grants.nih.gov/grants/peer/COI_Information.pdf.

[132] *See* Institute for Trade, Standards and Sustainable Development, *supra* note 130.

[133] United States Department of Commerce, National Oceanic and Atmospheric Administration, Office of the Chief Information Officer & High Performance Computing and Communications, *National Oceanic and Atmospheric Administration Policy on Conflicts of Interest for Peer Review Subject to OMB's Peer Review Bulletin*, available at: http://www.cio.noaa.gov/services_programs/NOAA_PRB_COI_Policy_110606.htm.

[134] *Id*. (emphasis added).

[135] *Id*.

[136] *Id*.

[137] *Id*.

[138] *Id*.

[139] *Id*.

[140] EPA-PRH (2006), *supra* note 58 at § 2.2.17, p. 41.

[141] *See* Public L. 06-554, § 515(b)(2)(B).

[142] OMB IQA Guidelines, *supra* note 32 at § III.3, p. 8,459.

[143] *Id*. at § III.3.ii, p. 8,459.

[144] *Id*.

[145] Office of Management and Budget, Administrator, Office of Information and Regulatory Affairs, *Memorandum, Information Quality Guidelines—Principles and Model Language* (Sept. 5, 2002), at 2-3, available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/pmcmemo.pdf.

[146] *See accord* Stephen Johnson, *Ruminations on Dissemination: Limits on Administrative and Judicial Review under the Information Quality Act* [Hereinafter "Johnson"], 55 CATHOLIC U. L. REV. 59, 65 (Fall 2005) available at: http://scholarship.law.edu/cgi/viewcontent.cgi?article=1188&context=lawreview ("[S]ince agencies will be basing regulations on the information that is disclosed in rulemaking, it may be more important to ensure that the information gets to the public, so that the public can review it and provide input to the agency, than when an agency publishes a report or puts information on the Internet. […] If Congress intended to exclude information disclosed in rulemaking from the substantive requirements of the Information Quality Act, it could have done so explicitly.").

[147] *Cf. id*. at 66. Contrary to the assertions of Professor Johnson, Congress *did* also intend, under certain circumstances, "to require agencies to establish administrative procedures to respond to [information quality] concerns in rulemaking when it required agencies to 'establish administrative mechanisms allowing affected persons to seek and obtain correction of information.'" This requirement was not included by Congress merely "to apply to information disclosed in reports and on the Internet"—*i.e.*, "freestanding distributions."

[148] OMB IQA Guidelines, *supra* note 32 at 8,458.

[149] EPA IQA Guidelines, *supra* note 57 at §8.5, p. 32; NOAA IQA Guidelines, *supra* note 57 at Part III, Sec. B.6.

[150] OMB IQA Guidelines, *supra* note 32 at 8,458.

[151] *Id*.

[152] *See* Institute for Trade, Standards and Sustainable Development, *ITSSD National Information Quality Act (IQA)-focused FOIA Education Campaign Summary—IQA's Application to EPA and Third Party-Developed and Peer Reviewed Scientific Assessments Supporting EPA's Clean Air Act GHG Endangerment Findings* (May 2013 - Dec. 2014), available at: https://nebula.wsimg.com/d6ca9c3fe099f8884bbff5286e72c8c6?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[153] 549 U.S. 497 (2007).

[154] *Id*. at 532-533.

[155] Endangerment Findings, *supra* note 2 at 66,497.

[156] *Id*. at 66,510.

[157] *See* United States Environmental Protection Agency, *Technical Support Document for Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act* [Hereinafter "EPA-TSD"], EPA–HQ–OAR–2009–0472–11292 (Dec. 7, 2009), at Table 1.1, at 6, available at: http://www.epa.gov/climatechange/Downloads/endangerment/Endangerment_TSD.pdf.

[158] *Id*. at 6.

[159] *See* U.S. Global Change Research Program, *SAPs*, available at: http://www.globalchange.gov/search/SAPs/gc.

[160] *See* U.S. Global Change Research Program, *About USGCRP*, available at: http://www.globalchange.gov/about.

[161] *Id*., at 5. *See also* Institute for Trade, Standards and Sustainable Development, *New ITSSD FOIA Request [FOIA Request EPA-HQ-2014-008026] Superseding Withdrawn FOIA Request No. EPA-HQ-2014-004938* (June 30, 2014) [Hereinafter "ITSSD June FOIA"], at "Appendix 2—EPA-TSD Table 1.1 'Core Reference Documents,'" available at: https://nebula.wsimg.com/e155ee64b03ea37237297cdbab7a2854?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[162] Endangerment Findings, *supra* note 2 at 66,511. In addition, the Endangerment Findings stated that, "[i]t is EPA's view that the scientific assessments of the IPCC, USGRCP, and the NRC represent the best reference materials for determining the general state of knowledge on the scientific and technical issues before the agency in making an endangerment decision." *Id*.

[163] EPA-TSD, *supra* note 157 at 4, Box 1.1, pp. 4-5.

[164] *Id*. at 5.

[165] *See* United States Environmental Protection Agency, Climate Change, *Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202(a) of the Clean Air Act—Response to Comments, Volume 1: General Approach to the Science and Other Technical Issues*, at "Appendix A—IPCC Principles and Procedures" [Hereinafter RTCs Vol. 1], at 4, n. 11 available at: http://www.epa.gov/climatechange/Downloads/endangerment/rtc_volume_1_app_a.pdf (emphasis added).

[166] *Id*. (emphasis added)

[167] *Id*. at 5, n. 12.

[168] *Id*. at 4.

[169] ITSSD June FOIA, *supra* note 161 at § I, p. 5.

[170] *Id*., at Sec. II.1, Explanation, pp. 11-17.

[171] *Id*. at Addendum, p. 59.

[172] *Id*. at Appendix 3: EPA-TSD "Core Reference Documents" and Assessments "Incorporated By Reference" Therein.

[173] *Id*. at Annotated Addendum, pp. 59-61.

[174] SAP4.1/CCSP(2009b) and SAP4.6/CCSP(2008b) Although the term "interpreted product" appears neither in EPA's IQA Guidelines nor in EPA's Peer Review Handbook, it does appear in NOAA's IQA Guidelines. *See* NOAA IQA Guidelines, *supra* note 57 at "Part I: Background, NOAA Information, Definitions, and Scope—Information Disseminated by NOAA and Covered by these Guidelines."

[175] *See* OMB-PRB, *supra* note 32 at Sec. VII.

[176] *See* Institute for Trade, Standards and Sustainable Development, *Supplement to FOIA Request No. EPA-HQ-008026* (Nov. 7, 2014) [Hereinafter "ITSSD November FOIA"], at Appendix 6A—"Author-Contributors, EPA-Developed USGCRP/CCSP SAP4.1"; Appendix 6B—"Technical Expert Reviewers, EPA-Developed USCRP/CCSP SAP4.1."

[177] *Id*. *See also* ITSSD June FOIA, *supra* note 161 at 69-72.

[178] *Id*.

[179] SAP4.6 at Acknowledgements, p. 4; *see also* ITSSD June FOIA, *supra* note 161 at 67-69.

[180] ITSSD November FOIA, *supra* note 176 at Appendix 7A—"Author-Contributors, USGCRP/CCSP SAP4.6;" Appendix 7B—"External Peer Review Panel HICCAC Federal Advisory Committee, USCRP/CCSP SAP4.6."

[181] *Id*. at Appendix 7B—"EPA External Peer Review Panel/HICCAC Federal Advisory Committee for USCRP/CCSP SAP4.6."

[182] *Id*.

[183] ITSSD June FOIA, *supra* note 161 at 67-69.

[184] *Id.*

[185] ITSSD November FOIA, *supra* note 176 at Sec. II.2, Explanation, pp. 21-23.

[186] Endangerment Findings, *supra* note 2 at 66,511.

[187] *See* United States Environmental Protection Agency and Department of Transportation National Highway Traffic Safety Administration, *Final Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards*, 75 Fed. Reg. 25,324 (May 7, 2010).

[188] *See* United States Environmental Protection Agency, *Final Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule*, 75 Fed. Reg. 31,514 (June 3, 2010).

[189] *See* United States Environmental Protection Agency, *Proposed Standards of Performance for Greenhouse Gas Emissions from New Stationary Sources: Electric Utility Generating Units*, 79 Fed. Reg. 1,430 (Jan. 8, 2014); United States Environmental Protection Agency, *Standards of Performance for Greenhouse Gas Emissions from New Stationary Sources: Electric Utility Generating Units—Notice of Data Availability*, 79 Fed. Reg. 10,750 (Feb. 26, 2014).

[190] *See* United States Environmental Protection Agency, *Notice of Proposed Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units and Solicitation for Public Comments*, 79 Fed. Reg. 34,830 (June 18, 2014).

[191] *See* InterAcademy Council, *Climate Change Assessments Review of the Processes and Procedures of the IPCC* [Hereinafter "IAC-2010 Report"] (Oct. 1, 2010), available at: http://www.interacademycouncil.net/24026/26050.aspx.

[192] *See* ITSSD September FOIA, *supra* note 85 at 39-41.

[193] *See* IAC-2010 Report, *supra* note 191 at iii, 59-65. The report found that, although "the IPCC has heightened public awareness of climate change, raised the level of scientific debate, and influenced the science agendas of many nations […] *some fundamental changes to the process and the management structure are essential*" (emphasis added).

[194] *Id.* at Executive Summary, pp. xii, 59.

[195] RTCs Vol. 1, *supra* note 165 at Response (1-14).

[196] *See* ITSSD September FOIA, *supra* note 85 at 12.

[197] *Id*. at 41, n. 288 (Harold Shapiro and Syukuro Manabe of Princeton niv., Maureen Cropper of the Univ. of Maryland, and Mario Molino of UC-Irvine & the Scripps Institution of Oceanography).

[198] *Id*. at Appendix 2B—"U.S. Government-Employed Scientists Author-Contributors/Reviewers IPCC-AR3-WGI/WGII," pp. 92-96; Appendix 2A—"U.S. Government-Employed Scientists Author-Contributors/Reviewers IPCC-AR4-WGI/WGII," pp. 87-91.

[199] *Id*.

[200] *Id*. at Appendix 3C—"Scientists Affiliated With NOAA Grant-Funded Entities Author Contributors/Reviewers IPCC-AR3-WGI/WGII," pp. 104-107; Appendix 3A—"Scientists Affiliated With NOAA Grant-Funded Entities Author Contributors/Reviewers IPCC-AR4-WGI," pp. 97-100; Appendix 3B—"Scientists Affiliated With NOAA Grant-Funded Entities Author Contributors/Reviewers IPCC-AR4-WGII," pp. 101-103.

[201] *Id*. at Addendum, pp. 59-60.

[202] *See, e.g.*, National Oceanic and Atmospheric Administration National Weather Service, *Aviation Quality Management System—Quality Management System: 1, 2, 3* (Mar. 2012).

[203] *See* United States Environmental Protection Agency Council for Regulatory Environmental Modeling, *History*, available at: http://www.epa.gov/crem/history.html; United States Environmental Protection Agency Council for Regulatory Environmental Modeling, *Information about the Council for Regulatory Environmental Modeling for the Science Advisory Board*. NOAA did not have in place anything similar to EPA's third-party environmental data and computer program quality guidelines.

[204] United States Environmental Protection Agency Board of Scientific Counselors, BOSC Subcommittee on Global Change Research, *Review of the Office of Research and Development's Global Change Research Program at the U.S. Environmental Protection Agency—Final Report* (Mar. 27, 2006) at 7-29.

[205] *See* United States Environmental Protection Agency Office of Inspector General, *EPA Needs a Comprehensive Research Plan and Policies to Fulfill its Emerging Climate Change Role*, Evaluation Report No. 09-P-0089 (Feb. 2, 2009), at Executive Summary, p. 10, available at: http://www.epa.gov/oig/reports/2009/20090202-09-P-0089.pdf.

[206] *Id*. at Executive Summary, pp. 2-3 and 10, Appendix B: "Agency Preliminary Comments and OIG Evaluation," pp. 23, 27-28, available at: http://www.epa.gov/oig/reports/2009/20090202-09-P-0089.pdf.

[207] United States Environmental Protection Agency Office of Inspector General, *Office of Research and Development Should Increase Awareness of Scientific Integrity Policies*, Audit Report No.11-P-0386 (July 22, 2011), at pp. 8, 11, available at: http://www.epa.gov/oig/reports/2011/20110722-11-P-0386.pdf (underlined emphasis added).

[208] *See* United States Environmental Protection Agency Office of Inspector General, *EPA Can Improve its Process for Establishing Peer Review Panels, Evaluation Report* No. 09-P-0147 (Apr.29, 2009), at Executive Summary, pp. 3-7, available at: http://www.epa.gov/oig/reports/2009/20090429-09-P-0147.pdf.

[209] EPA-OIG Procedural Review, *supra* note 2 at 13-18 and 24.

[210] *See* United States Environmental Protection Agency, *Conflicts of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents* (Mar. 21, 2013), available at: http://www.epa.gov/osa/pdfs/epa-process-for-contractor.pdf.

[211] *See Presidential Memorandum for the Heads of Executive Departments and Agencies, Scientific Integrity*, The White House (Mar. 9, 2009), available at: http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09.

[212] *See* United States Environmental Protection Agency, *Guidance on Quality Assurance Project Plans* (CIO 2106-G-05 QAPP), Final Draft Jan. 17, 2012), at Foreword, available at: http://www.epa.gov/oeitribalcoordination/2106-G-05%20QAPP%20Final%20Draft%2001-17-12.pdf.

[213] OMB-PRB, *supra* note 32 at Preamble, at p. 12.

[214] RTCs Vol. 1, *supra* note 165 at Comment (1-62).

[215] *Id*. at Response (1-63).

[216] *See, e.g.,* United States Environmental Protection Agency, *Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202(a) of the Clean Air Act - EPA's Response to Public Comments Volume 2: Validity of Observed and Measured Data* [Hereinafter "RTCs Vol. 2"] (Apr. 24, 2009), at Comments (2-37), (2-38), (2-39), (2-62), (2-65), and (2-68), available at: http://www.epa.gov/climatechange/endangerment/comments/volume2.html; United States Environmental Protection Agency, *Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202(a) of the Clean Air Act—EPA's Response to Public Comments Volume 4: Validity of Future Projections*, [Hereinafter "RPCs Vol. 4"} (Apr. 24, 2009), at Comments (4-1) thru (4-25), (4-26), (4-36), (4-37), (4-41), (4-45), (4-46), etc., available at: http://www.epa.gov/climatechange/Downloads/endangerment/rtc_volume_4.pdf.

[217] RPCs Vol. 4, *supra* at Response (4-25).

[218] *Id.*

[219] The USGCRP/CCSP "lead" development agency designation imposed on NOAA the responsibility for the development, peer review, production, release and dissemination of these HISAs. *See Climate Change Science Program, Guidelines for Producing CCSP Synthesis and Assessment Products*, at 1-2.

[220] These included SAPs 1.1, 1.2, 2.4, 3.2, 3.3, 3.4 5.2 and 5.3 and *Global Climate Change Impacts in the United States* (also known as the Second National Climate Assessment ("NCA2-2009")).

[221] They included: SAP1.1/CCSP(2006); SAP1.3/CCSP(2008g); SAP2.4/CCSP(2008h); SAP3.2/CCSP(2008d); and SAP3.3/CCSP(2008i). *See* ITSSD September FOIA, *supra* note 85 at 10.

[222] These included: SAP2.2/CCSP(2007); SAP5.2/CCSP(2009); and SAP5.3/CCSP(2008). *Id*.

[223] *See* United States Department of Commerce, National Oceanic and Atmospheric Administration, *Global Climate Change Impacts in the United States* (Thomas R. Karl, Jerry M. Melillo, and Thomas C. Peterson, (eds.). Cambridge University Press, 2009), at 7, available at: http://downloads.globalchange.gov/usimpacts/pdfs/climate-impacts-report.pdf.

[224] The USGCRP/CCSP SAPs, and the respective portions of the ITSSD September FOIA, *supra* note 85, in which they are referenced, are as follows: SAP 1.1 (Sec. II.3.b.i, pp. 61-64; Sec. III.4, Appendices 4A-4D, pp. 118-124); SAP 1.3 (Annotated Addendum, Sec. II.3.b.ii, pp. 64-66; Sec. III.5, Appendices 5A-5D, pp. 125-129.); SAP 2.4 (Annotated Addendum, Sec. II.3.b.iii., pp. 66-68; Sec. III.6, Appendices 6A-6D, pp. 130-133.); SAP 3.2 (Annotated Addendum Sec. II.3.b.iv, pp. 68-70; Sec. III.7, Appendices 7A-7D, pp. 134-137); SAP 3.3 (Annotated Addendum Sec. II.3.b.v, pp. 70-73; Sec. III.8, Appendices 8A-8D, pp. 138-143); SAP 5.2 (Annotated Addendum Sec. II.3.b.vi, pp. 73-75; Sec. III.9, Appendices 9A-9D, pp. 144-147); and SAP 5.3 (Annotated Addendum Sec. II.3.b.vii, pp. 75-78; Sec. III.10, Appendices 10A-10D, pp. 148-151).

[225] ITSSD September FOIA, *supra* note 85 at Appendix, pp. 60-85.

[226] NOAA, National Center for Atmospheric Research ("NCAR")-National Science Federation ("NSF"), DOE, and NASA.

[227] ITSSD September FOIA, *supra* note 85 at Annotated Addendum, Sec. II.2.a, p. 47.

[228] *Id.* at Annotated Addendum, Sec. I.3.b.i-vii, pp. 60-78.

[229] These USGCRP/CCSP SAPs, and the respective portions of the ITSSD September FOIA ,*supra* note 85, in which they are referenced, are as follows: SAP 2.2 (Sec. II.4.a, pp. 78-80; Sec. III.11, Appendices 11A-11D, pp. 152-160); NCA2-2009 (Sec. II.4.b, pp. 80-82; Sec. III.12, Appendices 12A-12B, pp. 161-164).

[230] *Id*., at Annotated Addendum, Sec. II.5, pp. 82-83; Sec. III.13, Appendix 13, pp. 165-170.

[231] These office lines included the National Environmental, Satellite, Data & Information Service, the National Marine Fisheries Service, the National Ocean Service, the National Weather Service, and the Office of Oceanic and Atmospheric Research. *Id*. at 48-54.

[232] *Id.,* at Annotated Addendum, Sec. I.2.b, pp. 51-54.

[233] *See* ITSSD September FOIA, *supra* note 85 at Annotated Addendum, Sec. I.b., pp. 53-54; Sec. II, "Appendix 3E—Approximate Reported Funding NOAA Cooperative Institute Programs FYs2004-2010," pp. 112-116.

[234] *Id*. at Sec. I.2.b., pp. 51-54; Sec. II, "Appendix 3E—Approximate Reported Funding NOAA Cooperative Institute Programs FYs2004-2010," pp. 112-116 and accompanying endnotes (specifically mentioning all participating indirect NOAA grant recipients in the annual reports of each CI program).

[235] *Id*., at Annotated Addendum, Sec. II.6, pp. 83-85.

[236] *See* ITSSD FOIA Request No. EPA-HQ-008026, *supra* at Sec. II.3, Explanation, pp. 27-29.

[237] *See* EPA-TSD, *supra* note 157 at Table 1.1, p. 6.

[238] *See* ITSSD June FOIA, *supra* note 161 at Appendix 2: "EPA-TSD Table 1.1 'Core Reference Documents'" and accompanying footnotes.

[239] EPA-OIG Procedural Review, *supra* note 2 at 20.

[240] EPA-TSD, *supra* note 157 at 4.

[241] *Id*. at 5 and Table 1.1, p. 6.

[242] Endangerment Findings, *supra* note 2 at 66,510.

[243] *See* EPA-TSD, *supra* note 157 at 4.

[244] *See* RTCs Vol. 1, *supra* note 165 at 70.

[245] *See* OMB-PRB, *supra* note 32 at Sec. I.7.

[246] *See* EPA-TSD, *supra* note 157 at 66,506.

[247] *See* Endangerment Finding, *supra* note 2 at 66,497.

[248] EPA-OIG Procedural Review, *supra* note 2 at Executive Summary, p. 1; p. 22; *Appendix G—Agency Comments on Draft Report and OIG Evaluation of Agency Comments*, "OIG Response 5," p. 55; "OIG Response 16," p. 61; "OIG Response 19" and "OIG Response 20," p. 63; "OIG Response 20" and "OIG Response 21," p. 64; "OIG Response 23," p. 65.

[249] *Id*. at *Appendix G—Agency Comments on Draft Report and OIG Evaluation of Agency Comments*, pp. 52-54; *Appendix H—OMB Comments on Draft Report and OIG Evaluation of OMB Comments*, pp. 87-89.

[250] *Id*. at *Appendix G—Agency Comments on Draft Report and OIG Evaluation of Agency Comments*, p. 63.

[251] *See* ITSSD June FOIA, *supra* note 161 at 29.

[252] EPA was required to ensure that a truly "external" peer review, which is expected for all HISAs, had been conducted. EPA-OIG Procedural Review, *supra* note 2 at 13, 18, *Appendix A—Answers to Specific Questions from the Ranking Member*.

[253] *Id*. at 13, 18 ("We also noted that this panel did not fully meet the independence requirements for reviews of highly influential scientific assessments because one of the panelists was an EPA employee. The OMB bulletin for peer review states that 'scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific assessments.'").

[254] *See* RTCs Vol. 1, *supra* note 165 at Response (1-10).

[255] *Id.* ("[T]he purpose of the federal expert review was to ensure that the TSD accurately summarized the conclusions and associated uncertainties from the assessment reports.")

[256] ITSSD June FOIA, *supra* note 161 at "Appendix 1: EPA-TSD Reviewers Who Authored Summarized 'Core Reference Documents'—Apparent Conflicts-of-Interest; Lack of Independence."

[257] *Id*. at Sec. V.B.2 (identifying the EPA regulations triggered by the Endangerment Findings).

[258] *See* RTCs Vol. 1, *supra* note 165 at Response (1-10) (emphasis added).

[259] *See* ITSSD November FOIA, *supra* note 176 at Sec. II.4, Explanation, pp. 30-37.

[260] ITSSD September FOIA, *supra* note 85 at Sec. II.4, Explanation, p. 33.

[261] *Id*. at Annotated Addendum, Sec. I.1.b, p. 44.

[262] *Id*. at 45 and accompanying endnotes 334-338.

[263] *Id*. at Annotated Addendum, Sec. I.1.b, pp. 45-46 and accompanying endnotes.

[264] *Id*. at 45, and accompanying endnotes 340.

[265] *Id*. at 46, endnote 345.

[266] *See* United States Environmental Protection Agency, *Regulating Greenhouse Gas Emissions under the Clean Air Act—Advanced Notice of Proposed Rulemaking*, 73 Fed. Reg. 44,354, 44,421 (July 30, 2008), available at: http://www.gpo.gov/fdsys/pkg/FR-2008-07-30/pdf/E8-16432.pdf.

[267] ITSSD September FOIA, *supra* note 85 at Annotated Addendum, Sec. I.1.b, p. 46, citing United States Environmental Protection Agency, *Technical Support Document for the Advanced Notice of Proposed Rulemaking for Greenhouse Gases; Stationary Sources, Section VII - EPA-HQ-OAR-2008-0318-0081* (June 5, 2008, Final Draft), available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0318-0081.

[268] *Id*. at Annotated Addendum, Sec. I.1.b, p. 46, citing United States Environmental Protection Agency, *Technical Support Document—Section 202 Greenhouse Gas Emissions—Roadmap to Annex—EPA-HQ-OAR-2008-0318-0083* (July 14, 2008), available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-

2008-0318-0083. *See also* United States Environmental Protection Agency, *Technical Support Document for Endangerment Analysis for Greenhouse Gas Emissions under the Clean Air Act; Sixth Order Draft June 21, 2008)—EPA-HQ-OAR-2008-0318-0082* (July 14, 2008), at Table 1.1, p. 4, available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0318-0082.

[269] *See* Endangerment Findings, *supra* note 2 at 44,355; United States Environmental Protection Agency, *Vehicle Technical Support Document: Evaluating Potential GHG Reduction Programs for Light Vehicles (Draft LD TSD 6/16/08) - EPA-HQ-OAR-2008-0318-0084* (July 14, 2008), available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2008-0318-0084.

[270] *See* United States Environmental Protection Agency, *Proposed Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act; Proposed Rule*, 74 Fed. Reg. 18,886, 18,888, 18,903 (Apr. 24, 2009), available at: http://www.gpo.gov/fdsys/pkg/FR-2009-04-24/pdf/E9-9339.pdf.

[271] *See* EPA-TSD, *supra* note 157.

[272] *See* RTCs Vol. 1*, supra* note 165 at Response (1-61), p. 53.

[273] *Id*. at Response (1-61).

[274] *Id.*

[275] *Id*.

[276] *Id.* at Comments (1-7), (1-10), (1-14), (1-15, (1-17), (1-18), (1-19) (1-20), (1-25), (1-26), (1-27), (1-28), (1-29), (1-30), (1-60), (1-61), (1-62), 1-63), (1-67), (1-68), (1-70), (1-74).

[277] *Id*. at Responses (1-7), (1-10), (1-14), (1-15), (1-19), (1-20), (1-25), (1-28), (1-67), (1-68), (1-70), (1-74) (emphasis added).

[278] *Id*. at Response (1-70).

[279] *Id*. at Comment (1-72).

[280] *Id*. at Response (1-72). This report was otherwise known as the "unified synthesis product."

[281] *Id.* at Comment (1-10) (emphasis added).

[282] *Id*. at Comment (1-46).

[283] *Id*. at Responses (1-46), (1-47), (1-48).

[284] *Id*. at Response (1-48).

[285] *Id*. at Responses (1-47), (1-48).

[286] RTCs Vol. 1, *supra* note 165 at Comment (1-64) (emphasis added).

[287] *Id*. at Response (1-64).

[288] *Id*. at Comments (1-62), (1-63).

[289] 293 F.3d 355, 372 (D.C. Cir. 2002).

[290] RTCs Vol. 1, *supra* note 165 at Response (1-62).

[291] *Id*. at 64-65.

[292] *See United States Environmental Protection Agency, PUBLIC HEARING: Proposed Rulemaking for EPA's Proposed Endangerment and Cause or Contribute Findings for Greenhouse Gases—Under the Clean Air Act, Transcript of the May 18, 2009 Public Hearing in Arlington, Virginia*, Docket No. EPA-HQ-OAR-2009-0171-2818 (9:01 a.m. through 8:14 p.m. Monday, May 18, 2009), at 285, available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2009-0171-2818; United States Environmental Protection Agency, *PUBLIC HEARING: Proposed Rulemaking for EPA's Proposed Endangerment and Cause or Contribute Findings for Greenhouse Gases Under the Clean Air Act, Transcript of the May 21, 2009 Public Hearing in Seattle, Washington*, Docket No. EPA-HQ-OAR-2009-0171-2895 (9:00 a.m. Thursday, May 21, 2009, 2211 Alaskan Way, Pier 66 Bell Harbor Conference Center, Seattle, Washington), at 10, available at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2009-0171-2895.

[293] ITSSD June FOIA, *supra* note 161 at Sec. II.4, Explanation, pp. 36-37 and accompanying endnotes.

[294] *See* United States Environmental Protection Agency, *EPA's Denial of the Petitions to Reconsider the Administrator's Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202(a) of the Clean Air Act*; *Final Rule*, 75 Fed. Reg. 49,556 (Aug. 13, 2010).

[295] 28 U.S.C. § 2401(a) provides a general six-year statute of limitations for civil actions brought against the United States. At the earliest, the six-year statute of limitations for bringing such a suit against EPA will expire on December 15, 2015, six years after the date on which EPA's CAA Section 202(a) GHG Endangerment Findings had been issued. However, it is more likely that the six-year statute of limitations will expire on August 10, 2016, six years after the date on which EPA issued its denial of stakeholder petitions to reconsider EPA's GHG Endangerment Findings.

[296] *See, e.g.*, Kirk T. O'Reilly, *Science, Policy and Politics: The Impact of the Information Quality Act on Risk-Based Regulatory Activity at the EPA*, 14 BUFF. ENVTL. L.J. 249, 272-73 (2006-2007), available at: http://thecre.com/pdf/20121029_DQABuffalo.pdf.

[297] *See* Sidney Shapiro, Rena Steinzor and Margaret Clune*, Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, Center for Progressive Reform White Paper #601 (Feb. 2006) at 1, available at: http://www.progressivereform.org/articles/CPR_IQA_601.pdf.

[298] Johnson, *supra* note 146 at 67, citing 5 U.S.C. § 706(2)(D).

[299] *See, e.g.*, Wendy Wagner, *Importing* Daubert *to Administrative Agencies Through the Information Quality Act*, 12 J. OF LAW & POL'Y 589, 603-604 (2005), available at http://www.thecre.com/pdf/20050505_jlp12ii_wagner.pdf (discussing the potential for agencies to abuse the IQA peer review process). *See also* EPA IQA Guidelines, *supra* note 57 at Appendix A, Sec. A.3.2, p. 40 (expressing the Agency's belief that the guidelines are not judicially reviewable).

[300] Office of Management Budget, *Memorandum for President's Management Council—OIRA Review of Information Quality Guidelines Drafted by Agencies* (June 10, 2002), at 14-15, available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/iqg_comments.pdf ("We note […] that a number of agencies emphasize that their guidelines are not intended to provide any right to judicial review. A few agencies even stress that their guidelines may not be applicable based on unspecified circumstances and that the agency may be free to differ from the guidelines where the agency considers such action appropriate. Regardless of what kinds of litigation-oriented disclaimers the agencies may include, agency guidelines should not suggest that agencies are free to disregard their own guidelines. Therefore*, if you believe it is important to make statements that your agency's guidelines are not intended to provide rights of judicial review, we ask that you not include extraneous assertions that appear to suggest that the OMB and agency information quality standards are not statements of government-wide policy, i.e., government-wide quality standards which an agency is free to ignore based on unspecified circumstances*. In addition, *agencies should be aware that their statements regarding judicial enforceability might not be controlling in the event of litigation.*" (emphasis added)

[301] *See* Paul R. Verkuil, *Agency Data Disclosure: Legal Requirements and ACUS Recommendations*, Administrative Conference of the United States, at 11, 15 (2014), available at: http://www.iom.edu/~/media/Files/Activity%20Files/Environment/EnvironmentalHealthRT/2014-03/Paul-Verkuil_March2014.pdf.

[302] *See* United States Department of Justice, *DOJ Information Quality Act Guidelines—Scope and Applicability of Guidance*, available at: http://www.justice.gov/iqpr/information-quality.

[303] Johnson, *supra* note 146 at 68. *See also* James W. Conrad, Jr., *The Information Quality Act—Antiregulatory Costs of Mythic Proportions?*, 12 KAN. J. L. PUB. POL'Y 521, 539 (2003), available at: http://www.thecre.com/pdf/2003_conrad.pdf ("[T]he availability of judicial review for agency denials of correction requests is one for the courts to decide [and…] case law also strongly supports the view that such denials are reviewable. First, the silence of the IQA on the question is of no moment…")

[304] *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 671-673, 681 (1986); *Block v. Community Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("where there is substantial doubt about Congressional intent in a specific circumstance, the presumption in favor of judicial review is controlling.")

[305] *See Califano v. Sanders*, 430 U.S. 99 (1977).

[306] *See, e.g.*, Environmental Law Institute, *Selected Provisions from Environmental Statues Conferring Jurisdiction on the D.C. Circuit (and the D.C. District Court)* (Nov. 2003), available at: http://www.eli.org/sites/default/files/docs/dc_cir_jurisdiction_11_03.pdf (identifying the many substantive environmental law statutes that "provide for jurisdiction by the D.C. Circuit (and/or the United States District Court for the District of Columbia) over environmental matters.").

[307] *See* 28 U.S.C. § 1331 ("The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.").

[308] *Califano*, 430 U.S. at 105.

[309] Jeffrey S. Gutman, *Federal Practice Manual for Legal Aid Attorneys* at "Sec. 2.3 Federal Question Jurisdiction," Sargent Schriver National Center on Poverty Law.

[310] Lumen N. Mulligan, *Federal Courts Not Federal Tribunals*, 104 NW U. L. REV. 175, 193 (2010), available at: http://www.law.northwestern.edu/LAWREVIEW/v104/n1/175/LR104n1Mulligan.pdf.

[311] *Id*. at 176.

[312] *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 230 n.4 (holding that, "A separate indication of congressional intent to make agency action reviewable under the APA is not necessary.")

[313] *Abbott Laboratories v. Garner*, 387 U.S. 136, 140 (1967).

[314] *Transactive Corp. v. United States*, 91 F. 3d 232, 236 (D.C. Cir. 1996). *See also Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852 (4th Cir. 2002).

[315] *See* 5 U.S.C. § 702. ("A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.") .

[316] *See* Sidney Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, 28 WM & MARY ENVTL. L. & POL'Y REV.339, 368-369 (2004), available at: http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1153&context=wmelpr.

[317] *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 488 (1998) quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 152 (1970).

[318] 749 F. Supp. 2d 1083 (E.D. Cal. 2010).

[319] 760 F. Supp. 2d 855 (E.D. Cal. 2010).

[320] *Family Farm Alliance*, 749 F. Supp. 2d at 1091, n. 4.

[321] *Id*. at 1091 citing *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 44 n. 11 (2000).

[322] *Id*.

[323] *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004) (the U.S. Supreme Court defined the types of agency actions that are reviewable under APA Sections 702 and 704, citing 5 U.S.C. §§ 551(4), (6), (8), (10), (11), (13)).

[324] *Bennett v. Spear*, 520 U.S. 154, 177-178 (1997), citing *Chicago & Southern Air Lines, Inc. v. Waterman S. S. Corp.*, 333 U.S. 103, 113 (1948) and *Port of Boston Marine Terminal Assn. v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970).

[325] *Bennett*, 520 U.S. at 178 (emphasis added).

[326] *Id*. at 177-178 (1997), citing *Franklin v. Massachusetts*, 505 U. S. 788, 798 (1992) (emphasis added) and *Dalton v. Specter*, 511 U. S. 462, 469-471 (1994) (holding that "final agency action" was lacking because reports recommending base closures submitted by the Secretary and the Commission, by themselves, "carried no direct consequences" for base closings, and that a final agency action would occur only when the President submits to Congress his certification of approval of proposed based closings).

[327] Johnson, *supra* note 146 at 71.

[328] *Id*. at 72 (emphasis added).

[329] *Id.* at. 71-72 (emphasis added).

[330] *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 601-602 (E.D. Va. 2004).

[331] *Id*. at 602.

[332] *Single Stick v. Johanns*, 601 F. Supp. 2d 307, 310-11 (D.D.C. 2009).

[333] *Id*. at 312.

[334] *Id*. at 316.

[335] *Id*. at 317, citing *Salt Institute v. Leavitt*, 440 F. 3d 156, 159 (4th Circ. 2006).

[336] *Id*., citing *Ams. for Safe Access v. HHS*, No. C 07-01049 WHA, 2007 WL 2141289, at *4 (N.D. Cal. Nov. 20, 2007), aff'd on other grounds, 399 F. App'x 314 (9th Cir. 2010).

[337] 2007 U.S. Dist. LEXIS 55597, at *3 (N.D. Cal. July 24, 2007).

[338] *Id.* at *3-4.

[339] *Id*. at *4.

[340] *Id*.

[341] *Id*. at *6.

[342] *Id*. at *5-6.

[343] *Ams. for Safe Access v. HHS*, No. 07-17388 D.C. No. CV-07-01049-WHA MEMORANDUM at *2 (Oct. 14, 2010).

[344] *Id*.

[345] *Ams. for Safe*, 399 F. App'x at 315-16.

[346] *Id*.

[347] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (quoting S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945)).

[348] *Heckler v. Chaney*, 470 U.S. 821, 830 (1985) (emphasis added).

[349] *Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (quoting *Heckler*, 470 U.S. at 830) (emphasis added).

[350] *Pinnacle Armor v. U.S.*, 648 F.3d 708, 719 (2011).

[351] *Webster v. Doe*, 486 U.S. 592, 600 (1988) ("Both *Overton Park* and *Heckler* emphasized that §701(a)(2) requires careful examination of the statute on which the claim of agency illegality is based.")

[352] *Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) quoting *Padula v. Webster*, 822 F.2d 97, 100 (D.C. Cir. 1987).

[353] *See American Petroleum Institute and Utility Air Regulatory Group v. EPA*, 684 F.3d 1342, 1348-49 (D.C. Cir. 2012).

[354] *San Luis & Delta-Mendota Water Auth.*, 760 F. Supp. 2d at 964.

[355] *Family Farm Alliance*, 749 F. Supp. 2d at 1086.

[356] 749 F. Supp. 2d at 1092; *Family Farm Alliance v. Salazar*, "Complaint for Declaratory and Injunctive Relief," No. 1:09-CV-01201 (July 10, 2009) at ¶¶ 54-56.

[357] *Family Farm Alliance*, 749 F. Supp. 2d at 1086.

[358] *Family Farm Alliance v. Salazar*, "Complaint for Declaratory and Injunctive Relief," No. 1:09-CV-01201 (July 10, 2009) *Id*. at ¶¶. 28-29.

[359] *Family Farm Alliance*, 749 F. Supp. 2d at 1093.

[360] *Id*. at 1090.

[361] *Id*. at 1095.

[362] *Id*.

[363] *Bennett*, 520 U.S. at 162, citing *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (citing *Barrows v. Jackson*, 346 U.S. 249 (1953)).

[364] *Id.* at 192, citing *Allen v. Wright*, 468 U.S. 737, 752 (1984).

[365] *Salt Institute v. Thompson*, 345 F. Supp. 2d at 598, citing *Lujan*, 504 U.S. at 560-561; *Friends of Ferrell Parkway, LLC v. Stasko*, 282 F.3d 315, 320 (4th Cir. 2002); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. Inc.*, 528 U.S. 167, 180-181 (2000). *See also Summers v. Earth Island Institute*, 129 S. Ct. 1142, 1148 (2009), citing *Laidlaw Environmental Services (TOC), Inc.*, 528 U. S. at 180–81.

[366] *Salt Institute v. Thompson*, 345 F. Supp. 2d at 598, citing *Lujan*, 504 U.S. at 573-574.

[367] *Family Farm Alliance*, 749 F. Supp. 2d at 1101, citing *Allen*, 468 U.S. at 752.

[368] *Id*., citing *Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 969 (9th Cir. 2009).

[369] *Summers*, 129 S. Ct. at 1151.

[370] *Id.*, citing *Lujan*, 504 U.S at 572, n. 7.

[371] *Id*. at 1152, quoting *Lujan*, 504 U.S. at 566.

[372] *Id*. at 1153.

[373] *See, e.g.*, Cass Sunstein, *Informational Regulation and Informational Standing:* Akins *and Beyond* [Hereinafter "Sunstein"], 147 U. OF PENN. L. REV. 613 (1999), available at: http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=3409&context=penn_law_review (discussing and explaining the motivations behind a broad range of statutes that endeavor to use information disclosure as a "regulatory tool.")

[374] *Id*. at 629.

[375] *Id*. at 631-632.

[376] *See* Bradford Mank, *Informational Standing after* Summers [Hereinafter "Mank (*Summers*)"], U. of Cinn. College of Law Faculty Articles and Other Publications, Paper 213 (2012) at 28, available at: http://scholarship.law.uc.edu/cgi/viewcontent.cgi?article=1215&context=fac_pubs

[377] *Id.* at 32.

[378] *Id*. at 2, citing *Wilderness Society v. Rey*, 622 F.3d 1251, 1257-60 (9th Cir. 2010) (emphasis added).

[379] *Id*. at 39 citing *Wilderness Society v. Rey*, 622 F.3d at 1258-1260 (emphasis added).

[380] *Bennett*, 520 U.S. at 162, citing *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 474-475, and *Warth*, 422 U. S. at 501.

[381] *Id*. at 162, citing *Allen*, 468 U. S. at 737, and *Warth*, 422 U. S. at 498.

[382] *Id*.

[383] *United States v. Windsor*, 133 S. Ct. 2675, 2687 (2013) quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962).

[384] *Association of Data Processing Service Organizations, Inc. v. Camp*, 397 U.S. 150, 153 (1970).

[385] *Bennett*, 520 U.S. at 175.

[386] *Id*. at 175-176.

[387] *Bangura v. Hansen*, 434 F.3d 487, 499 (6th Cir. 2006), citing *Nat'l Credit Union Admin.*, 522 U.S. at 492.

[388] *See* Jeremy A. Rabkin, *The Secret Life of the Private Attorney General*, 61 J. OF LAW AND CONTEMPORARY PROBLEMS 179, 183-184 (1998), available at: http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1077&context=lcp. The conception of the "private attorney general" so described represents only one of several forms of private attorney general. *See*

William B. Rubenstein, *On What a "Private Attorney General" Is—and Why it Matters*, 57 VAND. L. REV. 2128, 2142 (2004), available at: http://www.billrubenstein.com/Downloads/private_attorney_general.pdf

[389] 345 F. Supp. 2d at 601, citing *Regional Mgmt. Corp. Inc. v. Legal Serv. Corp.*, 186 F.3d 457, 461 (4th Cir.1999).

[390] *Id.*

[391] *Regional Mgmt. Corp. Inc., v. Legal Serv. Corp.*, 186 F. 3d 457, 461 (4th Cir. 1999) citing *Suter v. Artist M.*, 503 U.S. 347, 364 (1992) and *Cort v. Ash*, 422 U.S. 66 (1975).

[392] *Id.* at 461 (emphasis added).

[393] *Id*. at 461-462, citing *Suter*, 503 U.S. at 364 and *Donaldson v. Department of Labor*, 930 F.2d 339, 347-48 (4th Cir. 1991).

[394] *Salt Institute*, 345 F. Supp. 2d at 599, citing *Baur v. Veneman*, 352 F.3d 625, 636-37 (2d Cir. 2003).

[395] *Id*. at 598-599.

[396] *Id*. at 599.

[397] *Id*.

[398] *Id*., citing *Baur*, 352 F.3d at 636-37.

[399] *Id*. at 600.

[400] *Id*.

[401] *Id*. at 601, citing *In re: Operation of the Missouri River Sys. Litigation*, No. 03-MD-1555 at 49, 2004 WL 1402563 (D. Minn. June 21, 2004).

[402] 532 U.S. 275 (2001).

[403] *Id*. at 286 ("The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy […] Statutory intent on this latter point is determinative.").

[404] *See* Pamela S. Karlan, *Disarming the Private Attorney General*, U. OF ILL. L. REV. (2003), 183, 196, available at: http://illinoislawreview.org/wp-content/ilr-content/articles/2003/1/Karlan.pdf.

[405] *Salt Institute v. Leavitt*, 440 F. 3d 156, 158 (4th Cir. 2006).

[406] *Id*. at 159 ("Because the statute upon which appellants rely does not grant the rights that appellants claim were invaded, appellants cannot establish an injury in fact and, therefore, lack Article III standing to pursue their case in the federal courts.").

[407] *Id*.

[408] *Id*.

[409] *Id*.

[410] *Id*.

[411] 524 U.S. 11, 20 (1998).

[412] *Salt Institute v. Leavitt*, 440 F. 3d at 159.

[413] *Family Farm Alliance*, 749 F. Supp. 2d at 1102-1103.

[414] *Id*. at 1102.

[415] *Id*. at 1103.

[416] *Id*.

[417] Family Farm Alliance had alleged that several peer reviewers "had either conducted research on the delta smelt previously, or had mentorship connections with scientists who had done so, or had allegedly accepted grants from the agencies responsible for the Biological Opinion." *Id*.

[418] *Id*.

[419] 599 F.3d 678 (D.C. Cir. 2010), petition for rehearing denied *per curiam* (2010). Unlike the *API* case, the *Prime Time* case was brought under FETRA, the Information Quality Act, 44 U.S.C. § 3516, and the Due Process Clause of the Constitution.

[420] *Single Stick v. Johanns*, No. 1:06-CV-01077 (RWR), "Single Stick's Motion for Summary Judgment" (Feb. 6, 2007), at Sec. 2, pp. 23-25, available at: http://archive.recapthelaw.org/dcd/121140/.

[421] *Single Stick v. Johanns*, No. 1:06-CV-01077 (RWR), "Defendant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment" (Apr. 23, 2007), at 14-15.

[422] *Id*. at 15-16.

[423] *See Single Stick v. Johanns*, No. 1:06-CV-01077 (RWR), "Single Stick's Reply to Defendants' Opposition to Summary Judgment" (Apr. 27, 2007), at 12-15.

[424] *Prime Time Int'l*, 599 F.3d at 685; 44 U.S.C. § 3516 (note), P.L. 106-554 (2000), § 515(a), (b)(2)(A).

[425] *Id*. at 685-686.

[426] *See* William S. Jordan III, *D.C. Circuit—Is the Information Quality Act Ready for Prime Time?*, 35 ADMIN. & REG. LAW NEWS 17, American Bar Association (Summer 2010).

[427] OMB IQA Guidelines, *supra* note 32 at Sec. V.8 and Preamble, p. 8454; OMB-PRB, *supra* note 32 at § I.3; USDA Information Quality Guidelines, Definitions, § 2.

[428] *Prime Time Int'l*, 599 F.3d at 685 (emphasis added).

[429] *See* Office of Management and Budget, *Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies—[Notice and Request for Comment]*, 66 Fed. Reg. 34,489 (June 28, 2001).

[430] OMB IQA Guidelines, *supra* note 32 at 8,453-8,458.

[431] *Prime Time Int'l Co.*, 599 F.3d at 685-686.

[432] 533 U.S. 218 (2001).

[433] *Mead*, 533 U.S. at 235, citing *Skidmore v. Swift & Co.*, 323 U. S. 134, 140 (1944).

[434] *See Prime Time Int'l Co. v. Vilsack*, No. 09-5099, "Appellees' Petition for Rehearing" (Apr. 30, 2010), available at: http://thecre.com/pdf/20100603_Government_DQA_Appeal_to_Court.abrev.pdf.

[435] *Salt Institute v. Thompson*, "Memorandum in Support of Defendant's Motion to Dismiss" (June 25, 2004) at 30, n. 17.

[436] *Family Farm Alliance*, 749 F. Supp. 2d at 1096-1100; *San Luis & Delta-Mendota Water Auth.* 760 F. Supp. 2d at 959-964.

[437] *Salt Institute v. Thompson*, "Memorandum in Support of Defendant's Motion to Dismiss" (June 25, 2004), at 35 and n. 21 (emphasis added).

[438] *See, e.g.,* Antonin Scalia and Bryan A. Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXTS, Thomson West © 2012, 313-317. (The bold-faced headline to this section states, "A statute's mere prohibition of a certain act does not imply creation of a private right of action for its violation. The creation of such a right must be either express or clearly implied from the text of the statute.")

[439] *See* Heather Elliott, *The Functions of Standing* [Hereinafter "Elliott"], 61 STANFORD L. REV. 459, 471 (2008), available at: http://www.stanfordlawreview.org/sites/default/files/articles/Elliott.pdf, citing *Valley Forge Christian Coll.*, 454 U.S. at 472, *Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. at 191 (2000), and *Baker v. Carr*, 369 U.S. 186, 204 (1962).

[440] *Id*. at 474, citing David M. Driesen, *Standing for Nothing: The Paradox of Demanding Concrete Context for Formalist Adjudication*, 89 CORNELL L. REV. 808, 839-55 (2004).

[441] *See Cannon v. University of Chicago*, 441 U.S. 677 (1979). In *Cannon*, the Court recognized an implied cause of action under Section 901(a) of Title IX of the Education Amendments of 1972.

[442] *See* Brian J. Leske, *U.S. Supreme Court Jurisprudence on Implied Private Rights of Action: The Pendulum Swings Back*, The Federalist Society, (Mar. 26, 2008), available at: http://corporate.findlaw.com/litigation-disputes/u-s-supreme-court-jurisprudence-on-implied-private-rights-of.html, citing *Cannon v. University of Chicago*, 441 U.S. 677, 717 (1979) (Rehnquist, J., concurring)."

[443] *Id*., quoting *Cannon*. 441 U.S. at 743 (Powell, J., dissenting).

[444] *Id*.

[445] 552 U.S. 148 (2008).

[446] *Id*. at 164–65, quoting *American Fire & Casualty Co. v. Finn*, 341 U. S. 6, 17 (1951) and *Cannon*, 441 U. S. at 746.

[447] Elliott, *supra* note 439 at 462.

[448] *Id*. at 478, citing *Lujan*, 504 U.S. at 576. *See also id*. at 462 (It is presumed that undifferentiated injuries shared by a large group of people are better redressed by congress or the executive branch than by the courts.)

[449] *Id*. at 479, citing *Sierra Club v. Morton*, 405 U.S. 727, 737 (1972) (emphasizing that a plaintiff must satisfy standing limitations in order to sue, even if, after surviving that test, the plaintiff may then act as a "private attorney general" and "argue the public interest in support of his claim").

[450] *Id*. at 479, citing *Newman v. Piggie Park Enters.*, 390 U.S. 400 (1968) (per curiam) (interpreting attorney's fees provision of the Civil Rights Act of 1964.

[451] *Id*. at 479-80, citing *Massachusetts* 549 U.S. at, 535 ("[R]edress of grievances of the sort at issue here 'is the function of Congress and the Chief Executive,' not the federal courts."

[452] 524 U.S. 11 (1998).

[453] Elliott, *supra* note 439 at 481, citing *Akins*, 524 U.S. at 24.

[454] *Id*. at 482, citing *Massachusetts*, 549 U.S. at 516-21.

[455] *Id*. at 483, citing *Lujan*, 504 U.S. at 581 (Kennedy, J., concurring).

[456] *Id*. at 492-93.

[457] *Id*. at 493. "Without that brake, courts could, 'with the permission of Congress, . . .assume a position of authority over the governmental acts of another and co-equal department." *Id*., quoting *Lujan*, 504 U.S. at 577.

[458] *Id*. at 493-494, quoting *Lujan*, 504 U.S. at 577.

[459] *City of Arlington,* 133 S. Ct. at 1877 (Roberts, CJ, dissenting).

[460] 130 S. Ct. 827, 831 (2010).

[461] *See* Institute for Trade, Standards and Sustainable Development, *Placing APA/IQA Jurisprudence into Proper Perspective – Three Possible Prudential Uses of the Separation of Powers Doctrine to Curtail Standing*, available at: https://nebula.wsimg.com/722191b930b26410de9fc74d0921f2d1?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[462] Bradford Mank, *Should States Have Greater Standing Rights than Ordinary Citizens?:* Massachusetts v. EPA*'s New Standing Test for States* [Hereinafter "Mank (*Mass.*)"], 49 WM. & MARY L. REV., 1701, 1706 (2008), citing *Georgia v. Tennessee Copper Co.*, 206 U.S. 230 (1907).

[463] 127 S. Ct. 1428, 1454 (2007).

[464] Mank (*Mass*.), *supra* note 462 at 1706; Robert A. Weinstock, *The Lorax State:* Parens Patriae *and the Provision of Public Goods* [Hereinafter "Weinstock"], 1009 COLUM. L. REV. 798, 799 (2009).

[465] 458 U.S. 592 (1982).

[466] *Id*. at 601.

[467] *Id*. at 601-602. The State of Texas averred, in *Coalition for Responsible Regulation v. EPA*, that a State has a proprietary interest in its permanent structures and chattel. *See Coalition for Responsible Regulation v. EPA*, "Brief of Texas for State Petitioners and Supporting Intervenors," USCA Case #09-1322 (Doc. No. 1309213 (D.C. Cir., Filed May 20, 2011), at 13-14.

[468] *Snapp v. Puerto Rico*, 458 U.S. at 607.

[469] *Id*. at 602.

[470] *Id*. at p. 607 (emphasis added).

[471] *Id*.

[472] *See* Amy J. Wildermuth, *Why State Standing in* Massachusetts v. EPA *Matters*, 27 J. LAND, RESOURCES, & ENVT'L. LAW 273, 304-305 (2007), available at: http://epubs.utah.edu/index.php/jlrel/article/view/53/46.

[473] *See* Kathryn A. Watts and Amy J. Wildermuth, Massachusetts v. EPA*: Breaking New Ground on Issues Other than Global Warming*, 102 NW. U. L. REV. COLLOQUY 1 (2007), at 4; Wildermuth, *id*. at 304-305, Others have found that such interests include an interest in protecting state citizens' access to natural gas produced in another state (*Pennsylvania v. West Virginia*, 262 U.S. 553, 581, 591 (1923)), an interest in protecting against alleged antitrust violations resulting from "railroads conspir[ing] to fix freight rates in a manner that discriminates against a particular state's shippers"(*Georgia v. Pennsylvania Railroad Co.*, 324 U.S. 439, 443-44, 450-51 (1945)), and an interest in defending state citizens from a "'first use' tax imposed by [another state…] on certain uses of natural gas" (*Maryland v. Louisiana*, 451 U.S. 725, 737-39 (1981). *See* Mank (*Mass.*), *supra* note 462 at 1762-1763, citing *Snapp*, 458 U.S. at 605.

[474] Weinstock, *supra* note 464 at 799-800.

[475] Mank (*Mass*.), *supra* note 462 at 1785-86.

[476] *Id*. at 1785.

[477] *Id*. at 1786.

[478] *Id*.

[479] Weinstock, *supra* note 464 at 822-823.

[480] *Id*. at 824, n.154, citing *Massachusetts*, 127 S. Ct. at 1454.

[481] Mank (*Mass*.), *supra* note 462 at 1758.

[482] Weinstock, *supra* note 464 at 824, citing *Massachusetts*, 127 S. Ct. at 1463.

[483] *Massachusetts*, 127 S. Ct. at 1454-1455.

[484] 206 U.S. 230 (1907).

[485] Weinstock, *supra* note 464 at 817, 824.

[486] *Id*. at 237-238

[487] *Id*. at 817; *Alfred L. Snapp & Son, Inc.*, 458 U.S. at 612 ("As a sovereign entity, a State is entitled to assess its needs, and decide which concerns of its citizens warrant its protection and intervention.") (Brennan, J., concurring).

[488] *See Massachusetts v. Mellon*, 262 U.S. 447 (1923).

[489] *Massachusetts*, 127 S. Ct. at 1454-55, and n. 17.

[490] *Id.* at n. 17.

[491] *Id*. at 1771. (Professor Mank noted how "it was reasonable for the *Massachusetts* majority to conclude that Congress implicitly allowed states to bring *parens patriae* [citizen] suits against the EPA for allegedly failing to comply with the Act.") *See also* Weinstock, *supra* note 464 at 840 ("("[A]fter *Massachusetts*, it seems that *Mellon* does not bar *parens patriae* suits based upon the improper implementation of federal statutes.")

[492] 524 U.S. 11 (1998).

[493] 536 U.S. 273, 283-284 (2002) (holding that "[t]he question whether Congress…intended to create a private right of action [is] definitively answered in the negative' where a 'statute by its terms grants no private rights to any identifiable class.'" *Touche Ross & Co. v. Redington*, 442 U. S. 560, 576 (1979). For a statute to create such private rights, its text must be "phrased in terms of the persons benefited." *Cannon*, 441 U. S. at 692, n. 13.

[494] *Akins*, 524 U.S. at 19-20.

[495] *Gonzaga University*, 536 U.S. at 285-286.

[496] *Id*. at 284, citing *Cannon*, 441 U. S. at 691.

[497] *See, e.g*, Sunstein, *supra* note 373 at 631; Mank (*Summers*), *supra* note 376 at 28 et seq.

[498] *See* BLACK'S LAW DICTIONARY, 7th ed., B.A. Garner (ed.) (West Group, 1999), at 1323 (emphasis added).

[499] Jenna MacNaughton, *Positive Rights in Constitutional Law: No Need to Graft, Best Not to Prune*, 3 J. OF CON. LAW 750, 751 (2001), available at: https://www.law.upenn.edu/journals/conlaw/articles/volume3/issue2/MacNaughton3U.Pa.J.Const.L.750%282001%29.pdf (emphasis added).

[500] *Id*. at 750.

[501] *See DeShaney v. Winnebago County Department of Social Services*, 489 U.S. 189 (1989).

[502] 44 U.S.C. § 3516 note (emphasis added).

[503] 44 U.S.C. § 3504(d)(1)

[504] 44 U.S.C. § 3516.

[505] 44 U.S.C. § 3501(1)-(2) (emphasis added).

[506] 44 U.S.C. § 3501(4) (emphasis added).

[507] 44 U.S.C. § 3501(8)(C) (emphasis added).

[508] U.S. House of Representatives, *Paperwork Reduction Act of 1995—Committee on Government Reform and Oversight Report Together With Additional Views [To accompany H.R. 830]*, 104th Cong. 1st Sess., Rept. 104–37 (Feb. 15, 1995), at 1, 35 (emphasis added).

[509] *Id*. (emphasis added).

[510] *Id*. at 27 (emphasis added).

[511] As previously noted, Congress mandated in the IQA for OMB to issue guidelines under PRA § 3504(d)(1) strictly with respect to information *dissemination* (emphasis added).

[512] 44 U.S.C. §§ 3501(1) and 3502(10), as amended by Publ. L. 104-13, 109 Stat. 163, 104th Cong. (May 22, 1995). PRA § 3501(1) referred to "individuals, small businesses, educational and nonprofit institutions, Federal contractors, *State*, local and tribal governments, and other persons" (emphasis added). PRA § 3502(10) defined the scope of affected "persons" as including "an individual, partnership, association, corporate business trust, or legal representative, an organized group of individuals, *a State*, territorial, tribal, or local government or branch thereof, or a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision" (emphasis added).

[513] *Id*. at § 3502(2).

[514] *Id*. at § 3502(2)(C).

[515] *Id*. at § 3502(2)(D)-(F).

[516] 5 C.F.R. § 1320(3)(c)(4)(i)-(ii) ("(i) Any recordkeeping, reporting, or disclosure requirement contained in a rule of general applicability is deemed to involve ten or more persons. (ii) Any collection of information addressed to all or a substantial majority of an industry is presumed to involve ten or more persons.").

[517] *See* 44 U.S.C. § 3502(3)(A)(i).

[518] *See, e.g.*, NOAA IQA Guidelines, *supra note* 57 at Part III.A.3.

[519] Monica Youn, *The Chilling Effect and the Problem of Private Action*, 66 VAND. L. REV. 1437, 1505 (2013).

[520] *Id*. at 1505-06, n. 141, citing Frederick Schauer, *Fear, Risk and the First Amendment: Unraveling the Chilling Effect*, 58 B.U. L. REV. 685, 692, n.37 (1978). ("*Most constitutional rights*, such as the right against self-incrimination or the prohibition against cruel and unusual punishment, *are considered to be negative rights*, which convey no affirmative entitlement but simply confer protection against prohibited governmental action") (emphasis added).

[521] *See Jackson v. City of Joliet*, 715 F.2d 1200 (7th Cir.), *cert. denied*, 465 U.S. 1049 (1983).

[522] *Id.* at 1203.

[523] *Id*. at 478. *See also Olmstead v. United States*, 277 U.S. 438 (1928).

[524] 5 U.S.C. §§ 701(a), 701(a)(2), 704.

[525] *See* 44 U.S.C §3507(d)(6).

[526] *See* 44 U.S.C. § 3512.

[527] *Association of American Physicians & Surgeons, Inc. v. U.S. Department of Health and Human* Services, 224 F.2d 1115, 1129 (S.D. Tex. 2002) ("The PRA does not create a private right of action"), citing *Tozzi v. EPA*, 148 F. Supp. 2d 35, 43 (D.C.D.C. 2001) and *Saco River Cellular, Inc. v. FCC*, 133 F.3d 25 (D.C.Cir.1998) ("§ 3512 is only a defense to enforcement actions").; *Tozzi v. EPA*, 148 F. Supp. 2d 35, 43 (D.C.D.C. 2001) ("§ 3512 is only a defense to enforcement actions […].

[528] *Id*. (emphasis added).

[529] *See Tozzi v. EPA*, 148 F. Supp. 2d 35 (D.C.D.C. 2001).

[530] *Id*. at 43-44.

[531] 44 U.S.C. § 3507(d)(6) (emphasis added).

[532] 148 F. Supp. 2d at 48 ("§3507(d)(6) is nothing less than an explicit statement of clear Congressional intent that, under the PRA, OMB ICR approval decisions are unequivocally not subject to judicial review.").

[533] *See* 5 U.S.C. § 701(a) ("This chapter applies, according to the provisions thereof, *except to the extent that*— (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law" (emphasis added)).

[534] *See, e.g, Heckler*, 470 U.S. at 828 (holding that "before any review at all may be had [under [t]he APA's comprehensive provisions for judicial review of 'agency actions…'], a party must first clear the hurdle of § 701(a).").

[535] *See, e.g., Bennett*, 520 U.S. at 177-178.

[536] *See, e.g.,* Margo Thorning, *Impact of CAA GHG Regulations on U.S. Investment and Job Growth*, Testimony Before the Subcommittee on Energy and Power, Committee on Energy and Commerce, U.S. House of Representatives (Feb. 9, 2011) at 4.

[537] 129 S. Ct. at 1151, citing *Lujan*, 504 U.S. at 564.

[538] *See Lujan*, 504 U.S. at 572 n. 7 ("There is this much truth to the assertion that 'procedural rights'" are special: The person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy.")

[539] *See* Kate Galbraith, *Texas Files Challenge to EPA "Endangerment Finding,"* THE TEXAS TRIBUNE (May 23, 2011), available at: http://www.texastribune.org/2011/05/23/texas-files-challenge-epa-endangerment-finding/. The thirteen other states included: Alabama, Florida, Kentucky, Louisiana, Michigan, Mississippi, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, Utah and Virginia.

[540] *Id*.

[541] *See Coalition for Responsible Regulation v. EPA*, "Brief of Texas for State Petitioners and Supporting Intervenors," USCA Case #09-1322 (Doc. No. 1309213 (D.C. Cir., Filed May 20, 2011), at 13-14, available at: https://www.texasattorneygeneral.gov/newspubs/releases/2011/052311endangerment_brief.pdf.

[542] *Id*. at 14.

[543] *Id*. at 14-15.

[544] *Id*. at 15.

[545] *See Commonwealth of Virginia, et al., v. Environmental Protection Agency*, On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit, Petition for a Writ of Certiorari, Docket No. 12-1152 (Mar. 20, 2013), at 21-26, available at: http://www.scotusblog.com/case-files/cases/virginia-v-environmental-protection-agency/ and http://sblog.s3.amazonaws.com/wp-content/uploads/2013/08/Va.-v.-EPA-Cert-Petition-Ct.-filed-3-20-13.pdf.

[546] United States Department of Defense, Department of the Army, Corps of Engineers and United States Environmental Protection Agency, *Definition of Waters of the United States under the Clean Water Act*, Docket No. EPA-HQ-OW- 2011-0880 (Apr. 21, 2104), available at: http://www2.epa.gov/uswaters/definition-waters-united-states-under-clean-water-act; U.S. Environmental Protection Agency Office of Research and Development,

[547] *See* United States Environmental Protection Agency, *The Social Cost of Carbon*, available at: http://www.epa.gov/climatechange/EPAactivities/economics/scc.html; United States Government Interagency Working Group on Social Cost of Carbon, *Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866* (May 2013), available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/social_cost_of_carbon_for_ria_2013_update.pdf.

[548] *See* United States Environmental Protection Agency, *National Ambient Air Quality Standards for Ozone—Proposed Rule*, 79 Fed. Reg. 75,234 (Dec. 17, 2014), available at: http://www.gpo.gov/fdsys/pkg/FR-2014-12-17/pdf/2014-28674.pdf.

[549] *See* United States Environmental Protection Agency, *National Environmental Policy Act (NEPA) Review of the U.S. Department of State's Final Supplemental Environmental Impact Statement (SEIS) for a Presidential Permit application by TransCanada Keystone Pipeline, LP (Keystone)* (Feb. 2, 2015), available at: http://www.epa.gov/compliance/nepa/20140032.pdf.

[550] *See* United States Environmental Protection Agency, *EPA's Study of Hydraulic Fracturing for Oil and Gas and its Potential Impact on Drinking Water Resources*, available at: http://www2.epa.gov/hfstudy; United States Environmental Protection Agency, *EPA's Study of Hydraulic Fracturing and Its Potential Impact on Drinking Water Resources—Published Scientific Papers*, available at: http://www2.epa.gov/hfstudy/published-scientific-papers.

[551] *See* National Oceanic and Atmospheric Administration, NOAA, *EPA Disapprove Oregon's Coastal Nonpoint Pollution Control Program* (Jan. 30, 2015), available at: http://www.noaanews.noaa.gov/stories2015/20150130-noaa-epa-disapprove-oregons-coastal-nonpoint-pollution-program.html.

[552] *See* Rafe Petersen and Elizabeth A. Lake, *Proposed Endangered Species Act Regulations Would Revise Rules And Protections Related To 'Critical Habitat,'* Mondaq (May 21 2014), available at: http://www.mondaq.com/unitedstates/x/315218/Environmental+Law/Proposed+Endangered+Species+Act+Regulations+Would+Revise+Rules+and+Protections+Related+to+Critical+Habitat.

[553] *See e.g.*, Lawrence Kogan and Lucas Bergkamp, *Unbiased Safety Through Procedural Safeguards in TTIP*, Atlantic-Community.org (Nov. 14, 2014), available at: http://www.atlantic-community.org/-/unbiased-safety-through-procedural-safeguards-in-ttip; Jörg Wolf, Jillian Beytin, Christopher Huppertz, and Matthew Skinner, *How to Save TTIP*, Atlantic Community.org (Dec. 17, 2014), at pp. 9-10, available at: http://www.atlantic-community.org/documents/10180/66b96722-fc74-4c89-a75a-ad2e6312f34c.

[554] *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996).