Strengthening the Information Quality Act to Improve Federally Disseminated Public Health Information

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ABSTRACT

Information that can undermine public health can be widely disseminated. But what should be done when the federal government is the source disseminating this misinformation? The Information Quality Act (IQA), enacted in 2000, makes it possible for the public to serve as a check on government dissemination of information and the soundness of agency science. The text of the IQA requires federal agencies to "issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency." The IQA can help to ensure the accuracy and credibility of the information disseminated by agencies. Unfortunately, the IQA has not achieved its potential, in large part because of excessive agency discretion and insufficient agency accountability.

This Article explains the importance of ensuring the accuracy and credibility of federally disseminated information, provides background on the IQA, and explains how the law can be strengthened to achieve better information and policy outcomes.

I. INTRODUCTION[1]

In 2019, the Food and Drug Law Institute held a symposium entitled "Going Viral: Safeguarding Public Health in the Modern Era."[2] The primary focus of the symposium, as explained in the program description, was the flow of public health misinformation from private sources that can influence legislatures and administrative agencies.[3] This Article, which originated at the symposium, takes a different approach in addressing

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[1] This Article was originally presented and primarily written before COVID-19.

[2] *Food and Drug Law Journal Symposium*, FOOD & DRUG LAW INSTITUTE (FDLI), https://www.fdli.org/2019/11/food-and-drug-law-journal-symposium/ [https://perma.cc/7XLD-5SK4] (last visited Apr. 27, 2020).

[3] *Id.*

the flow of public health misinformation. It focuses on the flow of misinformation[4] coming from the federal government.

There is legitimate concern that private actors, especially with the Internet and social media, can create confusion regarding public health and even lead to social movements that can shape public opinion in a manner that is misleading and inaccurate. For example, there have been concerns over alleged misinformation "campaigns" covering issues from vaccines[5] to raw milk.[6]

More troubling, policymakers are not immune to these public pressures and may develop policy based on misinformation. The recent debate on mandatory labeling of genetically engineered foods provides a useful example. Public pressure led to state efforts to require mandatory labeling. Once Vermont's state mandatory labeling law's effective date was looming, Congress responded by passing a federal mandatory labeling law that created a national labeling requirement, preempting states on this issue.[7]

Both the Vermont and federal laws were enacted despite overwhelming evidence,[8] including from Food and Drug Administration (FDA), concluding that genetically engineered ingredients are no more harmful than their traditional counterparts.[9]

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[4] For purposes of this Article, "misinformation" refers to inaccurate information or information that taken in context, is in error or misleading.

[5] Joseph A. Hill, Stefan Agewall, Adrian Baranchuk, George W. Booz, Jeffrey S. Borer, Paolo G. Camici, Peng-Sheng Chen, Anna F. Dominiczak, Çetin Erol, Cindy L. Grines, Robert Gropler, Tomasz J. Guzik, Markus K. Heinemann, Ami E. Iskandrian, Bradley P. Knight, Barry London, Thomas F. Lüscher, Marco Metra, Kiran Musunuru, Brahmajee K. Nallamothu, Andrea Natale, Sanjeev Saksena, Michael H. Picard, Sunil V. Rao, Willem J. Remme, Robert S. Rosenson, Nancy K. Sweitzer, Adam Timmis & Christiaan Vrints *Medical Misinformation: Vet the Message!*, 8 J. AM. HEART ASS'N 3 (Jan. 28, 2019), https://www.ahajournals.org/doi/10.1161/JAHA.118.011838 [https://perma.cc/W27V-CMWR] (last visited Apr. 27, 2020); Katherine J. Igoe, *Establishing the Truth: Vaccines, Social Media, and the Spread of Misinformation* (July 10, 2019), HARVARD T.H. CHAN SCHOOL OF PUB. HEALTH, https://www.hsph.harvard.edu/ecpe/vaccines-social-media-spread-misinformation/ [https://perma.cc/X8A3-5WHY] (last visited Apr. 27, 2020); Stephanie Soucheray, *Studies Say HPV Vaccine Refusal, Misinformation Common*, CTR. FOR INFECTIOUS DISEASE RESEARCH & POLICY, (Sept. 16, 2019), http://www.cidrap.umn.edu/news-perspective/2019/09/studies-say-hpv-vaccine-refusal-misinformation-common [https://perma.cc/Q5WJ-TJD4] (last visited Apr. 27, 2020).

[6] *See, e.g.*, Cookson Beecher, *A Mom and a Dairyman Plead: Don't Feed Children Raw Milk*, FOOD SAFETY NEWS (Feb. 18, 2014), https://www.foodsafetynews.com/2014/02/a-mom-and-a-dairymans-plea-dont-feed-children-raw-milk/ (last visited Apr. 27, 2020) [https://perma.cc/A7QD-JB27]. *See also Raw Milk Misconceptions and the Danger of Raw Milk Consumption,* U.S. FOOD & DRUG ADMIN. (Nov. 1, 2011), https://www.fda.gov/food/buy-store-serve-safe-food/raw-milk-misconceptions-and-danger-raw-milk-consumption (last visited Apr. 27, 2020) [https://perma.cc/UN6W-JXTG]; *Food Safety: 5 Raw Milk Myths Busted!*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 14, 2017), https://www.cdc.gov/foodsafety/rawmilk/milk-myths.html (last visited Apr. 27, 2020) [https://perma.cc/555M-93RZ].

[7] *See, e.g.*, Daren Bakst, *5 Reasons We Don't Need Federally Mandated GMO Labeling*, THE DAILY SIGNAL (June 24, 2016), https://www.dailysignal.com/2016/06/24/5-reasons-we-dont-need-federally-mandated-gmo-labeling/ [https://perma.cc/MQT5-S55R] (last visited Apr. 27, 2020). *See also* National Bioengineered Food Disclosure Standard, PUB. L. NO. 114-216, 130 Stat 834 (2016), https://www.congress.gov/114/plaws/publ216/PLAW-114publ216.pdf [https://perma.cc/EEW8-49CY] (last visited Apr. 27, 2020); Vermont Genetically Engineered Food Labeling Act, H. 112, No. 120, § 6, 2014 Vermont Acts [codified at 9 V.S.A. §§ 3041, 3048 (2014)], http://www.leg.state.vt.us/docs/2014/Acts/ACT120.pdf [https://perma.cc/B9P3-MJ9R] (last visited Apr. 27, 2020).

[8] *GLP Infographic: International Science Organizations on Crop Biotech Safety*, GENETIC LITERACY PROJECT (Aug. 27, 2013), https://www.geneticliteracyproject.org/2013/08/27/glp-infographic-international-science-organizations-on-crop-biotechnology-safety/ [https://perma.cc/3TFR-8KYM] (last visited Nov. 5, 2019).

[9] *GMOs 101: Your Basic Questions Answered,* FOOD & DRUG ADMIN. (Mar. 2020), https://www.fda.gov/media/135279/download [https://perma.cc/4GW2-82H6] (last visited Aug. 31, 2020). Some of the laws' proponents might assert that it does not matter if there is any more harm from genetically

This public pressure and its impact on public health policy, though, pales in comparison to the impact that misinformation from the federal government can have on public health. Like the public, the federal government can more effectively disseminate its information through Internet outlets such as social media. Unlike the public, the imprimatur of the government carries significant weight (generally much greater than private sources), and government misinformation is often directly used in the formulation of public policy.

Therefore, what should be done when the federal government is the source of misinformation? This Article explores that critical question by focusing on the Information Quality Act (IQA),[10] a federal law enacted in 2000 designed to improve the quality of government-disseminated information and allow for the correction of information that is misleading or inaccurate.[11] The Article is structured in the following way:

- First, it examines the importance of accurate and credible government information and explains why there is a need for a strong federal law to focus specifically on the improvement and correction of government-disseminated misinformation.
- Second, it provides an overview of the IQA and then highlights the IQA's impact to date, including how the law has worked compared to initial expectations.
- Finally, the Article lays out numerous detailed recommendations on how to strengthen the IQA and, as a result, how to strengthen the quality of government information.

II. THE IMPORTANCE OF ENSURING ACCURATE AND CREDIBLE FEDERALLY DISSEMINATED INFORMATION

Federal agencies promulgate regulations that impact almost every facet of life. When developing regulations, federal agencies utilize information that serves as the foundation for making important policy decisions. The foundation for rules should therefore be accurate and credible information because this is the only way to ensure the integrity of the regulations.

It is not merely the regulations developed by agencies that should be of concern. Federal agencies can disseminate information to help with enforcement actions, such as product recalls or warning letters. Agencies involved in public health, such as FDA, widely disseminate information to educate the public about various products and alleged concerns regarding those products.[12] Some of these actions can damage reputations and change consumer behavior; therefore, accuracy is paramount.

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engineered ingredients compared to their traditional counterparts, consumers have a "right" to know about the existence of these ingredients. A key problem is these labeling requirements play into the misinformation and fears regarding genetically engineered ingredients.

[10] *See* Fiscal Year 2001 Consolidated Appropriations Act § 515(a), PUB. L. NO. 106-554, 114 STAT. 2763A-153 to 2763A-154. The IQA was enacted as Section 515 of the Treasury and General Government Appropriation Act for FY 2001.

[11] *Id.*

[12] For a good discussion on the use of information dissemination in the public health context, including specific issues connected to FDA, see, e.g., ADMIN. CONF. OF THE U.S., AGENCY PUBLICITY IN

Even when the federal government is simply disseminating a report, this can have major implications. The imprimatur of the government, rightly or wrongly, can shape the views of the public, provide regulatory justifications for other federal agencies, and establish the direction of the science on a specific issue.[13] Just as agencies tend to expand their power over time, making it difficult to remove regulations once on the books,[14] it is also very difficult to change the understanding that forms the basis for those regulations.

The science, once established by the government, even if incorrect, can start to become entrenched and be viewed as conventional wisdom. Like with any conventional wisdom, especially when backed up by the government, the chances of correcting the science becomes extremely difficult.[15]

THE INTERNET ERA (2015), https://www.acus.gov/sites/default/files/documents/agency-publicity-in-the-internet-era.pdf [https://perma.cc/KLT5-55YA] (last visited Apr. 27, 2020).

[13] The COVID-19 pandemic helps to illustrate how important federal government disseminated information can be to the public. The Centers for Disease Control and Prevention (CDC), along with other federal agencies, have been looked to as the primary sources of pandemic-related information to the public (from how the coronavirus spreads to how to avoid it), including what appears to have been initial misinformation recommending that the public not wear masks. *See* Colin Dwyer & Allison Aubrey, *CDC Now Recommends Americans Consider Wearing Cloth Face Coverings In Public*, NPR (Apr. 3, 2020), https://www.npr.org/sections/coronavirus-live-updates/2020/04/03/826219824/president-trump-says-cdc-now-recommends-americans-wear-cloth-masks-in-public [https://perma.cc/M6DB-SLBT] (last visited May 26, 2020); *see also* Elizabeth Redden, *CDC Issues New Guidance to Colleges*, INSIDE HIGHER ED (May 21, 2020), https://www.insidehighered.com/news/2020/05/21/cdc-releases-new-guidance-colleges-reducing-coronavirus-spread [https://perma.cc/P6BK-KZGW] (last visited May 26, 2020); Hannah Hagemann, *CDC Issues Tools To Guide Reopening Of Schools, Businesses, Transit*, NPR (May 14, 2020), https://www.npr.org/sections/coronavirus-live-updates/2020/05/14/856483424/cdc-issues-decision-tools-to-guide-reopening-of-schools-businesses-transit [https://perma.cc/L5PZ-TVLQ] (last visited May 26, 2020). It does not take a pandemic to see the influence of federally disseminated information. Even in everyday activities like eating, federally disseminated information can impact choices Americans make; the U.S. Dietary Guidelines for Americans has a major impact on nutritional policy and that impact filters throughout the nutrition and health communities. *US Dietary Guidelines for Americans—101*, NUTRITION COALITION, https://www.nutritioncoalition.us/dietary-guidelines-for-americans-dga-introduction [https://perma.cc/UMP8-UC5U] (last visited May 26, 2020).

[14] *See, e.g.*, Michael Mandel & Diana Carew, *Regulatory Improvement Commission: A Politically-Viable Approach to U.S. Regulatory Reform*, PROGRESSIVE POLICY INST. (May 2013), https://www.progressivepolicy.org/wp-content/uploads/2013/05/05.2013-Mandel-Carew_Regulatory-Improvement-Commission_A-Politically-Viable-Approach-to-US-Regulatory-Reform.pdf [https://perma.cc/52XX-ZA5P] (last visited May 26, 2020); Patrick McLaughlin & Richard Williams, *The Consequences of Regulatory Accumulation and a Proposed Solution*, SSRN (Mar. 6, 2014), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2403602 [https://perma.cc/6PKP-MSUE] (last visited May 26, 2020).

[15] As just one example, since the first federal Dietary Guidelines in 1980, the federal government had promoted reducing total dietary fat consumption. After thirty-five years, the federal government removed this recommendation in the Dietary Guidelines. For many years though, and despite significant evidence to the contrary, the federal government maintained this position. *New Dietary Guidelines Remove Restriction on Total Fat and Set Limit for Added Sugars But Censor Conclusions of the Scientific Advisory Committee*, HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH (Jan. 7, 2016), https://www.hsph.harvard.edu/nutritionsource/2016/01/07/new-dietary-guidelines-remove-restriction-on-total-fat-and-set-limit-for-added-sugars-but-censor-conclusions/ [https://perma.cc/JCC5-68N7] (last visited May 26, 2020); Dariush Mozaffarian & David Ludwig, *Why Is the Federal Government Afraid of Fat?*, N.Y. TIMES (July 9, 2015), https://www.nytimes.com/2015/07/09/opinion/why-is-the-federal-government-afraid-of-fat.html [https://perma.cc/GD56-SH3M] (last visited May 26, 2020); Dariush Mozaffarian & David Ludwig, *The 2015 US Dietary Guidelines – Ending the 35% Limit on Total Dietary Fat*, 313(24) J. AM. MED. ASS'N 2421–22 (June 23, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6129189/ [https://perma.cc/9Y2Y-EHJU] (last visited May 26, 2020); Kris Gunnars, *Do Low-Fat Diets Really Work?*, HEALTHLINE (Mar. 27, 2018), https://www.healthline.com/nutrition/do-low-fat-diets-work [https://perma.cc/6FEY-EJYM] (last visited May 26, 2020); Meir Stampfer & Walter Willett, *Rebuilding the Food Pyramid*, SCI. AM. (Dec. 1, 2006), https://www.scientificamerican.com/article/rebuilding-the-food-pyramid/ [https://perma.cc/Q3ZZ-D4KM] (last visited May 26, 2020).

The sheer scope of the issues in which the federal government develops policy and shapes public understanding is seemingly endless. In just the public health context, federal agencies and their federally disseminated information can impact everything from responses to pandemics, drugs available to save the lives of Americans, to the safety of the food supply.

III. THE NEED FOR A STRONG FEDERAL LAW TO IMPROVE AND CORRECT FEDERALLY DISSEMINATED INFORMATION

The importance of federal-government-disseminated information, by itself, is a compelling reason for an effective way to improve and correct this information. There are additional reasons as well, including delegation issues and the quality of peer reviewed scientific research.

A. Delegation to Agencies

When federal agencies use information as a foundation for rulemaking, there is already a need for that information to be accurate. This need becomes magnified though when those rules go beyond merely implementing the will of Congress, and the use of the disseminated information may not even be authorized by law.

Congress has delegated significant authority to federal agencies, sometimes arguably delegating away its lawmaking power in an unconstitutional manner.[16] Concerns over excessive delegation and violations of the non-delegation doctrine have generally not been reflected in court opinions. The U.S. Supreme Court has not struck down a law for violation of the non-delegation doctrine in over eighty years.[17] The delegation problem is exacerbated by the deference that courts afford federal agencies, not merely in agency policy judgments, but in their legal judgments as well.[18]

The branch of government that actually has the lawmaking power under the U.S. Constitution must rightfully jump through numerous hoops to get laws passed. Yet, federal agencies not granted lawmaking power have little in the way of obstacles.[19]

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[16] *See, e.g.*, Gary Lawson, *Delegation and Original Meaning*, 88 VA. L. REV. 327, 340 (2002); David Schoenbrod, *The Delegation Doctrine: Could the Court Give It Substance?*, 83 MICH. L. REV. 1223, 1260 (1985), https://repository.law.umich.edu/cgi/viewcontent.cgi?article=2535&context=mlr [https://perma.cc/VAA4-A3LC] (last visited May 26, 2020).

[17] A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935).

[18] CONG. RESEARCH SERV., R44699, *An Introduction to Judicial Review of Federal Agency Action*, (Dec. 7, 2016), https://fas.org/sgp/crs/misc/R44699.pdf [https://perma.cc/SFX9-2R5H] (last visited Apr. 27, 2020).

[19] The agency rulemaking process stands in stark contrast to the lawmaking power granted to Congress. Justice Gorsuch's dissent in *Gundy v. United States*, a case that brought up significant delegation questions, includes a very thoughtful discussion of delegation of lawmaking power. As part of this discussion, he explains how the framers of the U.S. Constitution intentionally created numerous obstacles in the lawmaking process:

> They [the framers] believed the new federal government's most dangerous power was the power to enact laws restricting the people's liberty. An "excess of law-making" was, in their words, one of "the diseases to which our governments are most liable." To address that tendency, the framers went to great lengths to make lawmaking difficult. In Article I, by far the longest part of the Constitution, the framers insisted that any proposed law must win the approval of two Houses of Congress—elected at different times, by different constituencies, and for different terms in office—and either secure the President's approval or obtain enough support

When there has been an improper delegation, this gets around the very protections the framers envisioned would exist in passing laws. As Justice Gorsuch explained in his dissent in *Gundy v. United States*:[20]

> If Congress could pass off its legislative power to the executive branch, the "[v]esting [c]lauses, and indeed the entire structure of the Constitution," would "make no sense." Without the involvement of representatives from across the country or the demands of bicameralism and presentment, legislation would risk becoming nothing more than the will of the current President. And if laws could be simply declared by a single person, they would not be few in number, the product of widespread social consensus, likely to protect minority interests, or apt to provide stability and fair notice.[21]

Agencies would improperly be exercising the legislative power reserved to Congress, with the very problems Justice Gorsuch warned about in *Gundy*. While by no means a solution to improper delegation, strong and enforceable requirements to correct disseminated federal information can at least help to provide a check on agencies. Even in situations where delegation is arguably not a problem, agencies are often doing a lot more than filling in the gaps to best implement legislation. They frequently use their discretionary power to interpret ambiguous statutes to increase the scope of their power and regulate in areas that Congress may not have envisioned. They make many discretionary choices, with questionable statutory authority that can also restrict liberty. Allowing the public to seek and obtain a correction of flawed government disseminated information can also provide a useful check on agencies in their use of their discretionary power. These checks will help to promote the legitimacy of agency policymaking and trust in the information that they disseminate.

B. Problems with Peer Reviewed Scientific Research

The federal government often disseminates scientific information and uses this information in formulating policy. When, for example, the federal government disseminates a report on the use of vaping or bans a product using specific scientific studies, it is critical that the best available science is used.[22]

Unfortunately, there are significant problems with peer review processes.[23] The Office of Management and Budget (OMB) in its IQA Guidelines explained, "there is a significant scholarly literature documenting quality problems with articles published in peer-reviewed research."[24]

> to override his veto. Some occasionally complain about Article I's detailed and arduous processes for new legislation, but to the framers these were bulwarks of liberty.

[20] Gundy v. United States, 588 U.S. ___ (2019) (Gorsuch, J., dissenting).

[21] *Id.* (internal citations omitted).

[22] For purposes of this Article, science is envisioned to be broad in scope. Consistent with the definition of "scientific information" under the IQA (see Figure 4), it covers behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences.

[23] This should not be viewed as diminishing the importance of proper peer review.

[24] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002), https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-

Richard Smith, former editor of the British Medical Journal wrote, "peer review is a flawed process, full of easily identified defects with little evidence that it works."[25] Stanford University professor John Ioannidis wrote a widely cited[26] essay in which he argued, "It can be proven that most claimed research findings are false."[27] Richard Horton, editor of The Lancet, asserted that "much of the scientific literature, perhaps half, may simply be untrue."[28]

In a 2013 *Science* article, the author performed a sting operation to see whether scientific journals would accept what he referred to as his bogus article. As it turned out, many of the journals did, including journals from major publishers.[29]

One of the major problems with the research deals with reproducibility. A 2016 *Nature* survey found that fifty-two percent of researchers surveyed agreed that there was a significant crisis of reproducibility, ninety percent of the respondents agreed that there was either a significant or slight crisis, and only three percent said there was no crisis.[30] This same survey found that "[m]ore than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments."[31]

Sometimes journals retract problematic articles, although retractions do appear to be rare, even as the total number of retractions has increased over the last few decades.[32] About sixty percent of the retractions are not due to errors or innocent mistakes, but due to unethical conduct. As explained in a 2018 *Science* article that analyzed retractions:

> About half of all retractions do appear to have involved fabrication, falsification, or plagiarism—behaviors that fall within the U.S. government's definition of scientific misconduct. Behaviors widely understood within science to be dishonest and unethical, but which fall

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the-quality-objectivity-utility-and-integrity-of-information [https://perma.cc/8FRZ-BFS9] (last visited Apr. 27, 2020).

[25] Richard Smith, *Peer Review: A Flawed Process at the Heart of Science and Journals*, 99 J. OF THE ROYAL SOCIETY OF MED. 178–82 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1420798/ [https://perma.cc/6KB4-XZRS] (last visited Apr. 27, 2020).

[26] Terence Kealey, *Why Does the Federal Government Issue Damaging Dietary Guidelines? Lessons from Thomas Jefferson to Today*, CATO INST. (2018), https://www.cato.org/publications/policy-analysis/why-does-federal-government-issue-damaging-dietary-guidelines-lessons [https://perma.cc/95ZX-C5AK] (last visited Apr. 27, 2020).

[27] John P. A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLOS MED. e124 (2005), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124 [https://perma.cc/6K8X-E59S] (last visited Apr. 27, 2020).

[28] Richard Horton, *Offline: What is Medicines 5 Sigma?*, 385 LANCET 1380 (2015), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2815%2960696-1.pdf?code=lancet-site [https://perma.cc/F36Z-XU87] (last visited Apr. 27, 2020).

[29] John Bohannon, *Who's Afraid of Peer Review?*, 342 SCI. 60 (2013), https://science.sciencemag.org/content/342/6154/60 [https://perma.cc/5A3F-DXYS] (last visited Apr. 27, 2020).

[30] Monya Baker, *1,500 Scientists Lift the Lid on Reproducibility*, 533 NATURE NEWS (2016), https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970 [https://perma.cc/N2XK-BS8M] (last visited Apr. 27, 2020).

[31] *Id.*

[32] Jeffrey Brainard & Jia You, *What a Massive Database of Retracted Papers Reveals About Science Publishing's 'Death Penalty'*, SCI. (Oct. 25, 2018), https://www.sciencemag.org/news/2018/10/what-massive-database-retracted-papers-reveals-about-science-publishing-s-death-penalty [https://perma.cc/W85W-PLVM] (last visited Apr. 27, 2020).

> outside the U.S. misconduct definition, seem to account for another 10%. Those behaviors include forged authorship, fake peer reviews, and failure to obtain approval from institutional review boards for research on human subjects or animals.[33]

Given all of these problems, there need to be proper checks to ensure that when the federal government uses scientific research, it is in fact using reliable studies.

IV. OVERVIEW OF THE INFORMATION QUALITY ACT

Before the IQA, the Administrative Procedure Act of 1946 (APA)[34] was arguably the best opportunity to improve government disseminated information, but it is not a law designed to improve or correct disseminated information. As explained by James Conrad, a former Chair of the American Bar Association's Section of Administrative Law and Regulatory Practice, "[a]s a general matter, the APA is not well-suited to address the risks posed by information activities. Requiring proposed websites or information products to undergo notice and comment in the Federal Register would be overkill in the great majority of cases and an administrative nightmare."[35]

The question then becomes how best to improve and correct federal government disseminated information.[36] This is where the IQA comes in. The IQA focuses on improving the quality of federally disseminated information. It was not a stand-alone bill but instead a two-paragraph provision[37] contained in the Treasury and General Government Appropriations Act for Fiscal Year 2001 that is technically codified as a

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[33] *Id.*

[34] Administrative Procedure Act (APA), PUB. L. NO. 79–404, 60 STAT. 237.

[35] James W. Conrad, Jr., *The Information Quality Act - Antiregulatory Costs of Mythic Proportions?*, 12 KAN. J.L. & PUB. POL'Y 521 (2003).

[36] *Id.* This article provides a good discussion of the laws prior to the IQA.

[37] The full IQA language reads:

> (a) IN GENERAL. — The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.
>
> (b) CONTENT OF GUIDELINES. — The guidelines under subsection (a) shall (1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and (2) require that each Federal agency to which the guidelines apply (A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency by not later than 1 year after the date of issuance of the guidelines under subsection (a); (B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and (C) report periodically to the Director (i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and (ii) how such complaints were handled.

Fiscal Year 2001 Consolidated Appropriations Act § 515(a), PUB. L. NO. 106-554, 114 STAT. 2763A-153 to 2763A-154. The IQA was enacted as Section 515 of the Treasury and General Government Appropriation Act for FY 2001.

note to the Paperwork Reduction Act of 1995 (PRA), a law that also addresses improving the quality of federal information.[38]

Congress directed OMB to implement the IQA through government-wide guidelines.[39] The IQA applies to most agencies because it covers the same agencies[40] covered under the PRA.[41]

There are two primary OMB documents on the IQA:

1) The final OMB Guidelines (Guidelines)[42] that were published in the Federal Register on February 22, 2002; and
2) OMB's "Final Information Quality Bulletin for Peer Review" (Bulletin)[43] published in the Federal Register on January 14, 2005.[44]

This overview of the IQA will highlight key terminology and requirements contained in these documents.[45] The specific language of this terminology and other IQA terminology is included in two glossaries of terms (see Figures 3 and 4 at the end of the Article).

A. Overview of the OMB Guidelines

There are three general IQA requirements for covered agencies, which are restated in the Guidelines. Agencies must:

1) Issue their own implementing guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency";

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[38] *Paperwork Reduction Act (PRA) Guide,* OFFICE OF PERS. MGMT. (Apr. 2011), https://www.opm.gov/about-us/open-government/digital-government-strategy/fitara/paperwork-reduction-act-guide.pdf [https://perma.cc/V49P-ZWC7] (last visited Apr. 27, 2020).

[39] Fiscal Year 2001 Consolidated Appropriations Act § 515(a), PUB. L. NO. 106-554, 114 STAT. 2763A-153 to 2763A-154. The IQA was enacted as Section 515 of the Treasury and General Government Appropriation Act for FY 2001.

[40] These agencies, as defined in the PRA, include "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." It does not include the Government Accountability Office, Federal Election Commission, "the governments of the District of Columbia and of the territories and possessions of the United States, and their various subdivisions," or "Government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities." 44 U.S.C. § 3502 (2019).

[41] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, *supra* note 27; Paperwork Reduction Act of 1995, PUB. L. NO. 104-13, 109 STAT. 163 (1995).

[42] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, supra* note 27.

[43] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-05-03, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (Dec. 16, 2004). While the final peer review bulletin was published in the Federal Register on this date, the final bulletin was issued to agencies on December 16, 2004. Throughout this Article, citations will be made to the December 16, 2004 document.

[44] Throughout this Article, "OMB Guidelines" or "Guidelines" will be used interchangeably. OMB's "Final Information Quality Bulletin for Peer Review" will be used interchangeably with "OMB Bulletin" and "Bulletin."

[45] This Article provides an overview of the IQA, and therefore focuses on key aspects of the Guidelines and Bulletin. It is therefore by no means exhaustive. There are plenty of details that exist within these documents that have not been mentioned.

2) Establish administrative procedures so that anyone affected by erroneous agency disseminated information can seek and obtain correction of that information; and
3) Report to OMB regarding the number and nature of complaints regarding the accuracy of its disseminated information and how the agency resolved those requests.[46]

1. Information Requirements Under the OMB Guidelines

The primary focus of the information requirements is on the quality of the information. "Quality" is a catch-all phrase that includes "objectivity," "utility," and "integrity":

- "Objectivity" is comprised of two elements: presentation and substance. Information must be presented in a manner that is "accurate, clear, complete, and unbiased."[47] OMB explains that this requires information to be presented with necessary context, including sources of the information[48] and supporting data and models[49] so that the public can evaluate the sources. In terms of substance, this objectivity requirement means that the information is in fact accurate, reliable, and unbiased.[50]
- "Utility" is concerned with "the usefulness of the information to its intended users, including the public."[51] For this utility requirement, agencies need to be concerned about how useful the information is from the perspective of the public, not just the agency.[52]
- "Integrity" requires that the information is secure, such as not at risk of being falsified.[53]

As explained in the Guidelines, "the more important the information, the higher the quality standards to which it should be held."[54] OMB expects agencies to take additional steps to ensure the quality of information when the information is deemed influential in nature (see Figure 3 for the definition of information that is "influential").[55]

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[46] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, supra* note 27.

[47] *Id.*

[48] *Id.* at 8459. Sources must be identified "to the extent possible, consistent with confidentiality protections."

[49] *Id.* The supporting data and models are required "in a scientific, financial, or statistical context." The Guidelines do have limits on the extent of disclosure of data and models.

[50] *Id.*

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *Id.* Agencies that disseminate influential scientific, financial, or statistical information are expected to help facilitate the reproducibility of the information. There is flexibility afforded to agencies in the application of the Guidelines' reproducibility requirements. According to OMB, this reproducibility requirement "is intended to ensure that information disseminated by agencies is sufficiently transparent in

In addition to understanding what is meant by information "quality," it is important to recognize that the IQA only applies to government disseminated information.[56] For information to be "disseminated," it must be agency initiated or agency sponsored distributed information to the public. Agency initiated distribution simply means "information that the agency disseminated."[57] This information could be created either by an agency or a third-party.

Agency sponsored distribution of information to the public "refers to situations where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release."[58]

There are also some specific types of documents when information is not considered to have been "disseminated," such as subpoenas, archival records, or responses to Freedom of Information Act (FOIA) requests.[59] The exceptions are generally reasonable and narrow in scope, but the list of exceptions also includes press releases, which can be broad in scope (this issue will be discussed later in the Article).

2. Administrative Mechanisms to Correct Information

The OMB Guidelines require[60] agencies to give the public[61] an opportunity to submit requests for correction of agency information that does not meet IQA requirements and appeal those decisions the requester would like reconsidered.[62]

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terms of data and methods of analysis that it would be feasible for a replication to be conducted." *Id.* at 8457. "'Reproducibility' means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased)." *Id.* "If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data). With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error." *Id.* at n.10.

[56] "Information" is broadly defined to include "any communication or representation of knowledge such as facts or data, in any medium or form." *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.* "Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes."

[60] The Guidelines restate the IQA administrative mechanisms requirement that OMB is implementing, a requirement that says OMB shall require agencies to have administrative mechanisms to seek and obtain the correction of information.

[61] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-19-15, IMPROVING IMPLEMENTATION OF THE INFORMATION QUALITY ACT (Apr. 24, 2019). The Guidelines specifically allow "affected persons" to seek corrections. In practice, this term has rightfully been broadly interpreted. OMB has explained that agencies should take a very broad approach.

[62] "To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.

> i. Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.

The correction process is guided by standards that appear to give agencies significant flexibility. As explained by OMB, "the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes."[63] In addition, agencies "are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved."[64]

To help create an objective process, the Guidelines clarify, "the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement."[65] In its new 2019 guidance to improve implementation of the IQA, OMB provided additional clarity on the correction process. For example, OMB indicated that agencies should not take more than 120 days to respond to requests for correction. In addition, individuals involved in reviewing and responding to initial requests for correction should not be the same individuals hearing the appeal.[66]

3. Reporting on the IQA

The IQA's reporting requirements under the Guidelines are fairly limited and focus on agencies annually reporting to OMB.[67] Agencies must report "on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved."[68] There is nothing that requires OMB to report back to Congress or to disseminate this information to the public.

> ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration."

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, supra* note 27.

[63] *Id.*

[64] *Id.*

[65] *Id.* "In addition, the agency guidelines should specify that if the agency believes other agencies may have an interest in the resolution of any administrative appeal, the agency should consult with those other agencies about their possible interest."

[66] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-19-15, IMPROVING IMPLEMENTATION OF THE INFORMATION QUALITY ACT (Apr. 24, 2019).

[67] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, supra* note 27. "On an annual fiscal-year basis, each agency must submit a report to the Director of OMB providing information (both quantitative and qualitative, where appropriate) on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved. Agencies must submit these reports no later than January 1 of each following year, with the first report due January 1, 2004." *Id.*

[68] *Id.*

B. Overview of OMB's Final Information Quality Bulletin for Peer Review

OMB "Final Information Quality Bulletin for Peer Review" was intended "to enhance the quality and credibility of the government's scientific information."[69] To do this, OMB developed peer review standards for two types of scientific information: "influential scientific information" and "highly influential scientific assessments."[70] The document also contains several other major provisions that apply to agencies in connection to peer review, including certification requirements, alternative procedures and exemptions, and peer review planning.

1. Peer Review for Influential Scientific Information

"Influential scientific information" is defined as "scientific information the agency reasonably can determine[71] will have or does have a clear and substantial impact on important public policies or private sector decisions."[72]

For influential scientific information, OMB clarified that agencies have significant discretion when it comes to application of peer review requirements. Agencies do not have to conduct additional peer review of information if the prior peer review, such as by academic journals, has been adequate.[73]

When deciding whether peer review was adequate, an agency is directed to "giv[e] due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."[74]

The Bulletin recognizes that the quality of peer review can differ greatly across journals. Even with OMB's recognition of potential problems with peer review, the decisions on adequacy of peer review appear to be subjective agency decisions without any clear requirements to ensure the adequacy of peer review.

OMB does explain that "prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary."[75] Therefore, agencies would be expected to at least do more than just point to the existence of peer review

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[69] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-05-03, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (Dec. 16, 2004).

[70] Highly influential scientific assessments are actually a subset of influential scientific information. In the Bulletin, this specific subset of influential scientific information is subject to more stringent peer review standards.

[71] The definition in the Bulletin is generally identical to how influential information is defined in the Guidelines. To restate language from the Guidelines, "Influential, when used in the phrase 'influential scientific, financial, or statistical information,' means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." This Guidelines language says "can reasonably determine" instead of "reasonably can determine" as used in the Bulletin. The other difference is the Guidelines focuses on whether the "dissemination of the information" will have or does have a clear and substantial impact, whereas the Bulletin focuses on whether the "scientific information" will have or does have a clear and substantial impact (the word "dissemination" is not used).

[72] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, *supra* note 69. OMB explained that "influential" should be interpreted consistent with how that term is defined in the Guidelines.

[73] *Id.*

[74] *Id.* at 22.

[75] *Id.*

and would have to conclude any peer review was adequate.[76]

The OMB Bulletin does provide significant discussion on peer review for influential scientific information. The discussion covers issues such as the timing of peer reviews, the scope of the reviews, conflicts of interest, independence, and public participation.[77] Most of the discussion though does not cover requirements, but instead lists peer review practices that are suggestions or otherwise afford agencies significant discretion.[78] There are some limited requirements. For example, "peer reviewers shall not have participated in development of work product" and agencies shall ensure reviewers serving as federal employees comply with federal ethics requirements.[79]

2. Peer Review for Highly Influential Scientific Assessments

A highly influential scientific assessment is "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."[80]

The OMB Bulletin requires stricter peer review standards for highly influential scientific assessments, although even these standards provide a significant amount of discretion to agencies.[81] The requirements for influential scientific information apply to highly influential scientific assessments, but the Bulletin adds additional requirements.

Some of the important additional requirements include:

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[76] It is not clear how this analysis regarding adequacy must be demonstrated or even if it has to be demonstrated.

[77] The following are the issues discussed in Section II of the Bulletin, which discusses the peer review requirements for influential scientific information: individual v. panel review; timing of peer review; scope of the review; selection of reviewers covering expertise, balance, independence, and conflict of interest; disclosure and attribution: anonymous versus identified; public participation; disposition of reviewer comments; and adequacy of peer review.

[78] *Id.* at 12. "Section II [which covers peer preview for influential scientific information] provides agencies broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers."

[79] *Id.* at 37. "The agency—or the entity selecting the peer reviewers—shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income)."

[80] *Id.* at 38. The preamble of the Bulletin, in addition to providing some additional details, includes somewhat different language than the "regulatory text" to define when there is a highly influential scientific assessment. It states, "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."

[81] *Id.* at 3. OMB itself explains, "Even for these highly influential scientific assessments, the Bulletin leaves significant discretion to the agency formulating the peer review plan."

- Agencies must conduct their own peer review unless the assessment comes from the National Academy of Sciences.[82]
- "Scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific assessments." Although, there is a limited exception to this ban.[83]
- Agencies are required "to provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers."[84]

3. Certification Requirement

The OMB Peer Review Bulletin includes an important transparency requirement when agencies rely on influential scientific information or highly influential scientific assessments to support a regulatory action.[85] Specifically, the Bulletin states:

> If an agency relies on influential scientific information or a highly influential scientific assessment subject to the requirements of this Bulletin in support of a regulatory action, the agency shall include in the administrative record for that action a certification that explains how the agency has complied with the requirements of this Bulletin and the Information Quality Act. Relevant materials are to be placed in the administrative record.[86]

4. Alternative Procedures and Exemptions

While OMB has specific peer review standards for influential scientific information and highly influential scientific assessments, as has been described, agencies do not have to meet these requirements if they employ alternative procedures as outlined in the Bulletin. According to OMB:

> [A]n agency may instead: (i) rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences; (ii) commission the National Academy of Sciences to peer review an agency's draft scientific information; or (iii) employ an alternative scientific procedure or process, specifically approved by the Administrator in consultation with the Office of Science and Technology

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[82] *Id.*

[83] *Id.* at 24. "The only exception to this ban would be the rare situation in which a scientist from a different agency of a Cabinet-level department than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere. In evaluating the need for this exception, agencies shall use the NAS criteria for assessing the appropriateness of using employees of sponsors (e.g., the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility)."

[84] *Id.*

[85] When the federal government uses scientific information to inform regulation, it would also be disseminating the information through a report, a preamble of a rule, guidance, or other means.

[86] *Id.*

> Policy (OSTP), that ensures the agency's scientific information satisfies applicable information quality standards.[87]

Further, not all information is subject to peer review. The Bulletin lists numerous yet narrow exceptions, such as an exception for information related to certain national security when "compliance with the Bulletin would interfere with the need for secrecy or promptness."[88] Of particular interest in the public health context, information is exempted if it is "a health or safety dissemination where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began)."[89]

5. Peer Review Planning

There is another important transparency requirement detailed in the Bulletin. Agencies are required to post on their websites an agenda of the peer review plans for influential scientific information and highly influential scientific assessments that they intend to disseminate in the foreseeable future. This agenda must be updated at least every six months.[90]

In addition, the agenda must list various details about each plan, including "whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment"[91] and whether the public will have a chance to provide comments on the peer reviewed work product. Agencies are also required to consider public comments regarding the peer review plans.[92] To clarify, this public comment requirement is connected to the peer review *plans*, not to the peer reviewed work product.

V. IMPACT OF THE INFORMATION QUALITY ACT

When the IQA was passed, many proponents thought it would significantly improve the work of federal agencies, including the rulemaking process. Critics thought the law

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[87] *Id.*

[88] *Id.* at 44. "Agencies need not have peer review conducted on information that is: 1. related to certain national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness; 2. disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent setting influence on future adjudications and/or permit proceedings; 3. a health or safety dissemination where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began); 4. an agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and analytical models used; 5. routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates); 6. accounting, budget, actuarial, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes; or 7. information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof."

[89] *Id.*

[90] *Id.*

[91] *Id.* at 41.

[92] *Id.*

would weaken regulatory protections.[93] In reality, the law has not resulted in either of these expected outcomes.

For those thinking the law would have a significant and beneficial impact, court decisions have not granted judicial review of agency decisions, which has hampered the potential of the law. The law does not have the teeth that some hoped for, and there does not seem to be much motivating agencies or OMB to take the IQA seriously.[94]

From the outset, OMB explained that the preconceived notions about the law were not coming to pass[95]: the law did not create a significant number of requests for correction; requests did not just come from industry but instead came from a wide range of sources;[96] requests did not produce a slowdown in the rulemaking process;[97]

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[93] CONG. RESEARCH SERV., RL32532, *The Information Quality Act: OMB's Guidance and Initial Implementation*, (Aug. 19, 2004), https://fas.org/sgp/crs/RL32532.pdf [https://perma.cc/DWB2-NQ4F] (last visited Apr. 27, 2020) (citing and discussing OFFICE OF MGMT. & BUDGET, INFORMATION QUALITY: A REPORT TO CONGRESS (2003)).

[94] For favorable discussions on the IQA and judicial reviewability of the law, *see* Conrad, *supra* note 35; Lawrence A. Kogan, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, WASHINGTON LEGAL FOUNDATION (2015), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2561619 [https://perma.cc/H9AZ-NF9N] (last visited Apr. 27, 2020); William Kelly, Jr., *A Closer and More Current Look at the 'Information Quality Act,' Its Legislative History, Case Law, and Judicial Review Issues*, SSRN (2018), https://ssrn.com/abstract=3122670 [https://perma.cc/36G5-DSXA] (last visited Apr. 27, 2020). For critical discussions of the IQA and judicial reviewability of the law, *see, e.g.*, Stephen Johnson, *Junking the "Junk Science" Law: Reforming the Information Quality Act*, 58 ADMIN. L. REV. 37 (2006), https://www.jstor.org/stable/40712004?seq=1 [https://perma.cc/PLN4-63GW] (last visited May 26, 2020); Sidney Shapiro, Rena Steinzor & Margaret Clune, *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, A CENTER FOR PROGRESSIVE REFORM PUBLICATION (Feb. 2006), https://cpr-assets.s3.amazonaws.com/documents/CPR_IQA_601.pdf [https://perma.cc/958W-YJ68] (last visited May 26, 2020); Margaret Pak, *An IQ Test for Federal Agencies? Judicial Review of the Information Quality Act under the APA*, 80 WASH. L. REV. 3 (2005), https://digitalcommons.law.uw.edu/wlr/vol80/iss3/5/ [https://perma.cc/XQN4-PM6C] (last visited May 26, 2020); Thomas McGarity, Sidney Shapiro, Rena Steinzor, Joanna Goger & Margaret Clune, *Truth and Science Betrayed: The Case Against the Information Quality Act*, A CTR. FOR PROGRESSIVE REG. PUBLICATION (Mar. 2005), https://cpr-assets.s3.amazonaws.com/documents/iqa.pdf [https://perma.cc/4YZE-6NU2] (last visited May 26, 2020).

[95] *See, e.g.*, OFFICE OF MGMT. & BUDGET, INFORMATION QUALITY: A REPORT TO CONGRESS (2003). *See also* OFFICE OF MGMT. & BUDGET, VALIDATING REGULATORY ANALYSIS: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 63 (2005); CONG. RESEARCH SERV., RL32532, *The Information Quality Act: OMB's Guidance and Initial Implementation*, (Aug. 19, 2004), https://fas.org/sgp/crs/RL32532.pdf [https://perma.cc/V8N8-6WVP] (last visited Apr. 27, 2020).

[96] In addition to the OMB report, GAO has published reports that include data on the source of requests for correction. In a 2006 report, GAO looked at the source of what it referred to as "substantive IQA requests" for fiscal years 2003 and 2004. In 2003, "business, trade group, or other profit-oriented organization" accounted for 52.4% of the requests, "nonprofit or other advocacy organization" accounted for 28.6%, "private citizen" accounted for 14.3%, and "government" accounted for 4.8%. In a 2015 report, the GAO looked at requests for correction for fiscal years 2010–2014 (there was no "substantive" qualifier listed to describe the nature of the requests). The categories were broken down differently but still demonstrated a wide range of sources. Unfortunately, by creating a combined category of "trade association/advocacy organization," the amount of requests from each of these two types of organizations is not available through the report. The breakdown is as follows: 58% for "trade association/advocacy organization," 18% for "private citizen," 15% for "business," 7% for "local governments," and 2% for "unknown." U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-765, INFORMATION QUALITY ACT: EXPANDED OVERSIGHT AND CLEARER GUIDANCE BY THE OFFICE OF MANAGEMENT AND BUDGET COULD IMPROVE AGENCIES' IMPLEMENTATION OF THE ACT (2006); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-110, INFORMATION QUALITY ACT: ACTIONS NEEDED TO IMPROVE TRANSPARENCY AND REPORTING OF CORRECTION REQUESTS (2016).

[97] This is not a statement about the speed of the current rulemaking process.

and most of the requests were not connected to rulemaking, but instead reports, web pages, and other sources for information.[98]

In a 2015 report analyzing fiscal years 2010–2014 data, the Government Accountability Office found that sixty-eight percent of the eighty-seven IQA requests for correction yielded no changes made by the agencies. Full corrections were made in response to eleven requests and partial corrections were made in response to fifteen requests. Therefore, about thirty percent of the requests did lead to some corrections made by the agencies.[99]

As shown in Figure 1, there have been a small number of requests for correction. Agencies involved in public health were generally some of the biggest targets of the requests. For example, the Environmental Protection Agency (EPA) received the most requests over the thirteen-year period (seventy-two requests). This still only required the agency to respond to about six requests a year.

Figure 1: Total Number of Requests for Correction, Government-Wide FY 2003–2015[100]

Access Board	1
Consumer Product Safety Commission	10
Department of Agriculture	25
Department of Commerce	25
Department of Defense	9
Department of Education	3
Department of Energy	2
Department of Health and Human Services	59
Department of Housing and Urban Development	1
Department of Interior	59
Department of Labor	11
Department of Transportation	9
Department of Treasury	1
Department of Veterans Affairs	2
Environmental Protection Agency	72
Federal Communications Commission	9
Federal Housing Financing Agency	4
Federal Reserve Board	1
Federal Trade Commission	1

[98] CONG. RESEARCH SERV., RL32532, *The Information Quality Act: OMB's Guidance and Initial Implementation*, (Aug. 19, 2004), https://fas.org/sgp/crs/RL32532.pdf [https://perma.cc/WW5H-HFBM] (last visited Apr. 27, 2020); Stuart Shapiro, *Embracing Ossification*, REGULATION 8–10 (2018), https://www.cato.org/sites/cato.org/files/serials/files/regulation/2018/12/regulation-v41n4-4.pdf [https://perma.cc/NA26-LTE2] (last visited Apr. 27, 2020).

[99] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-110, INFORMATION QUALITY ACT: ACTIONS NEEDED TO IMPROVE TRANSPARENCY AND REPORTING OF CORRECTION REQUESTS (Dec. 2015).

[100] OFFICE OF MGMT. & BUDGET, OFFICE OF INFO. & REGULATORY AFFAIRS, https://www.whitehouse.gov/omb/information-regulatory-affairs/reports/#ORC [https://perma.cc/D5E5-KNUF] (last visited Aug 31, 2020). This analysis is based on data from OIRA reports to Congress from 2005 to 2017. The 2016 OIRA Draft Report does not contain a table for departments and agencies that received Information Quality Correction Requests in FY 2015, instead that information is included in the 2017 Report. The 2017 Report does not contain the number of requests for correction from FY 2016.

General Services Administration	2
National Aeronautics and Space Administration	5
National Endowment for the Arts	1
National Transportation Safety Board	1
Office of Management and Budget	1
Office of National Drug Control Policy	1
Office of Science and Technology Policy	2

**This data was calculated using OIRA reports to Congress. This included using the numbers in the requests for correction tables and then subtracting those requests that OMB deemed not to be generated by the IQA. Please see the footnote for more information.*[101]

[101] The early annual requests for correction data, especially in FY 2003, included more requests for correction than otherwise should have been reported according to OMB. This is because some agencies initially counted simple and administrative requests as IQA requests, which they later dealt with through other means (as they had in the past, before the IQA). To be consistent with OMB, the chart excludes those requests that OMB believed were not generated by the IQA. In its 2005 report, OMB explained regarding FY 2003 requests for correction, "We will not be including discussion of the requests to FEMA, DOT—particularly those to Federal Motor Carrier Safety Administration (FMCSA), NARA, DOL, DOJ, Treasury, the National Aeronautics and Space Administration (NASA), the Commodity Futures Trading Commission (CFTC), and the Federal Deposit Insurance Corporation (FDIC). These requests seem to be no different in substance from the simple web page fixes or technical corrections that agencies have always received." VALIDATING REGULATORY ANALYSIS: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES, OFFICE OF MANAGEMENT & BUDGET 58, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/2005_cb/final_2005_cb_report.pdf [https://perma.cc/X7FD-VPM5]. The 2005 report considers there to be forty-eight IQA requests for correction. *Id.* at 58–59. When analyzing by agency to get to the total forty-eight number, it is important to follow exactly what OMB excluded. OMB included two DOT requests for correction, but not any requests that came from FMCSA. *See* INFORMATION QUALITY A REPORT TO CONGRESS, OFFICE OF MANAGEMENT & BUDGET 12, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/fy03_info_quality_rpt.pdf [https://perma.cc/KZG9-SBF9].

In that same report, when discussing FY 2004 requests for correction, OMB explained, "OMB considers only 37 of these to be generated by the Information Quality Act and different in substance from the simple web page fixes or technical corrections that agencies have always received. As for the FY03 requests, in cases where all of an agency's correction requests were not generated by the Act, we did not include them here. Thus, we will not be including discussion of the requests to NARA, Treasury, State, Department, and Energy." VALIDATING REGULATORY ANALYSIS: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES, OFFICE OF MANAGEMENT & BUDGET 59.

In its 2006 report, OMB explained regarding FY 2005 requests for correction, "Although there were 27 correction requests received in FY 2005, only 24 of these are considered by OMB to be different in substance from the simple webpage fixes or technical corrections that agencies have always received. Thus we are not including discussion of the three requests to the Department of State, the General Services Administration, and the National Highway Traffic Safety Administration at the Department of Transportation. Figure 4-1 shows the status of the 24 correction requests. For all the details relating to the specific requests, including agency responses, readers are encouraged to visit agency Information Quality websites." 2006 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES, OFFICE OF MANAGEMENT & BUDGET 45, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/inforeg/2006_cb/2006_cb_final_report.pdf [https://perma.cc/QE2B-FB84].

The data for FY2006–FY2014 came from the 2007–2015 reports. The data for FY2015 came from the 2017 report. These calculations as described within this footnote match up with the annual total requests for correction as listed by OMB in the "2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act." 2017 REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT, OFFICE OF MANAGEMENT & BUDGET 54, https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf [https://perma.cc/P8GT-BT5F].

As a practical matter, the OMB exclusion of certain requests *generally* do not change the overall picture

Figure 2 shows the number of requests for correction that the Department of Health and Human Services (HHS) has received since the enactment of the IQA. It breaks down these requests by agency. Both the Centers for Disease Control and Prevention (CDC) and FDA were the most frequent recipients of requests, yet they have not been barraged by requests. In the history of the IQA, FDA has only received fourteen requests for correction.

Figure 2: Department of Health and Human Services Requests for Correction since Enactment of the IQA, by Agency[102]

ACF - Administration for Children and Families	1
CDC - Centers for Disease Control and Prevention	28
CDC/ATSDR - Centers for Disease Control and Prevention/ Agency for Toxic Substances and Disease Registry	5
CMS - Centers for Medicare and Medicaid Services	3
FDA - Food and Drug Administration	14
NIH - National Institute of Health	6
NTP - National Toxicology Program	12
SAMHSA - Substance Abuse and Mental Health Services Administration	2
OPHS - Office of Public Health and Science	3

Even though the IQA has not had the impact some proponents may have expected, this does not mean the law has not been beneficial. Within just HHS, requests for correction have led to, among other things:

- Removing incorrect information regarding smokeless tobacco;
- Updating information and removing outdated information regarding bicycle helmet safety;
- Revising the CDC's Phthalates Chemical Factsheet to properly communicate the plastic products that contain these chemicals;
- Revising a press release and fact sheet regarding the National Toxicology Program's Report on Carcinogens to correct incorrect information on Styrene-7,8-oxide; and
- Properly attributing authorship of influential research on artificial *trans* fat used by FDA to individual authors, not the CDC.[103]

of the IQA. However, two of OMB's exclusions for FY2003 are especially important because they would have been major aberrations: FEMA's 24,000 requests for correction and the Federal Motor Carrier Safety Administration's 87 requests for correction.

[102] *Information Requests for Corrections and HHS' Responses*, U.S. DEPT. OF HEALTH & HUMAN SERVICES, OFFICE OF THE ASST. SEC. FOR PLANNING AND EVALUATION, https://aspe.hhs.gov/information-requests-corrections-and-hhs-responses [https://perma.cc/YWY3-Y69N] (last visited Apr. 27, 2020). This analysis is based on information from the Department of Health and Human Services web page entitled "Information Requests for Corrections and HHS' Responses."

[103] *Id.*

VI. STRENGTHENING THE QUALITY OF INFORMATION

One of the best ways to improve the quality of government disseminated information is to try to eliminate problems before the information is disseminated. OMB recognized this in the IQA Guidelines, explaining that "as a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality of information before it is disseminated."[104] Even after agencies have disseminated information, they should be expected to quickly fix errors on their own initiative once mistakes come to their attention.

To improve information quality, it will require more than simply expecting agencies or even OMB to meet this objective. There need to be independent actors within the government to improve information quality[105] and objective requirements that do not afford the discretion to get around them. The following are several recommended changes that OMB should make to improve information quality and Congress should codify into law.

A. OMB Should Direct Agencies to Quickly Fix Known Errors

Inevitably, agencies will make mistakes. Therefore, it is extremely important that agencies respond to those mistakes by correcting the information in a timely manner. It should be up to agencies to identify all of the sources, such as web pages, where the agency is still disseminating the incorrect information. A recent example highlights the importance of this recommendation.

CDC has a web page indicating that early estimates showed more than 80,000 people died from the flu during the 2017–18 flu season.[106] This same page links to an external website of a private organization about the press conference in which this unusually high number of deaths was announced. On this external site, there are additional sources restating the 80,000 deaths number.[107]

The problem is there were an estimated 61,000 deaths, not more than 80,000 deaths, during the 2017–18 flu season, according to updated data from CDC.[108] CDC should have already corrected this mistake on the webpage (an easily discoverable page) and taken steps to ensure that links to external sources do not perpetuate this error. To its credit, CDC did make a correction on another webpage in which this incorrect data was listed by including a yellow box at the top of the page listing the new data.[109]

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[104] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, *supra* note 27. A parenthetical containing "(including the objectivity, utility, and integrity)" was removed from this quote.

[105] At a minimum, the actors need to be more independent than OMB, which is still acting on behalf of an Administration.

[106] *National Press Conference Kicks Off 2018-2019 Flu Vaccination Campaign*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2018), https://www.cdc.gov/flu/spotlights/press-conference-2018-19.htm [https://perma.cc/E24L-U9MT] (last visited Apr. 27, 2020).

[107] *2018 NFID Influenza/Pneumococcal Disease News Conference*, NAT'L FOUND. FOR INFECTIOUS DISEASES, https://www.nfid.org/about-nfid/newsroom/news-conferences/2018-nfid-influenza-pneumococcal-news-conference-2/ [https://perma.cc/2SLD-4FHJ].

[108] *Estimated Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths in the United States—2017 –2018 Influenza Season*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2019), https://www.cdc.gov/flu/about/burden/2017-2018.htm [https://perma.cc/4NZD-YZTG] (last visited Apr. 27, 2020).

[109] *Archived Estimated Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths in the United States—2017–2018 Influenza Season*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2019),

This is not a trivial issue, and this point is only magnified in light of the COVID-19 pandemic. A quick Internet search of the number of deaths from the 2017–18 flu season will bring up numerous and widely read media sources announcing the more than 80,000 deaths.[110] According to the CDC web page, this number was record-breaking.[111] However, this was incorrect, too. As reported, CDC explained that it was the highest in at least four decades.[112] It shattered the most recent high of 56,000 deaths.[113] The actual number of 61,000 deaths is alarming, but it is at least somewhat in line with the 56,000 number. Whether CDC acted too hastily in announcing the number of deaths is itself an important question. It does not help that as reported in an Associated Press article, "CDC officials called the 80,000 figure preliminary, and it may be slightly revised. But they said it is not expected to go down."[114]

Regardless, when a mistake is made, especially of this magnitude, CDC and all agencies need to do whatever they can to make sure that it is not complicit in still disseminating misinformation. They should also take additional steps beyond this to mitigate the harm caused by the dissemination of the widely reported incorrect information.

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https://www.cdc.gov/flu/about/burden/2017-2018/archive.htm [https://perma.cc/3WLH-6ZMS] (last visited Apr. 27, 2020).

[110] The following publications simply reported what the CDC disseminated to the public: Lena H. Sun, *Flu Broke Records for Deaths, Illnesses in 2017-2018, New CDC Numbers Show,* WASH. POST (2018), https://www.washingtonpost.com/national/health-science/last-years-flu-broke-records-for-deaths-and-illnesses-new-cdc-numbers-show/2018/09/26/97cb43fc-c0ed-11e8-90c9-23f963eea204_story.html [https://perma.cc/U2Y4-EB7F] (last visited Apr. 27, 2020); Associated Press, *CDC: 80,000 People Died of Flu Last Winter in the U.S.*, STAT (2018), https://www.statnews.com/2018/09/26/cdc-us-flu-deaths-winter/ [https://perma.cc/3CSE-2ZWY] (last visited Apr. 27, 2020); Julia Belluz, *80,000 Americans Died of the Flu Last Winter. Get Your Flu Shot.*, VOX (2018), https://www.vox.com/2018/9/27/17910318/flu-deaths-2018-epidemic-outbreak-shot [https://perma.cc/88FS-EDZB] (last visited Apr. 27, 2020); Donald G. McNeil, *Over 80,000 Americans Died of Flu Last Winter, Highest Toll in Years,* N.Y. TIMES (2018), https://www.nytimes.com/2018/10/01/health/flu-deaths-vaccine.html [https://perma.cc/H68A-NDXD] (last visited Apr. 27, 2020); *80,000 Americans Died From Flu Last Year,* WEBMD (2018), https://www.webmd.com/cold-and-flu/news/20180927/80000-americans-died-from-flu-last-year [https://perma.cc/E745-DBF6] (last visited Apr. 27, 2020); Melissa A. Rolfes et al., *Effects of Influenza Vaccination in the United States During the 2017–2018 Influenza Season*, 69 CLINICAL INFECTIOUS DISEASES 1845–53 (2019) (data appearing in this academic journal); Chris Brock, *'It's Just the Flu' Remark Undermines How Seriously Influenza Should Be Taken,* NNY360 (2020), https://www.nny360.com/artsandlife/mindandbody/it-s-just-the-flu-remark-undermines-how-seriously-influenza-should-be-taken/article_e5f66c33-9e87-598d-aa75-471a722cb9fb.html [https://perma.cc/9LKQ-VD8C] (last visited Apr. 27, 2020) (data re-appearing in a more recent article).

[111] *National Press Conference Kicks Off 2018-2019 Flu Vaccination Campaign*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2018), https://www.cdc.gov/flu/spotlights/press-conference-2018-19.htm [https://perma.cc/4RA6-L62D] (last visited Apr. 27, 2020).

[112] *80,000 Americans Died From Flu Last Year,* WEBMD (2018), https://www.webmd.com/cold-and-flu/news/20180927/80000-americans-died-from-flu-last-year [https://perma.cc/MNW6-7DH6] (last visited Apr. 27, 2020).

[113] Lena H. Sun, *Flu Broke Records for Deaths, Illnesses in 2017-2018, New CDC Numbers Show*, WASH. POST (2018), https://www.washingtonpost.com/national/health-science/last-years-flu-broke-records-for-deaths-and-illnesses-new-cdc-numbers-show/2018/09/26/97cb43fc-c0ed-11e8-90c9-23f963eea204_story.html [https://perma.cc/3QK3-9H5R] (last visited Apr. 27, 2020).

[114] Associated Press, *CDC: 80,000 People Died of Flu Last Winter in the U.S.*, STAT (2018), https://www.statnews.com/2018/09/26/cdc-us-flu-deaths-winter/ [https://perma.cc/B3SS-M2ST].

B. OMB Should Stress to Agencies That They Must Properly Use the Imprimatur of the Federal Government

In 2013, FDA proposed its de facto[115] artificial *trans* fat ban.[116] Specifically, the agency was taking action against the primary source of artificial *trans* fat in processed food: partially hydrogenated oils. To support its action, FDA explained in the preamble of this proposal[117]:

> In addition, according to the Centers for Disease Control and Prevention (CDC), elimination of PHOs [partially hydrogenated oils] from the food supply could prevent 10,000 to 20,000 coronary events and 3,000 to 7,000 coronary deaths annually, if the marginal benefits of continuing to remove trans fats from food items remain constant.[118]

FDA, in support of this statement, then cited a study by two CDC employees that was published in the Journal of the American Medical Association. It should have been clear, then, to FDA that its statement was improperly attributing the data to CDC. The study also has a clear disclaimer, "The findings and conclusions in this report are those of the authors and do not necessarily reflect the official position of the US Centers for Disease Control and Prevention."[119] In addition, FDA in numerous places on its webpage restated this data and even used stronger language in connecting it to CDC, explaining that CDC "estimated" the data.[120]

There is a big difference between claiming the data came from CDC as opposed to two CDC employees whose study does not necessarily reflect the views of CDC. It impacts media coverage and it impacts public perception.[121] Even worse, this mistake was made in a regulatory action, which improperly gave greater perceived weight to the underlying support for the rule.

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[115] *See, e.g.*, Daren Bakst, *FDA's Proposed Trans Fat Ban: An Attack on Freedom*, THE DAILY SIGNAL (Nov. 8, 2020), https://www.dailysignal.com/2013/11/08/fdas-proposed-trans-fat-ban-an-attack-on-freedom/?_ga=2.254726540.585250879.1587402698-27129520.1584548405 [https://perma.cc/5L3E-LKMN] (last visited Apr. 27, 2020).

[116] Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169 (Nov. 8, 2013), https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for [https://perma.cc/VH6T-J2Y3] (last visited Apr. 27, 2020).

[117] *Id.* FDA action was referred to as a "tentative determination."

[118] Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, *supra* note 116.

[119] *Id.*

[120] Daren Bakst, *Request for Correction of Information Disseminated to the Public that Improperly Attributed a Study to the Centers for Disease Control and Prevention (CDC)*, U.S. DEP'T HEALTH & HUMAN SERVS. (Sept. 9, 2014), https://aspe.hhs.gov/cdc-%E2%80%94trans-fats [https://perma.cc/8DQD-RCNX] (last visited Apr. 27, 2020).

[121] *See, e.g.*, DLA Piper, *The End of Trans Fats? FDA Issues Tentative Determination on Trans Fats In Processed Foods*, LEXIS NEXIS (Dec. 16, 2013), https://www.lexisnexis.com/legalnewsroom/public-policy/b/public-policy-law-blog/posts/the-end-of-trans-fats-fda-issues-tentative-determination-on-trans-fats-in-processed-foods [https://perma.cc/4WYR-7Z6U] (last visited May 26, 2020); Julia Belluz, *The FDA Just Ordered Food Companies to Stop Using Trans Fat. Here's What it Means for You.*, VOX (Jun. 16, 2015), https://www.vox.com/2015/6/16/8790239/trans-fat-explainer [https://perma.cc/XJ8A-CCH5] (last visited May 26, 2020).

Agencies should not need OMB to tell them to be very careful when attributing information to the federal government, especially when information is used in a regulatory action. However, OMB should stress this point to agencies, because the imprimatur of the government can make a big difference in terms of how information is perceived. OMB itself should also be looking for such mistakes when it reviews proposed regulations[122] prior to them being published.

C. OMB Should Expressly State That Press Releases and Fact Sheets are Included Under the IQA

OMB should not inappropriately limit the scope of the IQA. Unfortunately, the Guidelines state that press releases are not information that is "disseminated" under the IQA.[123] This is in sharp contrast to the IQA's otherwise broad scope. After publication of the Guidelines, in a June 10, 2002 memo to the President's Management Council, OMB did indicate its support for narrowly interpreting the press release exemption, although there was no requirement to do so.[124] Despite this memo, various agencies have not taken a narrow interpretation, and have even interpreted the press release exemption to also include fact sheets and information often disseminated in conjunction with press releases.[125]

If the purpose of the IQA is to ensure the quality of federally disseminated information, it makes little sense to exempt press releases (and other similar documents, such as fact sheets) that are often the primary means in which agencies communicate information to the public. Further, federal agencies could game the system and simply disseminate information through these exempted publication formats (and simply slap a title such as "fact sheet" on a document) to get around IQA requirements.

In the public health context, this exemption can be especially harmful. For example, as explained in a 2015 Administrative Conference of the United States (ACUS) report:

> [A]gency announcements can be problematic when they are inaccurate, as demonstrated by the 2008 FDA and CDC salmonella press releases [regarding tomatoes], or by the series of inaccurate product safety

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[122] The Office of Information and Regulatory Affairs (OIRA), which is part of OMB, "is the United States Government's central authority for the review of Executive Branch regulations." OFFICE OF MGMT. & BUDGET INFORMATION AND REGULATORY AFFAIRS, https://www.whitehouse.gov/omb/information-regulatory-affairs/ [https://perma.cc/S2B4-B5TX] (last visited May 26, 2020).

[123] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002), https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information [https://perma.cc/86MN-EMGT] (last visited Apr. 27, 2020).

[124] JOHN D. GRAHAM, MEMORANDUM FOR PRESIDENT'S MANAGEMENT COUNCIL 4–5, 17, (June 10, 2002), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/iqg_comments.pdf [https://perma.cc/3GPE-BL9X] (last visited Apr. 27, 2020).

[125] ADMIN. CONF. OF THE U.S., APPENDIX G: AGENCY IQA GUIDELINES OF AGENCY PUBLICITY IN THE INTERNET ERA (Sept. 25, 2015), https://www.acus.gov/sites/default/files/documents/appendix-g.pdf [https://perma.cc/78UN-KGEN] (last visited Apr. 27, 2020).

> warnings by the CPSC that led Congress to amend the Consumer Product Safety Act in 1981. [internal citations omitted].[126]

By exempting these types of agency announcements, important and sensitive information will not get corrected under the IQA. This ACUS report did find that of forty-two agencies surveyed, twenty-three agencies narrowed the OMB press release exemption, eleven agencies kept the broad exemption, five agencies' policies were unclear, or three agencies have policies that conflict on whether a narrow or broad exemption applies.[127]

According to the ACUS report, HHS includes a more narrow exemption. HHS guidelines cover press releases except for "press releases that support the announcement or give public notice of information that the agency disseminates elsewhere."[128] OMB's June 10, 2002 memo indicated its support for the narrowing of the press release exemption in a manner similar to HHS.[129]

On the surface, HHS exemption may still be too broad since the language could still be interpreted to exempt substantive information. If a press release includes any substantive information (new or old), even excerpts from information the agency disseminates elsewhere, the press release should not be exempted from IQA requirements.[130] The press release could be disseminating inaccurate information derived from the referenced document. Even if the referenced document contains accurate information, this does not mean the press release will be accurate regarding substantive issues connected to the document.[131] For example, press releases, fact sheets, and similar documents are designed for general audiences and the simplification of the issues can lead to mistakes.

OMB should clarify that press releases, fact sheets, or other similar documents are not exempt under the IQA. The only exception should be if these documents are non-substantive communications, such as meeting notices or announcements that simply explain the existence of the disseminated information.

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[126] *Id.* at 11. In 2008, FDA and Centers for Disease Control and Prevention incorrectly identified tomatoes as the source of a salmonella outbreak, costing the tomato industry an estimated $200 million. *See* Denis G. Maki, *Coming to Grips with Foodborne Infection Peanut Butter, Peppers, and Nationwide Salmonella Outbreaks*, 360 NEW ENG. J. MED. 949 (2009), https://www.nejm.org/doi/full/10.1056/NEJMp0806575 [https://perma.cc/R3HP-G76N] (last visited Apr. 27, 2020).

[127] ADMIN. CONF. OF THE U.S., AGENCY PUBLICITY IN THE INTERNET ERA (2015), https://www.acus.gov/sites/default/files/documents/agency-publicity-in-the-internet-era.pdf [https://perma.cc/KLT5-55YA] (last visited Apr. 27, 2020).

[128] U.S. DEP'T HEALTH & HUMAN SERVS., HHS GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED TO THE PUBLIC (Oct. 1, 2002), https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public [https://perma.cc/2MSF-P5MU] (laying out scope and applicability of the guidelines) (last visited Apr. 27, 2020).

[129] GRAHAM, *supra* note 124, at 17. OMB suggests (at a minimum) that it supports EPA's additional language specifically exempting not just press releases, but also "fact sheets, press conferences, or similar communications."

[130] This is not to say that a press release would somehow be subject to any peer review requirements; only the underlying document would be subject to peer review. However, if a press release, for example, repeated inaccurate information from the underlying document that was subject to peer review, then the press release should certainly be corrected.

[131] The dissemination of inaccurate information from a press release is not offset because an agency may be disseminating accurate information on the issue through other means.

D. OMB Should Create Objective and Independent Ways of Designating Highly Influential Scientific Assessments

When an agency disseminates a scientific assessment, if there is a reasonable basis to conclude that it is a highly influential scientific assessment, then the assessment should be designated accordingly by an agency or OMB. It is much better to default to greater protections for information quality than weaker ones.

A highly influential scientific assessment is "influential scientific information that the agency or the Administrator *determines* to be a scientific assessment" that meets one of the several criteria listed in the definition.[132] As with the definition of "influential scientific information," the language should be changed to "reasonably can determine" to make it easier for the "highly influential scientific assessment" designation to be triggered.

Even with this change, the entire approach to designating a highly influential scientific assessment leaves too much discretion to the agency and OMB. The designation process as currently drafted is still very subjective, helping agencies and OMB avoid the highly influential scientific assessment. An agency is not an independent actor and might even have incentives to avoid making this designation, such as not wanting their disseminated information facing heightened scrutiny or their policy agenda hindered. OMB, while likely more independent than an agency, is still part of the administration. This is why there needs to be more objective and independent means in making this designation.[133]

1. An Example of Discretionary Misclassification

The discretion problem is exemplified by EPA's resistance to classify the technical support document[134] used to inform its greenhouse gas (GHG) endangerment finding as a highly influential scientific assessment. It is difficult to imagine any scientific assessment that better meets the requirements of a highly influential scientific assessment.[135]

EPA has argued that the technical support document is not even a scientific assessment. A scientific assessment is defined as "an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data,

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[132] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-05-03, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (Dec. 16, 2004).

[133] Under existing law, an agency or OMB can make the designation. As will be discussed, a more independent actor within the executive branch should also be given this authority. This Article recommends Inspectors General.

[134] ENVTL. PROTECTION AGENCY, ENDANGERMENT AND CAUSE OR CONTRIBUTE FINDINGS FOR GREENHOUSE GASES UNDER SECTION 202(1) OF THE CLEAN AIR ACT (Dec. 7, 2009), https://www.epa.gov/sites/production/files/2016-08/documents/endangerment_tsd.pdf [https://perma.cc/Q8WE-R2W2] (last visited Apr. 27, 2020).

[135] In addition to easily meeting the $500 million in any year requirement, all of the following requirements are met as well (even though only one is required): the technical support document is novel, controversial, precedent-setting, and has significant interagency interest. The document serves as the support for the EPA's greenhouse gas (GHG) regulations, including new regulations. It also helped to give the EPA justification to regulate something it never has before. Therefore, they are both novel and precedent-setting. There are few issues more controversial than the impact of GHGs and policy choices regarding GHGs. Given the scope of GHG policy across the federal government, these assessments are also of significant interagency interest.

models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information."[136]

In 2011, EPA's Inspector General concluded that the technical support document was a highly influential scientific assessment (and a scientific assessment).[137] In response, EPA disagreed and asserted the document was not a scientific assessment because it did not "synthesize multiple factual inputs, data, models, assumptions."[138] Instead, "[t]he TSD [technical support document] simply summarizes in a straightforward manner the underlying assessments of the National Academies, the USGCRP and IPCC." EPA also argued that even though a state of the science report is listed as an example of a scientific assessment, this example should not be read in isolation but must be informed by the preceding language defining scientific assessments (e.g., "an evaluation of a body of scientific or technical knowledge, which typically synthesizes . . .)."

Under the ordinary understanding of the term, the technical support document is a state of the science report. OMB expressly listed state of the science reports as an example of what they envisioned constituted a scientific assessment. To ignore this express language, there should be language within the scientific assessment definition that is clearly incompatible with considering the technical support document to be a scientific assessment. This simply does not exist, and the preceding language in the definition is actually consistent with the technical support document.

Further, and as pointed out by the Inspector General, EPA was in fact synthesizing and evaluating scientific information.[139] To bolster its argument, the Inspector General pointed to EPA's own language, such as in the proposed endangerment finding in which the agency explained: "EPA has developed a technical support document (TSD) which *synthesizes* major findings from the best available scientific assessments that have gone through rigorous and transparent peer review."[140]

Even if the technical support document is a summary, this does not mean it is not a synthesis; they are not mutually exclusive.[141] EPA was also evaluating the science in the document. The agency in the technical support document made many choices, including what studies to include in the document, what conclusions to draw from these documents, and what studies to exclude.[142]

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[136] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-05-03, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (Dec. 16, 2004).

[137] ENVTL. PROTECTION AGENCY, PROCEDURAL REVIEW OF EPA'S GREENHOUSE GASES ENDANGERMENT FINDING DATA QUALITY PROCESSES (Sept. 26, 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20110926-11-p-0702.pdf [https://perma.cc/Y75T-DUXA] (last visited Apr. 27, 2020).

[138] *Id.* at 62–63.

[139] The scientific assessment definition does not actually require synthesizing; it simply says a scientific assessment is an evaluation that "typically" synthesizes.

[140] ENVTL. PROTECTION AGENCY, PROCEDURAL REVIEW OF EPA'S GREENHOUSE GASES ENDANGERMENT FINDING DATA QUALITY PROCESSES (Sept. 26, 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20110926-11-p-0702.pdf [https://perma.cc/Y75T-DUXA] (last visited Apr. 27, 2020) (emphasis added).

[141] According to the Merriam-Webster's dictionary, a synthesis is "the composition or combination of parts or elements so as to form a whole." *Synthesis*, MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/synthesis (last visited Nov. 24, 2020). The EPA through the summaries is taking various parts (different assessments) to form a whole (a picture of the science).

[142] ENVTL. PROTECTION AGENCY, PROCEDURAL REVIEW OF EPA'S GREENHOUSE GASES ENDANGERMENT FINDING DATA QUALITY PROCESSES (Sept. 26, 2011), https://www.epa.gov/sites/production/files/2015-10/documents/20110926-11-p-0702.pdf [https://perma.cc/Y75T-DUXA] (last

The technical support document explains in its executive summary, "This document provides technical support for the endangerment and cause or contribute analyses concerning greenhouse gas (GHG) emissions under section 202(a) of the Clean Air Act."[143] If the document is not a scientific assessment and the EPA's evaluation of the science to inform the endangerment finding, is the agency acknowledging that the endangerment finding was not informed by the best available science? If the agency does assert that it is a reflection of the best available science, then that by itself is an acknowledgment that the technical support document is an evaluation of the science.

To avoid this problem in the future, OMB should make it clear that a scientific assessment is *any* evaluation of the science regardless of the form that evaluation takes and the extent of the evaluation. It is possible that the use of the term "scientific assessment" is too narrow or too prone to agency abuse when used in the context of "highly influential scientific assessments." OMB should change the terminology from "highly influential scientific assessments" to some other terminology if that is what is required to ensure the underlying science serving as the foundation for regulatory decisions or influential scientific information is subjected to the highest form of peer review (assuming the underlying science also meets the other requirements to be "highly influential").

2. Create Automatic Triggers for the Highly Influential Scientific Assessment Designation

One of the best ways to avoid any agency or OMB disincentive to trigger the highly influential scientific assessment designation is to create objective means that do not rely on subjective, discretionary decisions. Certain types of assessments should automatically trigger the highly influential scientific assessment designation. These assessments should be as objectively defined as possible. Some examples include:

- The agency or another agency is using the assessment as a basis to regulate something (or a new category of regulated entities) for the first time.
- The assessment reflects the agency's first evaluation of a scientific issue that will inform or has informed influential scientific information.[144]
- Agency calculation of a regulation's potential impact is $500 million or more in any one year.

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visited Apr. 27, 2020). The EPA Inspector General's report does a good job of explaining why the technical support document is a scientific assessment.

[143] ENVTL. PROTECTION AGENCY, ENDANGERMENT AND CAUSE OR CONTRIBUTE FINDINGS FOR GREENHOUSE GASES UNDER SECTION 202(1) OF THE CLEAN AIR ACT (Dec. 7, 2009), https://www.epa.gov/sites/production/files/2016-08/documents/endangerment_tsd.pdf [https://perma.cc/AR27-79KX] (last visited Apr. 27, 2020).

[144] Highly influential scientific assessments should not always be based on looking at future effect. In this example, the scientific assessment is precedent-setting even if it was developed in the past. Also, just because an assessment *was* used to inform influential scientific information does not mean it is less influential than a scientific assessment that *will be* used to inform scientific information. Past assessments should not be reviewed in perpetuity, but it should take a final agency action (as defined under the APA) concluding that the assessment was not highly influential to put an end to the matter (in general). However, even in that situation, if circumstances have changed so that the past assessment could currently be considered "highly influential," then the assessment should be reviewed again.

There should also be agency-specific automatic triggers. As just two examples, this should include assessments underlying EPA's setting of national ambient air quality standards and FDA's premarket approval of medical devices. Both of these examples illustrate major regulatory actions that reasonably can be assumed to meet the highly influential scientific assessment requirements.

3. Create an Independent Means to Ensure that Highly Influential Scientific Assessments are Properly Designated

OMB, as an institution, does not provide a truly independent means to address highly influential scientific assessments since, like an agency, they are part of any administration with its own agenda. The interests of both the agency and OMB could align, and therefore if an agency would like to avoid the highly influential scientific assessment designation, then so too could OMB. However, OMB plays an important role because it is the federal government's lead on IQA implementation. In its Peer Review Bulletin, OMB already gave itself the authority to make highly influential scientific assessment designations.[145] As a matter of course, OMB should regularly use this authority to review agency scientific assessments to determine if they are highly influential.

This alone, though, is insufficient to create an independent means to ensure scientific assessments are properly designated as highly influential. Therefore, each agency's Inspector General should also regularly review scientific assessments deemed influential scientific information to determine if they are highly influential.[146] Inspectors General have the benefit of being independent and familiar with the work of its respective agency. If the agency, OMB, or the Inspector General deems a scientific assessment to be highly influential, then this should trigger the designation. By taking these proactive steps, the public should have less need to submit requests for correction in order to have an agency properly designate a scientific assessment.

E. Strengthen Peer Review for Influential Scientific Information and Highly Influential Scientific Assessments

While the OMB Bulletin does have some non-discretionary peer-review requirements,[147] many of the requirements are merely suggestions, very limited in nature, or even illusory. In order to strengthen peer review processes for the most important disseminated information, there need to be more objective, non-discretionary peer review requirements applicable to both influential scientific

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[145] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-05-03, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (Dec. 16, 2004).

[146] There are inspectors general across the federal government. *See* CONG. RESEARCH SERV., R45450, *Statutory Inspectors General in the Federal Government: A Primer* (Jan. 3, 2019), https://crs reports.congress.gov/product/pdf/R/R45450/4 [https://perma.cc/9HB8-TTUS] (last visited Apr. 27, 2020). If an agency does not have an inspector general or does not have an inspector general office that has the requisite protections to be independent, then other alternatives should be considered that would include an independent individual or office to review IQA issues. Congress should ensure that inspectors general or other applicable offices are sufficiently independent to determine whether a scientific assessment is highly influential.

[147] While a "requirement" should by implication be mandatory and without discretion, in practice many "requirements" in law do have levels of discretion. To stress the importance of removing discretion, this Article stresses removing discretion by using the terminology "non-discretionary requirements."

information and highly influential scientific assessments.[148] Among these requirements, OMB should require agencies to conduct their own peer review and invite public participation. Further, OMB should remove the alternative procedures that allow agencies to get out of the specific peer review requirements in the Bulletin. The following are several specific changes that should be made.

1. OMB Should Create More Non-Discretionary Requirements in the Final Information Quality Bulletin for Peer Review

The Bulletin has numerous "requirements," but as mentioned, many of them are extremely weak because of the discretion afforded to agencies. For example, to determine adequacy of peer review for influential scientific information, OMB lists some factors an agency should consider (e.g., the "novelty and complexity of the science to be reviewed") without providing any standards by which to measure adequacy.[149] The agency is left with so much discretion in drawing its conclusion that so long as it can show it considered the issues, regardless of its conclusions or the thoroughness of its analysis, it will likely meet this "adequacy requirement."

A similar problem exists regarding the independence of peer reviewers. For influential scientific information, OMB provides a list of issues agencies should consider to ensure the independence of peer reviewers, but then does not detail any requirements that actually must be met. As OMB explains, "independence poses a complex set of questions that must be considered by agencies when peer reviewers are selected."[150] OMB does not explain how agencies must answer those questions (or even if they do have to answer them). Once again, an agency just needs to consider the questions.

When developing the Guidelines and Bulletin, OMB provided significant discretion and flexibility for agencies.[151] However, this does not mean that OMB should have created "suggestions" or illusory requirements. It is one thing for OMB to give an agency discretion and flexibility in how it implements a requirement; it is quite another thing for OMB Guidance to give an agency so much discretion regarding some requirements that it does not have to meet those requirements at all.

2. Require Agency Peer Review for Influential Scientific Information and Highly Influential Scientific Assessments

Highly influential scientific assessments already require agency peer review unless they are official reports of the National Academy of Sciences (NAS).[152] However,

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[148] Identifying solutions to address the problems with peer review would necessitate an article unto itself. This Article highlights just some of the most important changes that should be made in connection with influential scientific information and highly influential scientific assessments.

[149] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-05-03, FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW (Dec. 16, 2004). An agency is directed to "giv[e] due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review."

[150] *Id.*

[151] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, *supra* note 41; OFFICE OF MGMT. & BUDGET, *supra* note 149.

[152] The problem with this exception is addressed in the next section regarding alternative procedures. OFFICE OF MGMT. & BUDGET, *supra* note 149.

influential scientific information does not require additional peer review by agencies so long as the information has undergone adequate peer review. There are too many problems with the academic peer review process, which OMB itself has identified, to be so deferential to existing peer review. The purpose of the IQA is to ensure quality information. This can only be accomplished if proper steps are taken to ensure this quality, especially for the most important information. OMB should require that agencies conduct their own peer review of influential scientific information. There would be an additional burden to agencies, but this new requirement would be limited to influential scientific information. It would be justified given the importance of influential scientific information, which plays a critical role in major public policy decisions.

3. Remove the Alternative Procedures Allowed Under the Bulletin

The OMB Bulletin identifies peer review requirements for both influential scientific information and highly influential scientific assessments. However, it also states that these requirements do not have to be followed if certain alternative procedures are utilized. Two of these exceptions focus on the National Academy of Sciences (NAS): relying on a NAS report or commissioning the NAS to conduct a peer review.[153] Established by Congress, NAS is a private, nonprofit organization, which is "charged with providing independent, objective advice to the nation on matters related to science and technology."[154] The third exception allows OMB, in consultation with the Office of Science and Technology Policy (OSTP), to employ an alternative process if "the agency's scientific information satisfies applicable information quality standards."[155] The NAS-related exceptions do not even require agency compliance with OMB's peer review requirements.

NAS reports and peer review protections might be legitimate and even be consistent in many ways with the Bulletin's requirements, but OMB should be creating objective non-discretionary requirements that must be followed for scientific information and are non-negotiable. If there are protections in place that NAS employs that are worth utilizing, then OMB should write those into the Bulletin. Further, it should not be assumed that NAS requirements that OMB may deem sufficient today will still remain in place in the future.

As for the OMB-approved alternative process, at least it is supposed to satisfy "applicable information quality standards."[156] However, as drafted, this language suggests that OMB itself could have discretion as to what would be "applicable" information quality standards. This discretion could avoid the requirements that actually exist in the Bulletin. The lack of clear and consistent requirements and the excessive flexibility undermine the Bulletin's peer review protections.[157]

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[153] *Id.* at 41.

[154] *Mission,* NAT'L ACAD. OF SCI., http://www.nasonline.org/about-nas/mission/ [https://perma.cc/U87G-ARJ4] (last visited May 26, 2020).

[155] OFFICE OF MGMT. & BUDGET, *supra* note 149.

[156] *Id.*

[157] CONG. RESEARCH SERV., R45442, *Peer Review: OMB's Proposed, Revised, and Final Bulletins* (Feb. 3, 2005), https://www.everycrsreport.com/reports/RL32680.html#List_List_of_Tables_1 [https://perma.cc/T73U-R2CQ] (last visited Apr. 27, 2020). The proposed OMB Bulletin did not contain these alternatives.

4. Involve Public Participation to Review Influential Scientific Information and Highly Influential Scientific Assessments

The OMB Bulletin does not require public participation in the development of influential scientific information. For highly influential scientific assessments, the public participation is weak at best, and arguably illusory.[158] As is typical of the Bulletin, OMB lays out many suggestions, simply discussing public participation and some of its benefits. For highly influential scientific assessments, the Bulletin says "whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment . . . ."[159] While the use of "shall" is a strong directive to agencies, this requirement is undermined by the "feasible and appropriate" language. Based on this language, agencies should seek public comment unless it is genuinely not feasible and appropriate. However, there are no standards by which to measure whether it is feasible and appropriate.[160]

The OMB Bulletin explains that agencies should ensure that public comments processes do not pose undue delays in the peer review process. This is a reasonable concern, but this is not a concern that is unable to be addressed, nor does OMB suggest otherwise.[161] OMB should unambiguously require a public comment process for both influential scientific information and highly influential scientific assessments.[162] This requirement would help agencies and their peer reviewers receive much-needed feedback and insight that they otherwise would not have received. Agencies should also be required to consider and respond to the comments through the public comment process.

By receiving public comments, any expert (or non-expert) will also be providing a check on the agency and the scientific information that it would disseminate. Unlike a government peer review process that can be impacted by conflicts of interest and bias, among other problems, a public comment process can help get around these problems because anyone (including experts who the agency did not select to conduct the peer review) can share their expertise. The quality of public comments does vary, but even so, they can provide information the agency would not have otherwise received. Public comments, along with agency responses to those comments, should be made part of any administrative record if the scientific information is used in a rulemaking process.

VII. STRENGTHENING THE IQA CORRECTION AND REPORTING PROCESSES

For the IQA to work properly and achieve its potential, the public must have a meaningful way to compel the correction of federally disseminated information. Otherwise, agencies and OMB will likely fail to do what is necessary to improve the quality of the information.

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[158] OFFICE OF MGMT. & BUDGET, *supra* note 149.

[159] *Id.*

[160] However, especially given the "shall" language, OMB is still directing agencies to seek public comment. The feasible and appropriate language is not an excuse for agencies to simply ignore this requirement.

[161] OFFICE OF MGMT. & BUDGET, *supra* note 149.

[162] CONG. RESEARCH SERV., *supra* note 157. The proposed OMB Bulletin had a clear public participation requirement.

One way to improve the correction process has already been identified in this Article: OMB needs to include more non-discretionary and objective requirements in OMB's peer review bulletin. This recommendation also applies to the OMB Guidelines. By doing so, agencies and reviewing bodies will find it easier to review whether agencies have been in compliance with the IQA.

If there are not meaningful processes to review compliance, these new requirements would be in vain. OMB needs to create greater objectivity within the administrative mechanisms used to correct federally disseminated information. OMB also needs to do what it can to stop undermining the possibility of judicial review, because the most important change is giving the public a way to get into court to challenge agency action. This section discusses what OMB should do regarding administrative mechanisms and judicial review, as well as identifies ways to strengthen the law's reporting requirements.

A. Administrative Mechanisms

Beyond the lack of non-discretionary requirements and judicial review, the primary way to improve the administrative correction process is to promote objectivity. For both requests for correction and appeals, the agency responsible for creating or disseminating the information should not be the sole arbiter of whether to make corrections. If the agency is involved in resolving the request, OMB should review and approve of the response. This is consistent with the recent 2019 OMB IQA memo that explained, "Agencies should share draft responses to RFCs and appeals with OMB prior to release to the requestor for assessment of compliance with the above norms."[163]

The "above norms" in question appear to be a reference for agencies not to opine on policy positions and to properly respond to data quality arguments.[164] Regardless of whether this specific sharing language is broad enough in scope, OMB should be reviewing the requests to ensure compliance with all applicable IQA requirements.

There are some other protections in place already, as explained earlier in the Article. For appeals, the Guidelines already clarify, "the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement."[165] In the 2019 memo, OMB explained that individuals involved in reviewing and responding to initial requests for correction should not be the same individuals hearing the appeal.[166] There are also some provisions related to timing. The OMB memo stated that agencies should not take more than 120 days to respond to requests for correction.[167] OMB should place a similar limit on the length of the appeals process as well.[168]

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[163] OFFICE OF MGMT. & BUDGET, *supra* note 149.

[164] The "should" language should be changed to "shall." OMB needs to be very clear that these are requirements.

[165] Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, supra* note 27.

[166] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB MEMO No. M-19-15, IMPROVING IMPLEMENTATION OF THE INFORMATION QUALITY ACT (Apr. 24, 2019).

[167] OFFICE OF MGMT. & BUDGET, *supra* note 149.

[168] Agencies should not be able to push back these deadlines. One possible way to enforce this: If they fail to meet a deadline, then a request for correction or appeal, along with the requesting corrections, could automatically be granted.

One way to both help facilitate the administrative correction process and create greater objectivity would be the creation of an office similar to the Office of Government Information Services (OGIS).[169] This office, located within the National Archives, an independent agency, works with agencies and the public on FOIA issues, including by providing voluntary mediation services. By being located within an independent agency and insulated from political pressures, or at least presumably more so than OMB, this office is well-suited to serve as an impartial FOIA resource. This type of framework could be a useful means to address IQA disputes, with the mediation being a complement to the existing process. OGIS also provides many other services to improve the entire FOIA process. A similar IQA office could be particularly helpful for the public in figuring out the complexities of the IQA.

Administrative mechanisms to correct federally disseminated information inherently have limited benefit without independent review. The most prominent reform to improve the administrative correction process is judicial review. This would incentivize agencies and OMB to follow the IQA and provide the necessary independent means of review.

B. Judicial Review

To date, no federal court has held that an agency's denial of an IQA correction request is judicially reviewable.[170] Although, there is some hope that, under the APA, federal courts could hear IQA challenges. OMB action could make this more likely, and ideally, Congress would make the requisite changes to ensure judicial review. Beyond simply identifying how to make judicial review possible, it is also important to clarify what courts should be reviewing in IQA cases and what remedies would be appropriate.

1. OMB and Congress Should Take Steps to Establish Judicial Review

For there to be APA review, OMB needs to address several problems. The language in the OMB Guidelines and the OMB Bulletin should include clearer and more objective requirements and in no way suggest that compliance with the law (or major parts of the law) is completely discretionary for the agencies.[171] Some federal district courts have latched on to some of the discretionary language as a way to deny judicial review under the APA, claiming agency action has been left to the discretion of the agency, and therefore, there is nothing to review.[172]

OMB should also make it very clear that the Guidelines and Bulletin are not advisory documents, but legislative rules that impose legal obligations on federal agencies. The DC Circuit in *Prime Time International Co. v. Vilsack*[173] did clarify that

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[169] U.S. Nat'l Archives & Rec. Admin., *Office of Government Information Services (OGIS)*, https://www.archives.gov/ogis [https://perma.cc/F3SF-RFAE] (last visited Apr. 27, 2020).

[170] To get more detail on judicial review and the IQA, *see, e.g.*, Conrad, Kelly, and Kogan. For some specific cases, *see, e.g.*, Mississippi v. EPA, 744 F. 3d 1334 (D.C. Cir. 2013); Prime Time International Co. v. Vilsack, 599 F.3d 678 (D.C. Cir. 2010); Americans for Safe Access v. HHS, 399 F. App'x 314 (9th Cir. 2010); and Salt Institute v. Leavitt, 440 F.3d 156 (4th Cir. 2006).

[171] See, e.g., Kelly, Jr., *supra* note 94, at 32–71 for a detailed discussion on how agencies and district courts have used OMB's discretionary language to avoid judicial review.

[172] *Id.*

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

the Guidelines are "binding," but no court has yet relied on this holding to find that an agency violated the Guidelines. Further, OMB should take the position that when an IQA appeal is denied, this is a "final agency action," which is required for APA judicial review.[174] Ideally, it would also encourage the Justice Department not to take the opposite position in defending these cases.

Unfortunately, OMB has taken affirmative steps to try and restrict judicial review. The OMB Peer Review Bulletin currently includes standard boilerplate language about it not creating any rights enforceable against the United States.[175] This disclaimer may have been included as a matter of course, but Lawrence Kogan, in an extensive IQA paper, explained that OMB may very well have been concerned that judicial review was a real possibility.[176] While disclaimers are not dispositive on whether judicial review actually exists, this language and any other comparable language should be removed from OMB IQA documents and any agency IQA documents. OMB instead should expressly clarify that judicial review is available.

Ultimately, congressional action is the best way to ensure judicial review. Congress should codify express language that makes it clear that the public can challenge IQA decisions under the APA.[177] In 2017, the House passed the Regulatory Accountability Act that clarified that the APA provides judicial review of final agency action under the IQA.[178]

There may be concerns that judicial review would open the floodgates for IQA requests for correction. However, clearer IQA requirements, if adopted, will dissuade parties from bringing pointless requests for correction because parties will know upfront such requests are not covered. In addition, reviews of IQA challenges should also be easier and faster to conduct because agencies will spend less time trying to interpret the law and making subjective decisions. Further, the goal should be to ensure accurate and credible federally disseminated information, not agency efficiency to disseminate information at the expense of information quality.

FOIA helps to put this judicial review issue into perspective. Congress decided that the public should be able to request records containing government information and go to court if the records are not provided.[179] Similarly, the IQA should be viewed as a related law that allows the public to ensure that government information is correct and go to court in the same manner allowed by FOIA. In terms of the alleged IQA burden, in fiscal year 2018, there were 863,729 FOIA requests (a record high).[180] The highest number of annual IQA requests (from fiscal years 2003–2015) was just forty-

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[174] 5 U.S.C. § 704 (2020).

[175] OFFICE OF MGMT. & BUDGET, *supra* note 149.

[176] Kogan, *supra* note 94, at 25 (n.300 citing June 10, 2002 memo).

[177] For the IQA administrative mechanisms, there should not be obstacles as to who should be able to bring a request for correction (and appeal). The law does say it applies to "affected persons," but this language, at least generally, has not served to block IQA requests for correction. If a party wants to bring an IQA action in court challenging a final agency action, Congress should make it possible to the greatest extent allowable under law for parties to bring those actions.

[178] Regulatory Accountability Act of 2017, H.R. 5, 115th Congress (2017).

[179] U.S. Dep't of Justice, *FOIA*, https://www.justice.gov/archives/open/foia [https://perma.cc/B2Q9-NUWE] (last visited May 26, 2020); U.S. Dep't of Justice, *Freedom of Information Act Statute*, https://www.foia.gov/foia-statute.html [https://perma.cc/4TB9-YDAE] (last visited May 26, 2020).

[180] OFFICE OF INFO. POLICY, U.S. DEP'T OF JUSTICE, SUMMARY OF ANNUAL FOIA REPORTS FOR FISCAL YEAR 2018 2, https://www.justice.gov/oip/page/file/1170146/download [https://perma.cc/E4PU-UQKK].

eight (in 2003).[181] The FOIA fiscal year 2018 number is about 18,000 times greater than the highest IQA year.[182]

2. The Nature of the Reviews and Remedies

There are many IQA issues that courts would be able to easily resolve, especially if OMB creates the clear requirements described in this Article. A court is more than capable of determining, for example, whether an agency met objective peer review requirements or whether a scientific assessment automatically triggers the highly influential scientific assessment designation.[183]

Courts will have to make some subjective decisions, such as reviewing whether disseminated information meets IQA quality requirements, such as for "objectivity" (e.g., accuracy and reliability). Judges should not be developing policy themselves and the IQA should not be a law to second-guess policy decisions. However, it should be a law that ensures agencies reached their conclusions in an appropriate manner. This could include assessing whether agencies have drawn conclusions that are reasonably supported by the evidence. This might be akin to requiring that the agency has substantial evidence to support its decision.[184]

If a court has decided that an IQA request for correction was improperly denied, a court should direct the agency to take action to correct the information consistent with the IQA. This might mean going back and conducting proper peer review on a study or simply correcting incorrect information in government documents. The remedy issue would be more complex when a court has been asked to review an IQA challenge in the context of a rulemaking.

For IQA violations where correction undermines the key justification for the rule, a court should remand the rule to the agency, and vacate it pending remand. This is appropriate given the rule might not even exist if there had been proper peer review.[185] In general, though, most IQA violations, especially by themselves, should not lead to such significant outcomes. After all, a party seeking correction of government information disseminated in connection with a rulemaking may be focused solely on that information and may not have any objection to the associated rule.

This interplay between the review of IQA issues and the review of regulations relates to another critical point. OMB has allowed agencies to review IQA requests for

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[181] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-110, INFORMATION QUALITY ACT: ACTIONS NEEDED TO IMPROVE TRANSPARENCY AND REPORTING OF CORRECTION REQUESTS (Dec. 2015); OFFICE OF MGMT. & BUDGET, OFFICE OF INFO. & REGULATORY AFFAIRS, https://www.whitehouse.gov/omb/information-regulatory-affairs/reports/#ORC [https://perma.cc/D5E5-KNUF] (last visited Aug 31, 2020).

[182] The number of requests by itself is not necessarily a complete measure of the burden imposed on agencies by FOIA requests and IQA requests. The time involved in responding to requests also would play a role. While FOIA requests require agencies to find and disclose records, which may seem simpler than correcting information, identifying the location of numerous records is not as easy a task and there are legal questions the agency must consider when determining whether records even have to be disclosed (the IQA also poses legal questions). IQA requests for correction often involve fairly straightforward changes and the affected person making the request is expected to identify where the changes should be made (the agency does not have to do a search like with FOIA). Even when an agency is asked to correct more complicated issues, the agency should already have a basis for why it decided to disseminate the information in the first place. By creating more objective IQA requirements, this should also help speed up the request process.

[183] The automatic trigger is one of the recommendations in this Article.

[184] Substantial evidence means "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *See, e.g.*, Richardson v. Perales, 402 U.S. 389, 401 (1971).

[185] Kelly, Jr., *supra* note 94, at 90–91.

correction of information associated with the rulemakings within the notice and comment process for the rulemaking rather than via an independent IQA process.[186] This creates numerous problems, including burying the distinct IQA issue within a much larger rulemaking and agencies having even more incentive to reject the requests since they could undermine the promulgation of a rule.[187] OMB should revise its Guidelines to require IQA challenges to government-disseminated information associated with rulemakings to be considered under the normal IQA correction process, independently from the rulemaking process.[188] This would also increase the likelihood that different courts would review the IQA issues and the rule itself.[189]

C. Strengthening Reporting Under the IQA

The IQA does not require OMB to update Congress on the IQA, although OMB, to its credit, has provided IQA data to Congress in its annual reports to Congress on the costs and benefits of regulations. OMB, though, has not been consistent in developing these reports. The most recent finalized report (and the last report with IQA data) is the "2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act."[190] This report was released in December 2019. Prior to that report, the last finalized report (and previous report with IQA data) was the "2015 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities."[191]

Congress should require OMB to provide annual updates to Congress on the IQA. OMB and federal agencies should also be required to make IQA data easily accessible to the public. If the public does not know about the IQA or how it works, then the law is not going to be used to its fullest potential.

The current OMB website does not appear to have a page that provides links to the different agency IQA websites.[192] An older OMB page from the Obama

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[186] *See* OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, MEMORANDUM FOR THE PRESIDENT'S COUNCIL: INFORMATION QUALITY GUIDELINES – PRINCIPLES AND MODEL LANGUAGE (Sept. 5, 2002), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/pmcmemo.pdf [https://perma.cc/7VJZ-JF2D].

[187] In addition to these problems, waiting on a rulemaking may unnecessarily delay evaluating whether disseminated information meets IQA requirements, and it appears that utilizing such an approach might allow an agency to avoid the appeal process that should exist for IQA requests for correction.

[188] For a good discussion of this issue, see Conrad, *supra* note 35, at 539–45.

[189] If there is a timing issue, it might be appropriate for the court reviewing the rule to also review an IQA challenge that affects the rule being reviewed. In that situation, the IQA challenge should still be treated distinctly from the overall regulatory challenge. The Bulletin requires that a certification be included in the administrative record explaining how the agency complied with IQA requirements for influential scientific information and highly influential scientific assessments. In this situation, a court reviewing a rule and the administrative record should still ensure that compliance with these IQA requirements is independently considered.

[190] OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, 2017 REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT (2017), https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf [https://perma.cc/F89K-HC3F].

[191] *See* OFFICE OF MGMT. & BUDGET, OFFICE OF MANAGEMENT AND BUDGET REPORTS, https://www.whitehouse.gov/omb/information-regulatory-affairs/reports/#ORC [https://perma.cc/E2AY-S7DU] (last visited Apr. 27, 2020). The 2016 and 2017 draft reports do not contain IQA data.

[192] OFFICE OF MGMT. & BUDGET, OFFICE OF MANAGEMENT AND BUDGET, https://www.whitehouse.gov/omb/ [https://perma.cc/SRK4-ZSH6] (last visited Apr. 27, 2020).

Administration does have a list of links to agency IQA pages.[193] However, of the fifty-eight links for agency IQA correspondence, twenty-four of those links were broken, and six additional links did not go to an IQA page.[194] The current OMB website also does not appear to include many IQA-related guidance documents, although they can be found on an older OMB page from the Obama Administration.[195]

OMB and agency websites should feature a prominent link to an IQA page on their home pages. These IQA pages should provide background on the IQA, including an agency's own guidelines, a clear explanation of how to submit a request for correction and appeal, and a list of past requests that have been submitted to the specific agency. Many agencies in fact do provide this information to some extent,[196] although it is generally difficult to find.

VIII. CONCLUSION

Strengthening the IQA might, on balance, create some additional requirements for federal agencies and OMB. Even if true, agency efficiency should not come at the expense of accurate government-disseminated information. These requirements could also create a more deliberative rulemaking process. That is not a flaw, but a feature of developing policy supported by quality information. If there is an arduous process for legislation, which was the goal of the framers of the U.S. Constitution, then it should not be too much of a burden to simply make sure agencies do not disseminate or use flawed information that can have a major negative impact on Americans.

Unfortunately, to date, there has not been the means to effectively ensure the accuracy of federally disseminated information across the government. The IQA can be effective, but it must be implemented and strengthened in a manner that will allow it to achieve its potential. Both OMB and Congress need to make this happen.

Federal agencies, when they speak on an issue or formulate public policy, need to get things right. There is too much at risk when they fail to do so. Misinformation and poorly considered policies based on misinformation can take the country down the wrong path. On public health issues, these wrong paths can have dire consequences.

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[193] OFFICE OF MGMT. & BUDGET, AGENCY INFORMATION QUALITY GUIDELINES, https://obamawhitehouse.archives.gov/omb/inforeg_agency_info_quality_links/ [https://perma.cc/RH5R-J6LE] (last visited Apr. 27, 2020).

[194] The calculations were based on going through the links on Office of Mgmt. & Budget, *Agency Information Quality Guidelines*, https://obamawhitehouse.archives.gov/omb/inforeg_agency_info_quality_links/ [https://perma.cc/RH5R-J6LE] (last visited Aug. 31, 2020).

[195] Office of Mgmt. & Budget, *Office of Management and Budget*, https://www.whitehouse.gov/omb/ (last visited Apr. 27, 2020) [https://perma.cc/SRK4-ZSH6]; Office of Mgmt. & Budget, *Information Policy*, https://obamawhitehouse.archives.gov/omb/inforeg_infopoltech [https://perma.cc/N36W-MVYM] (last visited May 26, 2020).

[196] The following comes from an older OMB page, Office of Mgmt. & Budget, *Agency Information Quality Guidelines*, https://obamawhitehouse.archives.gov/omb/inforeg_agency_info_quality_links/ [https://perma.cc/RH5R-J6LE] (last visited Apr. 27, 2020).

Figure 3: Glossary of Terms from the OMB Guidelines

Term	**Definition from OMB Guidelines Regulatory Text (except where noted)**
Agency initiated distribution of information to the public*	Information that the agency disseminates, e.g., a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory or other action. In addition, if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines. *Author comment: This definition does not prevent federal employees, grantees, or contractors from publishing their research findings so long as there is a disclaimer clarifying that the information does not reflect the views of the agency.*[197]
Agency sponsored distribution of information to the public*	Situations where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release. *Author comment: If the third party, not the agency, decides whether to disseminate the information and the content and presentation of any dissemination, then this would not be considered agency-sponsored distribution of information. The third party is expected to include a disclaimer that clarifies the information does not reflect the views of the agency. If the agency later disseminates the information, then it would be subject to IQA requirements.*[198]

[197] As explained in the definition, "By contrast, an agency does not 'initiate' the dissemination of information when a Federally employed scientist or Federal grantee or contractor publishes and communicates his or her research findings in the same manner as his or her academic colleagues, even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency agrees with the information (and is therefore disseminating it through the employee or grantee), the researcher should include an appropriate disclaimer in the publication or speech to the effect that the 'views are mine, and do not necessarily reflect the view' of the agency."

[198] The rest of the definition states: "Therefore, for example, if an agency through a procurement contract or a grant provides for a person to conduct research, and then the agency directs the person to disseminate the results (or the agency reviews and approves the results before they may be disseminated), then the agency has 'sponsored' the dissemination of this information. By contrast, if the agency simply provides funding to support research, and it is the researcher (not the agency) who decides whether to

Dissemination	Agency initiated or sponsored distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas, or adjudicative processes.[199]
Government information	Information created, collected, processed, disseminated, or disposed of by or for the Federal Government.
Information	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. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.
Influential when used in the phrase 'influential scientific, financial, or statistical information'	The agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Each agency is authorized to define 'influential' in ways appropriate for it

disseminate the results and—if the results are to be released—who determines the content and presentation of the dissemination, then the agency has not 'sponsored' the dissemination even though it has funded the research and even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency is sponsoring the dissemination, the researcher should include an appropriate disclaimer in the publication or speech to the effect that the 'views are mine, and do not necessarily reflect the view' of the agency. On the other hand, subsequent agency dissemination of such information requires that the information adhere to the agency's information quality guidelines. In sum, these guidelines govern an agency's dissemination of information, but generally do not govern a third-party's dissemination of information (the exception being where the agency is essentially using the third-party to disseminate information on the agency's behalf). Agencies, particularly those that fund scientific research, are encouraged to clarify the applicability of these guidelines to the various types of information they and their employees and grantees disseminate."

[199] This definition includes this language: see 5 C.F.R. § 1320.3(d) (2020) (definition of "Conduct or Sponsor")).

	given the nature and multiplicity of issues for which the agency is responsible.
Information dissemination product	Any books, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or web page.
Integrity	The security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.
Objectivity	Involves two distinct elements, presentation, and substance. a) 'Objectivity' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context.[200] b) In addition, 'objectivity' involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.[201]
Quality	An encompassing term comprising utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms, collectively, as 'quality.'
Reproducibility	The information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to

[200] The remainder of this presentment requirement reads: "Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users."

[201] There are subsections further clarifying the accuracy requirement, covering issues such as external peer review, reproducibility, and transparency.

	specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (e.g., standards for replication of laboratory data). With respect to analytic results, "capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.
Utility	The usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.

Note: The definitions are from the regulatory text of the OMB Guidelines, except where the definition is only included in the preamble. This is indicated with a *.

Figure 4: Glossary of Key Terms from the OMB "Final Information Quality Bulletin for Peer Review"

Term	**Definition from OMB Bulletin Regulatory Text**
Influential scientific information	Scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.
Scientific information	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. This definition includes

	information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes clear that what is being offered is someone's opinion rather than fact or the agency's views.
Scientific assessment	Evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.
Highly influential scientific assessment	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.

Note: The definitions come from the OMB Bulletin's regulatory text. There are other definitions, but this glossary covers definitions of terms not already defined in the OMB Guidelines.[202]

[202] The definition of dissemination is consistent with the OMB Guidelines but includes some additional details: "[T]he term 'dissemination' means agency initiated or sponsored distribution of information to the public (*see* 5 C.F.R. § 1320.3(d) (2020) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term 'dissemination' also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: 'THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PREDISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY]. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY.' For the purposes of this Bulletin, 'dissemination' excludes research produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if that information does not represent the views of an agency. To qualify for this exemption, the information should display a clear

disclaimer that 'the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency.'"