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BACKGROUNDER

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Promoting Transparency in Federal Agencies' Use and Dissemination of Science

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KEY TAKEAWAYS

Science helps to provide the underlying rationale for federal regulations that affect the lives of all Americans.

Stronger transparency requirements for federal agencies' use of science will provide much-needed accountability in policymaking and uphold democratic principles.

The Trump Administration should implement government-wide transparency requirements for agency use of science and Congress should codify key requirements.

Science plays a critical role in the policy work of federal agencies.[1] When federal agencies issue regulations, science often helps to provide the underlying rationale and scope for these laws that affect the lives of all Americans.

Even when a federal agency merely disseminates scientific information, it can have a major impact, as the imprimatur of the federal government carries significant weight. For example, the results of a single federal scientific study may be widely disseminated in media reports shaping public opinion, or be used by other federal agencies in their rulemakings.[2]

It therefore is critical that federal agencies properly use science in policymaking and when disseminating scientific information. In a 2009 memorandum on scientific integrity, President Barack Obama explained, "The public must be able to trust the science and scientific process informing public policy decisions."[3] He

was right. It is also important that the science and the scientific process are, in fact, deserving of the public's trust.

For agency science to deserve this trust, there must be transparency in how federal agencies utilize the science.[4] This Backgrounder discusses numerous issues that should be addressed to promote transparency in federal agencies' use of science.[5]

What Is Transparency?

The term "transparency" is commonly used when discussing the work of the government, but there is no clear and objective definition of what "transparency" means. A 2012 Congressional Research Service (CRS) report[6] on transparency in the executive branch examined this issue:

> [T]here is no single definition of what constitutes transparency or method for measuring it. For the purposes of this report, transparency comprises not only the disclosure of government information, but also the access, comprehension, and use of this information by the public. Transparency, as such, requires a public that can acquire, understand, and use the information that it receives from the federal government. This concept of transparency, however, is not the only possible designation of the term.[7]

The CRS report highlights other definitions that include "the publicizing of incumbent policy choices,"[8] and "the availability and increased flow to the public of timely, comprehensive, relevant, high-quality and reliable information concerning government activities."[9] All of these definitions help to capture what is meant by transparency.

Quite simply, when the federal government uses or disseminates science, the public should be able to know the details of this science and have the necessary information to evaluate and test it, receive accurate information about the science, and have ways to challenge and correct the science.

To aid in the discussion of this broad topic, this *Backgrounder* divides[10] transparency into the following five categories:

1. Public availability of the science;

2. Reproducibility and validation of the science;

3. Distinction between science and policy;

4. Proper characterization and presentation of the science; and

5. Meaningful public participation that allows a voice in the use and dissemination of the science.

The Importance of Transparency

Before examining transparency issues, it is helpful to recognize why transparency in general is so important. Transparency is a fundamental requirement for the work of federal agencies, including the rulemaking process.

Consistent with the nation's democratic principles, agency bureaucrats are not authorized to develop whatever policies they desire. Federal agencies must have statutory authority for their actions, comply with various process requirements, and conduct their work in an open manner that involves the public.[11]

For example, the Administrative Procedure Act of 1946 is the primary law governing the federal regulatory process.[12] This law promotes transparency in the rulemaking process by establishing processes that require public notice and opportunities for public participation.

Through a transparent system, the public can help to provide a much-needed check on agency officials and their broad policymaking. This helps the members of the public by ensuring that they have a voice in the process and can evaluate how agencies have reached certain conclusions. However, it also benefits the agencies themselves. Public feedback, including from top scientists, can provide insight and useful criticism that can better inform the science, and as a result, help to formulate better policy.

Further, just as it is difficult to remove regulations once they are on the books, it is also difficult to challenge the underlying science that provide justification for those regulations. The agencies have a self-interest to protect this science that can quickly become entrenched and viewed as conventional wisdom. As a result, agency science is often not susceptible to changes to reflect new understanding. Instead, it often reflects the science that has existed to serve the agency's policy agenda for years.

This need for transparency is especially important because Congress delegates too much power to federal agencies. In fact, much of the lawmaking reserved to Congress is arguably exercised by the agencies themselves. As a result, unelected and generally unaccountable agency officials are, in fact, creating laws, as opposed to merely implementing the will of Congress.

While more transparency will not offset the harm resulting from unlawful or excessive delegation of power that undermines representative government, it can instill some democratic principles into federal rulemaking that can help to mitigate the harm.

I. Public Availability of the Science

A primary way to ensure transparency is to make the science available to the public. This does not merely include the underlying studies. It also includes any data, assumptions, computer code, or other relevant material that the public could use to properly evaluate the science.

Federal agencies should inform the public in a clear fashion which science has been used in any of its decision making. This includes explaining why some studies were chosen while other reliable studies were excluded. Agencies should not be able to, inappropriately, limit the studies that they consider when reaching conclusions. By providing the public a comprehensive picture of the applicable science on a specific issue, and identifying and explaining the decisions that went into deciding the best available science, the agencies are less likely to cherry pick results.

These requirements should not be controversial. In congressional testimony, former senior Environmental Protection Agency (EPA) official Jeff Holmstead correctly explained: "I don't think anyone can object to the basic premise that scientific information used to support regulatory actions should be made public."[13]

Yet, critics of EPA and congressional efforts to promote transparency at the EPA have used narrow concerns as a way to discredit the overall efforts to promote transparency. These concerns, to the limited extent they exist, such as potential improper disclosure of personally identifiable information or confidential business information (such as trade secrets), are solvable.

They are certainly not an excuse to ignore the basic premise that scientific information needs to be made available to the public. The redaction of information, for example, is one way of addressing the improper disclosure of personally identifiable information or confidential business information.

These concerns can also be overstated. In its 2013 report on the use of science in regulation, the Administrative Conference of the United States addressed the exaggerations that can occur in the context of confidential business information.[14] The report recommended:

> Agencies that provide CBI [confidential business information] protections for studies or data that inform regulation should ensure that the CBI claims

> are justified. Given the strong incentives to regulated parties for overclaiming CBI protection and the resultant costs from this overclaiming to public health protection and research, it is important that the agencies' CBI programs not provide a safe haven for unjustified suppression of relevant regulatory research. To that end and as a first step, the agencies should review their CBI programs to ensure that there is rigorous oversight of CBI and related trade secret claims on health and environmental research. Agencies should, where possible, penalize those CBI claims that, upon review, appear unjustified.[15]

Privacy and confidentiality protections should be respected. However, these protections should not be abused to block the disclosure of information that can be made available in a manner compliant with the law.

II. Reproducibility and Validation of the Science

The science should be available to the extent that it can be fully evaluated and validated.[16] This means being able to determine whether scientific findings are the results of sound methodology and assumptions. It also means, in part, that the public should have the necessary information to reproduce the results of studies used by the agencies. Reproducibility is critical in science. As explained in the *Scientific American*:

> Scientific ideas that are true should be reproducible: other researchers should be able to repeat the experiments and get similar results or use other methods to arrive at the same conclusions. You can't say that you discovered something new if someone else can't reproduce your result.[17]

Concerns over reproducibility in the science used by agencies is even more pronounced because there is major concern that a reproducibility crisis currently exists in science.[18] A 2016 *Nature* survey found that 52 percent of researchers surveyed agreed that there was a significant crisis of reproducibility, 90 percent of the respondents agreed that was either a significant or slight crisis, and only 3 percent said there was no crisis.[19] 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."[20]

While reproducibility is important, this does not mean that legal and privacy protections should be violated.[21] It also does not mean that the public must be able to do the impossible, such as replicate the exact results of a study when those results are unique to a particular time and place, including

replicating rare events, such as disasters.[22] An expectation of reproducibility does not mean common sense is thrown out the window.

In general, the public should have the information necessary to independently evaluate and validate the merits of a study consistent with what is in fact necessary and feasible to conduct such an evaluation.

Some assert that journal peer review processes are sufficient to protect the public's interest in ensuring the credibility of the science that is used by agencies.[23] But these peer review processes have significant problems and there can be a big difference in the quality of the peer review processes across journals.[24] In addition, the independence of peer review is not something that can merely be assumed, especially when many of the peers could be close colleagues.

Concern over peer review is not just about independence or quality, but also about its limitations. George Wolff, a former chairman of the EPA's Clean Air Scientific Advisory Committee has explained:

> In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science [the proposed EPA rule], will provide an opportunity for such evaluations.[25]

There seems to be an assumption, at least by some, that the agencies and scientific sources should be trusted without question. This notion completely ignores basic democratic principles. It is one thing when the peer review process is used for strictly academic purposes, but once studies are used by federal agencies, often as the basis for public policies that have serious real-world impacts on the lives of Americans, protections must exist to preserve these important democratic principles.[26]

Some critics of transparency efforts have tried to suggest that they are simply means to block certain science from being utilized by agencies, including the best available science.[27] To the extent the critics are referring to flawed science, they would be correct. Transparency efforts are designed to help ensure that the best available science is appropriately employed by federal agencies. Requirements, such as reproducibility, are not obstacles to the use of the best available science, they are the means necessary to ensure the use of the best available science.

III. Distinction Between Science and Policy

Science does not answer policy questions. Science can inform policy decisions by providing answers to objective questions, without making value judgments. Policy decisions, though, require value judgments and subjective decision making. For example, science can inform policymakers about the likelihood that a product may cause harm to humans, but it does not answer the inherent value question about what constitutes an acceptable level of risk.

There is also a flawed assumption that scientists only answer science questions and that their conclusions will be independent of personal opinion. They may use a scientific process and the guise of science to actually conduct policy analysis with policy conclusions, or allow their own beliefs to inappropriately influence what are supposed to be scientific conclusions.

As just one example, ideological preference played such a prominent role during the 2015 federal Dietary Guidelines for Americans process that it veered the entire "scientific" process off mission. The Dietary Guidelines Advisory Committee (DGAC) was working on recommendations to provide to the Departments of Agriculture (USDA) and Health and Human Services (HHS).[28] Instead of focusing on dietary and nutritional factors, the DGAC started to work on climate change and environmental sustainability. As a result, the legitimacy of their nutritional recommendations were undermined by allowing their environmental policy preferences to influence their work.[29]

Susan Dudley, director of the GW Regulatory Studies Center, explained concerns over the conflating of science and policy in 2017 congressional testimony:

> It is this tendency to "camouflag[e] controversial policy decisions as science" that Wendy Wagner called a "science charade" and it can be particularly pernicious. For instance, a 2009 Bipartisan Policy Center (BPC) 2009 report, Improving the Use of Science in Regulatory Policy, concluded that "a tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today." Both of these problems, hidden policy judgments and the science charade, can be the result of officials falling prey to the "is-ought fallacy": incorrectly mixing up positive information about what "is" with normative advice about what "ought to be."[30]

The EPA regulatory process defining "waters of the United States" (WOTUS) under the Clean Water Act (CWA) provides just one example

of an agency using science to improperly legitimatize its policy choices. In 2014, when the EPA proposed its WOTUS definition rule (defining which waters can be regulated under the CWA), the agency stressed that the rule was informed by science.

The EPA developed a report called the "Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence."[31] In January 2015, the EPA announced the release of this final report in a fact sheet.[32] The end of the document states: "Now final, this scientific report can be used to inform future policy and regulatory decisions, *including the proposed Clean Water Rule* being developed by EPA's Office of Water and the U.S. Army Corps of Engineers."[33] (Emphasis added.)

There was a problem, though. This scientific report was finalized *after* the proposed rule was published. As a result, the proposed rule was not informed by the report, and the public ended up providing comments on a proposal that did not take into account the "scientific basis needed to clarify CWA jurisdiction," as the EPA explained was a purpose of the report.[34]

The EPA appeared to be using the scientific report as a way to create improper scientific legitimacy to the proposed rule, giving its policies a stamp of scientific approval.

Conflating science and policy certainly can involve improper agency actions. However, it is also extremely important that Congress not make similar mistakes by asking agencies to answer "science" questions that are, in fact, policy questions or that are impossible to separate from policy considerations.

For example, the decision to classify a species as threatened or endangered under the Endangered Species Act (ESA) should be based solely on the science, but currently these classification decisions can trigger regulatory requirements that will involve policy considerations. To promote and ensure purely scientific analysis, any decision on whether a species is threatened or endangered should be decoupled from any analysis of which policy steps, if any, should be taken. By keeping science and policy separated for the ESA, and across the board, the science used or disseminated by agencies is more likely to be genuinely based on science, and not on the conscious or subconscious policy concerns of agency officials.[35]

IV. Proper Characterization and Presentation of the Science

Even when the federal government does properly distinguish between science and policy, it too often presents this science in an inaccurate or misleading manner.

Credibility of Science. When federal agencies use and disseminate science, the accuracy of that science should be a priority. When certain important procedural steps are required, it is more likely that the public can have confidence in the science that the government disseminates to the public.

One important procedural step is to ensure the independence and objectivity of the science. When selecting reviewers of the science, the government can help to ensure this independence and objectivity by selecting individuals who do not have conflicts of interest. The National Academies conflict of interest policy states: "[T]he term 'conflict of interest' means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization."[36]

The National Academies conflict of interest policy also includes additional points, such as:

- "The term 'conflict of interest' applies only to current interests. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior";[37]

- "The term 'conflict of interest' applies not only to the personal financial interests of the individual but also to the interests of others with whom the individual has substantial common financial interests if these interests are relevant to the functions to be performed";[38] and

- "[A]n individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work, or that of his or her immediate employer, is the central purpose of the activity, because that would constitute a conflict of interest, although such an individual may provide relevant information to the program activity."[39]

These are important considerations, but the entire issue of how to address conflicts of interest is very complicated. Bias can exist in numerous ways that may not be evident. Further, conflict of interest policies themselves could lead to biased outcomes based on selection criteria that favor or disfavor individuals. This is yet another reason why it is so critical that the public have access to the science, as well as a means to evaluate and address the science. Too much focus on the messengers can also be a distraction from what is ultimately the key issue: What is the message?

There should be skepticism of the government science regardless of the strength of conflict of interest policies, the evaluation by the "experts," and the types of studies used in drawing conclusions. The only way to remove this skepticism is for the public to provide the necessary check on the science.

One important way to provide this check is to remove questionable assumptions about science that are entrenched across the board into the work of federal agencies. For example, the linear no-threshold (LNT) model is an assumption that has been employed throughout the federal government without regard for differences across scientific fields, even as evidence counters this assumption.

In very simple terms, the LNT model assumes that there is no safe level of exposure to a chemical or other alleged hazard. If a chemical is harmful at a high exposure, the LNT model assumes that the chemical is also harmful at a low level. The Heritage Foundation's *Environmental Policy Guide* explains why the LNT assumption is inaccurate: "There are always thresholds at which any chemical can pose a health risk, and smaller exposures at which toxic effects do not exist. In many cases, very low exposures may actually produce benefits."[40]

In an article on the LNT model and radiation in the peer-reviewed journal *Dose-Response,* authors John Cardarelli and Brant Ulsh, explain:

> The current [EPA] policy takes the position that the LNT model is accurate unless "compelling evidence to the contrary" is presented. This approach is included in the agency's guidelines that direct the use of the LNT even if the scientific evidence cannot substantiate that conclusion. This is a circular argument that excludes the option of other alternative models from being considered.[41]

This approach is exactly the opposite of what should occur in agency science, especially when promoting transparency. Broad sweeping assumptions that are not even open to challenge should not exist in agency science. It very well may be true that the LNT model could be accurate in a specific situation, but the onus should be on the federal government to demonstrate that science supports this conclusion. If nothing else, there should not be an assumption one way or another.

When science is being used and disseminated, the government should not be able to simply point to some level of agreement among various scientific bodies or old conclusions that have become conventional wisdom. This is not to say that this information has no value, but testing and challenging the science should be the norm. The focus should be on what the

science actually says (and does not say), not merely relying on the conclusions drawn by so-called experts. Overreliance on old data and outdated assumptions ignores new scientific understanding and breakthroughs and makes it less likely that the best available science will be used by agencies.

Accurate Communication of the Science. Often, it is not just a question of the merits of the science itself or how the science was conducted, but how the scientific findings are communicated to the public. The following provide examples of how two of the leading agencies disseminating critical public health and safety information, the Food and Drug Administration (FDA) and the EPA, have disseminated information about the science that is either inaccurate or misleading:

In 2013, the FDA proposed its de facto ban on artificial trans fat.[42] In helping to make its case for this action, the FDA cited a Centers for Disease Control and Prevention (CDC) study (or what it claimed was a CDC study).[43] The proposed regulatory action asserted:

> 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.[44]

The study, though, was not a CDC study, and the CDC did not make any of the estimates that the FDA had widely promoted. Two authors who worked at the CDC published a study in the *Journal of the American Medical Association* in which they made the estimates.[45] The end of the published study expressly states: "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."[46]

This was not a minor error. The FDA was incorrectly claiming the data was from a CDC study, thereby improperly giving the data much greater legitimacy due to the imprimatur of the government. This characterization of the data as coming from the CDC affected public perception. Had it been made clear to the public that the study was not a CDC study, it is less likely that the FDA would have used it as a major justification for its de facto ban. It also would have weakened its case for such a drastic change to the food supply.[47]

The EPA has also disseminated misleading information about science to the public, such as for its proposed 2015 ozone standard. To sell a more stringent ozone standard, the EPA listed a series of alleged facts in its "By

the Numbers" document[48] to persuade the public to believe that a more stringent standard was necessary. For example, according to the EPA, setting the ozone standard to between 65 parts per billion and 70 parts per billion would avoid:

- 65,000 to 180,000 missed work days, and
- 790 to 2,300 cases of acute bronchitis among children.[49]

This information was misleading, at best. Both of these alleged facts are based on reductions in fine particulate matter ($PM_{2.5}$) alone, not ozone. The public was being led to believe that reducing ozone achieves these health benefits. In reality, these benefits had nothing to do with a reduction in ozone.[50]

Federal agencies should portray the science accurately, and not play fast and loose in presenting the findings to achieve agency objectives. It should not be difficult for an agency to properly attribute authorship or provide relevant context so that the public is not left with a misimpression about the science.[51]

A significant part of this problem is likely connected to the desire of agencies to go overboard in pushing their policy agendas.[52] There is nothing wrong with an agency communicating its rationale for its proposals, but in doing so, it should be cognizant of the fact that the agency is, rightly or wrongly, considered a reliable and objective source. Agencies should not take actions that threaten the legitimacy that the public often assumes is connected with government information.

V. Meaningful Public Participation

Meaningful public participation is critical to transparency. This public role reflects important democratic principles and is a central aspect of the agency decision-making process. In order to have this meaningful level of participation, agencies should provide the necessary information in an accurate and understandable fashion. The main requirement, though, is for the public to have a direct voice in how the science is used and disseminated, and to be able to influence the science in a way that ensures its legitimacy.

Agencies try to take away this voice, such as when they inappropriately use regulatory guidance instead of conducting a proper rulemaking on issues that make substantive changes to the law.[53] This voice can also be silenced when agencies engage in what is known as "sue and settle."

Sue and Settle. It is impossible for the public to have a meaningful voice when it is excluded from the rulemaking process. This is what happens through the "sue and settle" process. In general, sue and settle refers to a party suing, and then settling with, the government in order to compel the government to take action allegedly required by law. This may sound innocent enough, but in reality, this can lead to behind-the-scene policymaking and rushed rulemakings in order to get around the usual procedural requirements. This way, the public's voice on the science can effectively be silenced.

The case of the Hine's emerald dragonfly provides a good example of how sue and settle can work. As explained by the U.S. Chamber of Commerce:

> In 2008, environmental advocacy groups sued FWS [Fish and Wildlife Service] to protest the exclusion of 13,000 acres of national forest land in Michigan and Missouri from the final "critical habitat" designation for the endangered Hine's emerald dragonfly under the Endangered Species Act. Initially, FWS disputed the case; however, while the case was pending, the new [Obama] administration took office, changed its mind, and settled with the plaintiffs on February 12, 2009. FWS doubled the size of the critical habitat area from 13,000 acres to more than 26,000 acres, as sought by the advocacy groups. Thus, FWS effectively removed a large amount of land from development without affected parties having any voice in the process. Even the federal government did not think FWS was clearly mandated to double the size of the critical habitat area, as evidenced by the previous administration's willingness to fight the lawsuit.[54]

The Fish and Wildlife Service's settlement may have led to a critical habitat area that was not substantiated by the science. If so, any property-use restrictions on the newly designated land was unnecessary, and likely imposed significant economic costs. Regardless, the public had no meaningful voice in the process, nor the chance to evaluate and provide public feedback on the science.

Information Quality Act (IQA). One of the best ways to promote public trust in the science and the scientific process is to allow the public to have a means to directly challenge the science. The 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.[55]

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."[56] The IQA can help to ensure the accuracy of the information disseminated and promote transparency of the science used by agencies.

Unfortunately, the potential of the IQA to promote sound science has been undermined by insufficient agency accountability and judicial decisions holding the IQA does not authorize judicial review.[57] There need to be teeth put into IQA enforcement. This would involve requirements that agencies respond thoughtfully and in a timely manner to public requests under the IQA.[58] There should also be judicial review to ensure, in part, that agency science meets the established IQA guidelines, especially when informing policy decisions.

Recommendations

There have been recent efforts to promote transparency in federal agency use of science, but the primary focus has been on improving transparency only at the EPA. In 2018, the EPA published a proposed rule entitled "Strengthening Transparency in Regulatory Science."[59] In 2017, the House passed the HONEST Act.[60] Both of these measures, among other things, would have improved public access to the science.

These are important efforts, but there need to be major steps to promote transparency across the federal government. President Barack Obama did issue the above-referenced memorandum on scientific integrity in 2009; the memorandum is very broad, though, and only touches upon the importance of transparency. Much more is needed.

The Trump Administration should develop an executive order[61] that provides specifics to guide the agencies and directs them to issue regulations to implement these requirements. Congress should codify key transparency requirements into law.

Public Availability of the Science. Federal agencies should:

- Make the science they disseminate or use in policymaking available to the public.
- Include any data, assumptions, computer code, or other relevant material for the public to properly evaluate the science.
- Inform the public in a clear fashion which science has been used in any of their decision making. This includes explaining why some studies were chosen while other reliable studies were excluded.
- Take appropriate steps to prevent improper disclosure of personally identifiable information or confidential business information.

- Ensure that privacy and confidentiality concerns are not abused to block the disclosure of information unnecessarily.

Reproducibility and Validation of the Science. Federal agencies should:

- Provide the public with the information that is necessary to independently evaluate and validate the merits of a study.
- Provide the public with the necessary information to reproduce the results of studies used by the agencies.
- Recognize the wide problem of reproducibility in science generally, and ensure that the problem does not undermine agency use of science.
- Promote reproducibility to the greatest extent possible, recognizing that this does not mean the public must be able to do the impossible, such as replicate the exact results of a study when those results are unique to a particular time and place.
- Recognize that academic peer review processes are insufficient to protect the public's interest in ensuring the adequacy of the science that is used by agencies, especially given the numerous problems with academic peer review.

Distinction Between Science and Policy. Federal agencies should:

- Ensure that science is not conflated with policy.
- Develop protections so that scientists charged with providing scientific analysis for the agency only answer science questions, and that their conclusions are independent of personal opinion.
- Keep scientific advisory boards focused on their scientific responsibilities.
- Draw clear lines between science and policy analysis. (This also applies to Congress in what it expects agencies to do.)

Proper Characterization and Presentation of the Science. Federal agencies should:

- Develop strong conflict of interest policies, recognizing that any such policies themselves should be free of bias.
- Remove questionable assumptions about science that are entrenched in the work of federal agencies, including the assumption that the LNT model is accurate unless shown otherwise. (The burden should be the other way around.)
- Make the testing and challenging of the science the norm.
- Consider new scientific understanding and breakthroughs without defaulting to old data and outdated assumptions.
- Attribute authorship of studies properly and do not mislead the public about scientific conclusions.
- Do not exaggerate the science to help justify agency proposals; be cognizant of the fact that the agency is considered a reliable and objective source (rightly or wrongly).

Meaningful Public Participation that Allows a Public voice in the Use and Dissemination of Science. Federal agencies should:

- Recognize and embrace the fact that meaningful public participation in the agency's use and dissemination of the science is a fundamental democratic principle.
- Conduct notice and comment rulemakings instead of inappropriately using regulatory guidance; this ensures the public has a voice on the issue in question.
- Stop "sue and settle" abuse, which can leave the public out of the rulemaking process.
- Promote ways for the public to have a way of directly challenging the science, such as through the IQA.

- Strengthen the IQA by responding thoughtfully and in a timely manner to public requests under the IQA. (Congress should expressly authorize judicial review to ensure, in part, that agency science meets the established IQA guidelines, especially when informing policy decisions.)

Conclusion

Promoting transparency in federal agency use of science will create new requirements that would make it more challenging for agencies to simply adopt whatever science they deem as meeting their needs. To some, these requirements might seem like artificial obstacles blocking agencies from fulfilling their missions. However, these protections are designed to ensure that agencies are, in fact, fulfilling their missions, not developing policy that reflects the interests of agency officials and special interests.

Agencies should have to evaluate the science more carefully. They should not be able to work backwards by identifying desired policy outcomes and then selecting the science that helps to reach those outcomes. Some critics of transparency promotion seem more concerned with efficiency and ease of using desired science. They fail to recognize that this entire transparency discussion is not occurring within the vacuum of a scientific community. Instead, it is occurring within the context of the lawmaking process.

The transparency issue is first and foremost about protecting democratic principles and promoting processes that can instill confidence and trust in the use and dissemination of science by federal agencies. Fortunately, achieving these objectives helps to simultaneously ensure that the best available science is used. Legitimate doubts about agency use of science should begin to be replaced by well-earned trust.

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Endnotes

1. For the purpose of this *Backgrounder*, "science" refers to both natural and social science.
2. Concern over the dissemination of science is not limited to federal studies. When the federal government disseminates any science, especially science on which an agency has relied for a rulemaking, this can have a major impact.
3. Executive Office of the President, "Presidential Memoranda: Memorandum for the Heads of Executive Departments and Agencies 3-9-09," *Federal Register*, Vol. 74, No. 46 (March 11, 2009), p. 10671, https://www.federalregister.gov/documents/2009/03/11/E9-5443/scientific-integrity (accessed October 23, 2019).
4. This *Backgrounder* focuses on how federal agencies use science in rulemaking and in other policy-related matters, along with how federal agencies disseminate scientific information. The terminology "agency use of science" refers to these specific agency issues, not to all aspects of federal science, which are beyond the scope of this *Backgrounder*.
5. There should be transparency in the federal government generally, especially when it comes to rulemaking or information dissemination that can impact policy formulation. This *Backgrounder*, though, is focused on science.
6. Wendy Ginsberg et al., "Government Transparency and Secrecy: An Examination of Meaning and Its Use in the Executive Branch," Congressional Research Service, November 14, 2012, https://fas.org/sgp/crs/secrecy/R42817.pdf (accessed October 23, 2019).
7. Ibid.
8. Ibid., p. 2 (citing Richard W. Oliver, *What Is Transparency?* (New York: The McGraw-Hill Companies, 2004)).
9. Ibid., p. 2 (citing Justin Fox, "Government Transparency and Policymaking," paper for the Midwest Political Science Association Annual Convention, March 14, 2005.
10. There are no clear bright lines between these categories; there will be overlap. These categories are also not all-encompassing, but simply help to organize some of the bigger issues connected to transparency.
11. In reality, agencies do not always meet these requirements. This is just another reason why transparency is so important.
12. Administrative Procedure Act (APA; Public Law 79–404; 60 Stat. 237; 5 U.S. Code § 551, *et seq.*).
13. Jeff Holmstead, "Making the Environmental Protection Agency Great Again," testimony before the Sciences, Space and Technology Committee, U.S. House of Representatives, 115th Cong., 1st Sess., February 7, 2017, https://science.house.gov/imo/media/doc/Holmstead%20Testimony_2.pdf (accessed October 25, 2019).
14. Wendy Wagner, "Science in Regulation: A Study of Agency Decisionmaking Approaches," University of Texas School of Law, February 18, 2013, prepared for the Administrative Conference of the United States, https://www.acus.gov/sites/default/files/documents/Science%20in%20Regulation_Final%20Report_2_18_13_0.pdf (accessed October 23, 2019).
15. Ibid., p. 152.
16. "Validation" is used in this *Backgrounder* as it would be used in common parlance.
17. Bonnie Swoger, "You Can't Read Just One: Reproducibility and Multiple Sources," *Scientific American* blog, October 29, 2013, https://blogs.scientificamerican.com/information-culture/you-cane28099t-read-just-one-reproducibility-and-multiple-sources/ (accessed October 23, 2019).
18. Shannon Palus, "Make Research Reproducible," *Scientific American*, Vol. 319, No. 4 (October 2018), pp. 56–59, https://www.scientificamerican.com/article/science-under-scrutiny-the-problem-of-reproducibility/ (accessed October 23, 2019).
19. Monya Baker, "1,500 Scientists Lift the Lid on Reproducibility," *Nature*, Vol. 533, No. 7604 (May 2016), pp. 452–454, https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970 (accessed October 23, 2019).
20. Ibid. This *Nature* survey appeared to be focused on reproducibility in terms of repeating experiments.
21. "Reproducibility," as in this *Backgrounder*, is often used broadly to cover concepts, such as being able to reproduce results using the same data as a previous researcher or being able to replicate studies to show the legitimacy of a previous study when new data is used. It is helpful to bear in mind the different aspects of "reproducibility." A May 2019 National Academy of Science report drew a distinction by using different definitions for "reproducibility" and "replicability." According to the report, "'Reproducibility' is obtaining consistent results using the same input data; computational steps, methods, and code; and conditions of analysis." "'Replicability' is obtaining consistent results across studies aimed at answering the same scientific question, each of which has obtained its own data. Two studies may be considered to have replicated if they obtain consistent results given the level of uncertainty inherent in the system under study." News release, "New Report Examines Reproducibility and Replicability in Science, Recommends Ways to Improve Transparency and Rigor in Research," The National Academies of Sciences, Engineering, and Medicine, May 7, 2019, http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=25303 (accessed October 23, 2019). For the report itself, see National Academies of Sciences, Engineering, and Medicine, *Reproducibility and Replicability in Science* (Washington, DC: The National Academies Press, 2019), https://www.nap.edu/catalog/25303/reproducibility-and-replicability-in-science (accessed October 23, 2019). For another discussion on terminology, see Fiona Fidler and John Wilcox, "Reproducibility of Scientific Results," *The Stanford Encyclopedia of Philosophy* (Winter 2018), https://plato.stanford.edu/entries/scientific-reproducibility/ (accessed October 23, 2019).

22. For a good discussion of how the concept of reproducibility can be misconstrued, see Marlo Lewis Jr., "Booker and Holt Caricature Science Transparency Rule at Senate Hearing," Competitive Enterprise Institute, October 5, 2018, https://cei.org/blog/booker-and-holt-caricature-science-transparency-rule-senate-hearing (accessed October 23, 2019).
23. Gina McCarthy and Janet McCabe, "Scott Pruitt's Attack on Science Would Paralyze the E.P.A.," *The New York Times*, March 26, 2018, https://www.nytimes.com/2018/03/26/opinion/pruitt-attack-science-epa.html (accessed October 23, 2019).
24. The following articles provide some concerns regarding peer review and the academic publishing process: Jeffrey Brainard and Jia You, "What a Massive Database of Retracted Papers Reveals about Science Publishing's 'Death Penalty,'" *Science* (October 25, 2018), https://www.sciencemag.org/news/2018/10/what-massive-database-retracted-papers-reveals-about-science-publishing-s-death-penalty (accessed October 25, 2019). The authors explain: "A retraction does not always signal scientific misbehavior." However, the authors also point out: "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 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." See also Tom Jefferson, Philip Alderson, and Elizabeth Wager, "Effects of Editorial Peer Review: A Systematic Review," *Journal of the American Medical Association* (June 5, 2002), https://jamanetwork.com/journals/jama/fullarticle/194989 (accessed October 25, 2019); Fred Barbash, "Major Publisher Retracts 43 Scientific Papers Amid Wider Fake Peer-Review Scandal," *The Washington Post*, March 27, 2015, https://www.washingtonpost.com/news/morning-mix/wp/2015/03/27/fabricated-peer-reviews-prompt-scientific-journal-to-retract-43-papers-systematic-scheme-may-affect-other-journals/ (accessed October 25, 2019); John Bohannon, "Who's Afraid of Peer Review?" *Science*, Vol. 342, No. 6154 (October 2013), pp. 60–65, https://science.sciencemag.org/content/342/6154/60 (accessed October 25, 2019); and Julia Belluz and Steven Hoffman, "Let's Stop Pretending Peer Review Works," Vox, December 7, 2015, https://www.vox.com/2015/12/7/9865086/peer-review-science-problems (accessed October 25, 2019).
25. News release, "EPA Administrator Pruitt Proposes Rule to Strengthen Science Used in EPA Regulations," Environmental Protection Agency, April 24, 2018, https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations (accessed October 25, 2019)
26. Federal agencies do have expert bodies, such as scientific advisory boards, that can provide an important way to help ensure the integrity of the science. However, they are not a substitute for providing the general public with access to the science. In addition, the agencies can have many problems themselves in terms of reviewing the science and drawing scientific conclusions.
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28. U.S. Department of Health and Human Services and U.S. Department of Agriculture, "Dietary Guidelines for Americans: 2015–2020," 8th ed., December 2015, http://health.gov/dietaryguidelines/2015/guidelines/ (accessed October 23, 2019).
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30. U.S. Senate, "Hearing on Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability," 115th Cong. 1st sess., statement of Susan E. Dudley, Director, GW Regulatory Studies Center, March 9, 2017, (citations omitted), https://www.hsgac.senate.gov/imo/media/doc/DUDLEY%20TESTIMONY.pdf (accessed October 25, 2019).
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38. Ibid.
39. The National Academies of Sciences, Engineering, and Medicine, "Conflicts of Interest for Committees Used in the Development of Reports," May 12, 2003, http://www.nationalacademies.org/coi/ (accessed October 25, 2019).
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