### Essay

### Science in the Modern Administrative State: Examining Peer Review Panels and the Federal Advisory Committee Act

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#### ABSTRACT

The use of science is integral to the modern administrative state. Scientific studies conducted by government agencies ought to be subject to peer review by external experts. The government's current use of such outside experts, however, is subject to many constraints—notably the Federal Advisory Committee Act ("FACA") and Executive Order ("E.O.") 12,838, issued by President Bill Clinton. This Essay first considers what requirements FACA and the subsequent Executive orders bearing on federal advisory committees impose and what those elements of law mean for the use of external panels of peer reviewers. Next, the Essay outlines the important roles science and peer review play in the formulation of government policy and regulations, with specific reference to the peer review practices of the U.S. Forest Service. Finally, this Essay proposes an Executive order and amendments to FACA, which would exempt peer review panels from the most burdensome restrictions imposed by FACA and E.O. 12,838.

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#### INTRODUCTION

The use of science is integral to the modern administrative state. Shortly after entering office, President Barack Obama issued a memorandum to the heads of all the executive departments and agencies stating that "[s]cience and the scientific process must inform and guide decisions of my Administration on a wide range of issues . . . ." Peer review is an "essential aspect of the scientific process," without which "most scientists will not consider a scientific pronouncement as valid." It has been used to judge the quality of science for over three centuries. Scientific studies conducted by government agencies ought to be subject to peer review by external experts; however, the govern-

<sup>&</sup>lt;sup>1</sup> Memorandum on Scientific Integrity, 74 Fed. Reg. 10,671, 10,671 (Mar. 11, 2009); see also Memorandum from John P. Holdren, Dir., White House Office of Sci. & Tech. Policy, to the Heads of Exec. Dep'ts & Agencies (Dec. 17, 2010) [hereinafter Holdren Memo], available at http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.

<sup>&</sup>lt;sup>2</sup> Frank Gannon, The Essential Role of Peer Review, 2 EMBO Reports 743, 743 (2001).

<sup>3</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-99-99, FEDERAL RESEARCH: PEER REVIEW PRACTICES AT FEDERAL SCIENCE AGENCIES VARY 3 (1999) [hereinafter GAO, FEDERAL RESEARCH]. This report generally defines peer review as "a review of technical or scientific merit by individuals with sufficient technical competence and no unresolved conflict of interest." Id. at 4. Peers are "scientists or engineers who have qualifications and expertise equivalent to those of the researcher whose work they review" and who are "capable of making an independent judgment of the merits and relevance of the research." Id.

ment's current use of such outside experts is subject to many constraints, notably the Federal Advisory Committee Act ("FACA")<sup>4</sup> and Executive Order ("E.O.") 12,838 issued by President Bill Clinton.<sup>5</sup>

The requirements of FACA may discourage the use of external peer review for science produced by or used by government agencies and thereby inhibit the policy goal of scientific integrity in the administrative process.<sup>6</sup> These problems are particularly pressing in light of the billions of dollars the government spends on research each year.<sup>7</sup> To address these problems, this Essay proposes that Congress amend FACA by adding an exemption for peer review panels, and President Obama issue an Executive order exempting peer review committees from certain limitations imposed by President Clinton in E.O. 12,838.

In Part I, this Essay first considers what requirements FACA and the subsequent Executive orders bearing on federal advisory committees impose and what those elements of law mean for the use of external panels of peer reviewers. In Part II, the Essay outlines the important roles science and peer review play in the formulation of government policy and regulations. Finally in Part III, this Essay proposes an Executive order and amendments to FACA, which would exempt peer review panels from the most burdensome restrictions imposed by FACA and E.O. 12,838.

# I. THE FEDERAL ADVISORY COMMITTEE ACT AND GOVERNMENT SCIENCE

When Congress passed FACA in 1972, it was responding to the perceived proliferation of advisory committees.<sup>8</sup> Not only did Congress question the efficiency of how existing advisory committees op-

<sup>4</sup> Federal Advisory Committee Act (FACA), 5 U.S.C. app. §§ 1-16 (2012).

<sup>&</sup>lt;sup>5</sup> Exec. Order No. 12,838, 58 Fed. Reg. 8207 (Feb. 12, 1993) (establishing a cap on the number of advisory committees each agency may use); see also Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular No. A-135, Management of Federal Advisory Committees (1994) [hereinafter OMB Circular A-135] (implementing Executive Order 12,838).

<sup>6</sup> See Admin. Conference of the U.S., Administrative Conference Recommendation 2011-7: The Federal Advisory Committee Act—Issues and Proposed Reforms 1, 3–5 (2011), available at http://www.acus.gov/sites/default/files/documents/Recommendation-2011-7-Federal-Advisory-Committee-Act.pdf; Wendy Wagner, Science in Regulation: A Study of Agency Decisionmaking Approaches 115, 127–28 (2013).

<sup>&</sup>lt;sup>7</sup> See Matt Hourihan, Federal R&D in the FY 2013 Budget: An Introduction, in AAAS REPORT XXXVII 5, 9 (2012) (stating that the President's proposed Fiscal Year 2013 Budget would invest \$142.2 billion in research and development programs).

<sup>&</sup>lt;sup>8</sup> S. Rep. No. 92-1098, at 1, 3 (1972) (noting that at the time there were at least 1,800 advisory committees with budgets of about \$75 million annually, membership of over 20,000, and staffs of 4,400).

erated, it also sought to slow the creation of new ones.<sup>9</sup> Further, certain members of Congress worried that advisory committees were not operating transparently or representing the public interest because the advisory committees had become too reliant on committee members who represented one particular stakeholder, industry, or point of view.<sup>10</sup> Congress also sought to create a mechanism by which advisory committees could be disbanded to reduce government bureaucracy.<sup>11</sup>

### A. Important Components of the Federal Advisory Committee Act

FACA addressed these concerns in several different ways: it made it more difficult for agencies to establish advisory committees; it required advisory committee meetings to be open to the public; it required advisory committees to follow various reporting requirements; and finally, it established a two-year sunset provision after which advisory committees would be terminated unless renewed by the President, an appropriate officer of the Federal Government, or by statute. Congress began the Act by announcing that "new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary" and, further, that "advisory committees should be terminated when they are no longer carrying out the purposes for which they were established."<sup>13</sup>

In order to make the formation of advisory committees more difficult, the Act only allowed advisory committees to be formed when authorized (1) by statute, (2) by the President or (3) by an agency

<sup>9</sup> Id. at 3, 6 (expressing concern that "committee reports were ignored or forgotten, that many committees existed in name only; and that there was a substantial duplication of responsibilities").

<sup>10</sup> Id. at 6 (remarking on testimony of witnesses at Senate hearings that showed that "advisory committees tend[ed] to operate in a closed environment, permitting little or no opportunity for the public to learn either about their deliberations and recommendations or about the information on which they base[d] those recommendations"); see H.R. Rep. No. 91-1017, at 6 (1972) (observing that "[o]ne of the great dangers in the unregulated use of advisory committees is that special interest groups may use their membership on such bodies to promote their private concerns").

<sup>11</sup> See S. Rep. No. 92-1098, at 6 ("[N]either the Federal agencies, the Executive Office of the President, nor the Congress, have developed any effective mechanisms for evaluating these advisory committees and determining which should be reorganized or abolished.").

<sup>12 5</sup> U.S.C. app. §§ 2, 5-15 (2012). The Act defines "advisory committee" as "any committee, board, commission, council, conference, panel, task force, or other similar group . . . which is . . . established . . . in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government." *Id.* § 3.

<sup>13</sup> Id. § 2.

head if he or she certifies as a matter of public record that the advisory committee is in the public interest to help the agency carry out its statutorily assigned duties. In addition, the Act established various administrative and reporting requirements to open the advisory committees to public scrutiny. For example, the advisory committees must have on file with Congress a charter and the President must make annual reports to Congress on the status and conduct of the advisory committees. The Act also required that advisory committees provide notice of their meetings in the Federal Register, that their meetings be open to the public, and that the advisory committees make available to the public transcripts of their meetings. Finally, the Act provided an automatic sunset clause whereby newly established advisory committees terminate after two years unless the President, the appropriate officer of the Federal Government, or Congress renews the advisory committee's term.

# B. Additional Executive Restrictions on Federal Advisory Committees

In the years since its passage, presidents have sought to refine and apply FACA in various ways.<sup>19</sup> One of the most important initiatives was President Clinton's E.O. 12,838 issued in 1993.<sup>20</sup> The Order indicates that even after twenty years of FACA, President Clinton thought that advisory committees were still too common and too inefficient.<sup>21</sup> In E.O. 12,838, the President ordered that each agency decrease the number of its associated advisory committees by at least one-third within the year.<sup>22</sup> The Order also enacted a moratorium on the creation of new advisory committees unless the creation is mandated by statute or the agency head "finds that compelling considerations necessitate creation of such a committee" and receives the approval of the Director of the Office of Management and Budget ("OMB").<sup>23</sup> The President required OMB approval to be granted "only sparingly" and "only if compelled by considerations of national

<sup>14</sup> Id. § 9(a).

<sup>15</sup> Id. §§ 6-13.

<sup>16</sup> Id. §§ 6, 9.

<sup>17</sup> Id. §§ 10-11.

<sup>18</sup> Id. § 14.

<sup>&</sup>lt;sup>19</sup> See generally id. §§ 2, 14 (including relevant Executive orders by Presidents Carter, Clinton, and Obama).

<sup>20</sup> Exec. Order No. 12,838, 58 Fed. Reg. 8207 (Feb. 12, 1993).

<sup>21</sup> See id.

<sup>22</sup> Id. § 1.

<sup>23</sup> Id. § 3.

security, health or safety, or similar national interests."<sup>24</sup> These new requirements were imposed in addition to the charter, notice, and reporting requirements contained in FACA.<sup>25</sup>

Pursuant to E.O. 12,838, the OMB Director issued further guidelines fleshing out the requirements of the E.O.<sup>26</sup> In Circular A-135, the OMB interpreted the underlying policy driving the E.O. as: "Advisory committees should get down to the public's business, complete it and then go out of business."27 To this end, the reduction requirement contained in E.O. 12,838 was interpreted as imposing a ceiling on the total number of advisory committees available to each agency.28 The total number of discretionary advisory committees federal agencies may maintain is 534.29 The Circular required that agencies submit to the OMB director an annual report "on the results of its efforts to maintain discretionary committee levels required by E.O. 12838, and other actions to reduce its inventory of non-discretionary statutory committees."30 These reports will "be used by the Director of OMB as the basis for approving requests to establish new committees." which seems to set up an explicit link between an agency's past success in eliminating advisory committees and the agency's likelihood of receiving approval for a new committee.31

# C. Critiques of FACA's Application to Scientific Peer Review Committees

Although FACA does seem to be achieving its main objectives—surveys of federal agencies and advisory committees indicate that they are complying with FACA's provisions and are in general agreement with the purposes behind the law<sup>32</sup>—in the decades since its passage, many improvements to FACA have been suggested.<sup>33</sup> The current

<sup>24</sup> Id.

<sup>25</sup> Id.; 5 U.S.C. app. §§ 9-13.

<sup>26</sup> OMB CIRCULAR A-135, supra note 5.

<sup>27</sup> Id.

<sup>28</sup> Id.

<sup>29</sup> Admin. Conference of the U.S., supra note 6, at 5.

<sup>30</sup> OMB CIRCULAR A-135, supra note 5.

<sup>31</sup> Id.

<sup>32</sup> See Steven P. Croley & William F. Funk, The Federal Advisory Committee Act and Good Government, 14 Yale J. on Reg. 451, 538–47, 552 (1997); see also U.S. Gov't Accountability Office, GAO/T-GGD-98-163, Federal Advisory Committee Act: Advisory Committee Process Appears to Be Working, but Some Concerns Exist 1, 6 (1998) (noting advisory committees' general adherence to FACA and reporting that over ninety-six percent of committee members view committees as having worthwhile purpose).

<sup>33</sup> See, e.g., Croley & Funk, supra note 32, at 527-32 (proposing various solutions to improve FACA's administration and effectiveness).

definition of advisory committee could be amended in order to clarify the scope of the compliance requirements and exempt some types of committees from these requirements.<sup>34</sup> For example, FACA might violate separation of powers principles by ensnaring presidential advisors under its existing definition of advisory committee.<sup>35</sup> Broadly speaking, the transparency and efficiency rationales behind FACA are implicated more directly in the case of advisory committees that participate in the formulation of policy and which include interested stakeholders, such as industry representatives or members of citizens groups, than they do for advisory committees of disinterested, outside experts who are convened to address only technical or scientific issues. The former type of advisory committee may have to balance competing policy objectives or political interests, while the latter is designed only to ensure that the agency is using reliable information in the formulation of its policies.

Other suggestions from academics include amendments to the regulations governing the General Services Administration ("GSA"), the agency that administers FACA compliance, to address concerns that the Act may discourage agencies' use of peer review.<sup>36</sup> Proposals have also been made to establish financial disclosure requirements for advisory committee members.<sup>37</sup> With respect to the impact FACA has had on scientific committees, certain observers have argued that some advisory committees are failing to comply with FACA or that others are refraining from using outside experts because of the administrative burdens imposed by FACA.<sup>38</sup>

<sup>34</sup> Id. at 527-28.

<sup>35</sup> Jay S. Bybee, Advising the President: Separation of Powers and the Federal Advisory Committee Act, 104 Yale L.J. 51, 128 (1994) ("FACA violates the separation of powers to the extent that it regulates the President's use of outside advisory committees funded at their own expense.").

<sup>&</sup>lt;sup>36</sup> Croley & Funk, *supra* note 32, at 506–10, 528. In a survey by Croley and Funk, over one-quarter of agencies with an opinion on the subject said that FACA discouraged the agency's use of peer review. *Id.* app. A at 543.

<sup>37</sup> Michelle Nuszkiewicz, Note, Twenty Years of the Federal Advisory Committee Act: It's Time for Some Changes, 65 S. Cal. L. Rev. 957, 993-95 (1992).

<sup>38</sup> See Dover A. Norris-York, Comment, The Federal Advisory Committee Act: Barrier or Boon to Effective Natural Resource Management?, 26 Envtl. L. 419, 425, 441 (1996) (noting that the burdens of FACA discouraged the use of outside experts by governmental agencies and outlining the Department of Interior's efforts to both be FACA-compliant and to reduce FACA burdens in a specialized Rangeland Management Plan); see also Eva Stensvad & Ralph F. Hall, Left to Their Own Devices: IOM's Medical Device Committee's Failure to Comply, 13 MINN. J.L. SCI. & TECH. 75, 116 (2012) (arguing that an advisory committee of the National Academy of Sciences was violating FACA's § 15 fair balance requirements). For additional discussion of FACA § 15, see infra notes 52–55 and accompanying text.

The problems of applying FACA to peer review committees are illustrated by the controversy that arose when FACA was briefly found applicable to the committees of the National Academy of Sciences ("NAS").<sup>39</sup> Currently, the NAS is exempt from many of FACA's requirements.<sup>40</sup> When drafting FACA, Congress did not intend the Act to apply to the NAS because the NAS has a charter from Congress itself.<sup>41</sup> The intent to exempt the NAS was explicitly expressed on the floor of the House before FACA was passed.<sup>42</sup> Twenty-five years after the passage of FACA, however, the U.S. Court of Appeals for the District of Columbia Circuit interpreted FACA as applying to committees of the NAS in *Animal Legal Defense Fund, Inc. v. Shalala*.<sup>43</sup>

The decision of the District of Columbia Circuit prompted strong opposition. The President of the NAS, Bruce Alberts, believed that the application of FACA to the NAS would make the Academy's scientific advice vulnerable to government control and political pressures.<sup>44</sup> In a released statement, he contrasted a FACA-governed process with the previous process of the NAS.<sup>45</sup> Where FACA governs, the government chooses committee members, chairs committee meetings, approves committee agendas, and places "severe" limits on the total number of committees.<sup>46</sup> In contrast, prior to the D.C. Circuit's ruling in *Animal Legal Defense Fund*, the NAS president selected committee members on the basis of their specific scientific or technical competence, and the scientists themselves controlled the committees.<sup>47</sup>

Alberts also objected to the imposition of FACA's open meeting requirements because of the negative impact he foresaw them having

<sup>39</sup> See Animal Legal Def. Fund, Inc. v. Shalala, 104 F.3d 424, 425 (D.C. Cir.) (applying FACA to committees of the National Academy of Sciences), cert. denied, 522 U.S. 949 (1997).

<sup>40 5</sup> U.S.C. app. § 3(2).

<sup>41</sup> See H.R. Rep. No. 92-1403, at 10 (1972) (Conf. Rep.) ("The Act does not apply to . . . advisory committees not directly established by or for such [federal] agencies."); see also 36 U.S.C. § 150301 (2012).

<sup>42 143</sup> Cong. Rec. H10,580 (daily ed. Nov. 9 1997) (statement of Sen. Horn) (quoting 118 Cong. Rec. H3142 (daily ed. Sept. 20, 1972)).

<sup>43</sup> Animal Legal Def. Fund, Inc. v. Shalala, 104 F.3d 424, 425 (D.C. Cir.) (applying FACA to committees of the NAS), cert. denied, 522 U.S. 949 (1997).

<sup>44</sup> Special Report, Legal Challenges to ILAR Threaten Independence of the National Academy of Sciences, 38 ILAR J. 94, 94-95 (1997).

<sup>45</sup> Id.

<sup>46</sup> Id. at 95.

<sup>47</sup> Id.

on the NAS's peer review process.<sup>48</sup> He vigorously defended the benefits of the existing non-FACA peer review process:

[O]ur final committee deliberations are closed, so that committee members may sort through the technical issues free from external pressure, arriving at their tentative conclusions and recommendations based on the scientific evidence. A preliminary report prepared by a committee is not yet a report endorsed by the Research Council, and for that reason is kept confidential from government sponsors and others who may want to influence the outcome. This preliminary report is subjected to a rigorous, independent peer review by carefully selected scientists who remain anonymous to the committee. Changes are made to the report based on the reviewers' comments. A report is released as a product of the National Research Council only if it has passed review as judged by the scientists appointed to oversee our review process. Thus, a report from the Research Council is not a report from a committee, but the product of an institutional process.49

Alberts believed that conforming to FACA regulations would irreparably undermine the independence of the NAS.<sup>50</sup>

Congress agreed and promptly—only ten days after the Supreme Court denied certiorari from the District of Columbia Circuit—amended FACA to exempt the NAS and to ensure that the NAS remained "independent of agency influence."<sup>51</sup> The amendment did, however, impose some new requirements on the NAS.<sup>52</sup> The new law required that the NAS committees publish the names and biographies of their members, ensure that their membership is "fairly balanced as determined by the Academy," and appoint members that are free from conflicts of interest.<sup>53</sup> The NAS was also required to make public its final reports, including the names of peer reviewers, but only after the completion of the peer review process.<sup>54</sup> The amendment,

<sup>48</sup> Id. at 94.

<sup>49</sup> Id. at 95.

<sup>50</sup> Id. at 94-95.

<sup>51</sup> See H.R. 2977, 105th Cong. (1st Sess. 1997); 143 Cong. Rec. H10,580 (daily ed. Nov. 9 1997) (statement of Rep. Horn). The Supreme Court denied certiorari on November 3, 1997. Animal Legal Def. Fund, Inc. v. Shalala, 522 U.S. 949 (1997). The House passed H.R. 2977 on November 9, followed by the Senate on November 13. 143 Cong. Rec. 25,845, 26,243 (1997).

 <sup>52</sup> See Federal Advisory Committee Act Amendments of 1997 § 2(b), Pub. L. No. 105-153,
111 Stat. 2689, 2689-90 (1997) (codified at 5 U.S.C. app. § 15 (2012)).

<sup>53 5</sup> U.S.C. app. § 15(b)(1).

<sup>54</sup> Id. § 15 (b)(6).

including the additional requirements, "delighted" Alberts and, in his view, adequately kept the NAS "independent" from improper government control.<sup>55</sup>

Because of FACA's broad definition of "advisory committee," scientific peer review panels at many agencies are often ensnared by the Act's requirements.<sup>56</sup> Specifically, the cap limiting the number of advisory committees applies to committees established by agencies to peer review agency science.<sup>57</sup> In 1991, the General Accounting Office ("GAO")58 conducted a study which revealed that about ninety percent of peer review panels at six selected agencies were chartered under FACA during the 1990 fiscal year.<sup>59</sup> The same GAO study, however, also recommended that all peer review panels be chartered under FACA and pointed specifically to unchartered panels in use by the National Institutes of Health, Department of Energy, and National Oceanic and Atmospheric Administration.<sup>60</sup> The GAO wanted more peer review panels chartered, because it felt that agencies ran a high risk of using unchartered panels in a way that violated FACA and that the use of unchartered panels prevented the public from knowing the existence of such panels.<sup>61</sup> The GAO, commissioned only to evaluate agency compliance with FACA, failed to consider why agencies might seek to avoid the costs imposed by FACA.62 Additionally, the

<sup>55</sup> Special Report, Independence of the National Academy of Sciences Restored by Congressional Legislation, 38 ILAR J. 155, 155 (1997).

<sup>56</sup> See 5 U.S.C. app. § 3.

<sup>57</sup> Exec. Order No. 12,838, 58 Fed. Reg. 8207 (Feb. 12, 1993) (establishing a cap on the number of advisory committees each agency may use).

<sup>58</sup> In 2004, the name of the General Accounting Office was changed to the Government Accountability Office. See Our Name, U.S. Gov't Accountability Office, http://www.gao.gov/about/namechange.html (last visited Sept. 28, 2014). For simplicity's sake, the acronym "GAO" is used to denote both agencies.

<sup>59</sup> GAO, GAO/GGD 91-48, PEER REVIEW: COMPLIANCE WITH THE PRIVACY ACT AND FEDERAL ADVISORY COMMITTEE ACT 10-11 (1991) [hereinafter GAO, PEER REVIEW]. Chartering is one of the elements of FACA designed to ensure advisory committees' transparency and transience. See 5 U.S.C. app. § 9(c). Each advisory committee must file a public charter containing information such as the committee's objectives and scope, the time necessary to achieve the objectives, the agency responsible for the advisory committee, and an estimate of the annual cost to run the advisory committee. Id.

<sup>60</sup> GAO, PEER REVIEW, supra note 59, at 13.

<sup>61</sup> Id. at 12 ("We... believe that unchartered committees require agency officials to provide careful, day-to-day vigilance of individual panel meetings to ensure that panels do not provide consensus or that the agency does not use the panel results as a source of consensus advice—either of which would violate FACA. Furthermore, establishing panels outside the scope of FACA limits the benefits the act is intended to provide ... [such as] public notice of the existence of the panels and when and where they meet.").

<sup>62</sup> Id. at 1-3.

GAO study was performed two years before the issuance of E.O. 12,838, which imposed mandatory caps on the numbers of advisory committees, providing an additional incentive for agencies to leave peer review committees unchartered so as not to eat into their quotas of chartered advisory committees.<sup>63</sup>

Agencies complain that FACA and E.O. 12,838 inhibit their use of scientific peer review panels.<sup>64</sup> For example, the U.S. Environmental Protection Agency ("EPA") complains that the compliance costs of FACA causes it to abandon efforts to convene peer review committees and opt instead to use individual independent reviewers.65 The advice of the independent reviewers is sought individually, so their use does not constitute the convening of a "committee" under the definitions in FACA.66 If more than one reviewer were to be consulted at the same time, the reviewers would fall under FACA's definition of advisory committee triggering the chartering, approval, reporting, and disclosure requirements.<sup>67</sup> Although the use of individual reviewers allows the EPA to avoid FACA burdens, the reviewers are unable to confer with each other—one of the key benefits of peer review panels—and that may in turn slow down the agency's review process by generating a slew of conflicting or duplicative comments to which the agency must respond.<sup>68</sup> In addition, the method requires the agency to accept a fundamental change in the collaborative aspect of traditional peer review processes. The effect of FACA and subsequent executive branch expansions of its requirements on the ability of agencies to use external peer review panels is particularly troubling given the importance of science in the modern regulatory state.

<sup>63</sup> See Exec. Order No. 12,838, 58 Fed. Reg. 8207 (Feb. 12, 1993).

<sup>64</sup> See Wagner, supra note 6, at 138 (citing Environmental Protection Agency complaints); see also Admin. Conference of the U.S., supra note 6, at 10 (recommending repeal of the caps on the number of advisory committees established in E.O. 12,838 and OMB Circular A-135).

<sup>65</sup> WAGNER, supra note 6, at 138.

<sup>66</sup> See 5 U.S.C. app. § 3.

<sup>67</sup> *Id.* (referring to a "group" used to obtain "advice or recommendations"). *But see* Byrd v. EPA, 174 F.3d 239, 246–47 (D.C. Cir. 1999) (finding that the EPA did not "establish" an external peer review panel when it hired a contractor to convene and manage the panel and that, therefore, FACA did not apply to the peer reviewers); Food Chem. News v. Young, 900 F.2d 328, 333 (D.C. Cir. 1990) (Ginsburg, J.) (reaching the same conclusion in the context of a peer review panel convened by an FDA contractor).

<sup>68</sup> WAGNER, supra note 6, at 138.

## II. THE IMPORTANCE OF PEER REVIEW FOR GOVERNMENT AGENCIES

Generally speaking, peer review serves several important functions in administrative policymaking. Peer review, because it strengthens the reliability of the information used in formulating decisions, tends to strengthen the legitimacy of administrative rulemaking.<sup>69</sup> Peer review, if used early in agency decisionmaking processes, can improve administrative efficiency by helping agency officials to narrow contested issues and identify problems early.<sup>70</sup> Peer review may also be a tool to promote more thorough deliberation as it brings citizens from outside the agency into the rulemaking process to discuss technical issues.<sup>71</sup> The use of peer review may increase the likelihood that courts will defer to agency judgments if the agency action is challenged.<sup>72</sup>

Furthermore, the executive and legislative branches may use peer review to maintain control over the administrative agencies.<sup>73</sup> Peer review allows individuals outside the agency to overcome asymmetries of information and can serve as a useful source of external advice, separate from that rendered by the agency.<sup>74</sup> A system of regulatory peer review empowers independent experts as "watchdogs" to prevent, or at least provide notice of, bureaucratic or political "drift" within an agency that might frustrate the intent of Congress in having established the agency in the first place.<sup>75</sup> Thus, regulatory peer review represents one possible tool for political control of administrative decisionmaking.<sup>76</sup>

As science plays an ever more important role in government decisionmaking, the Federal Government at many levels of the executive branch seeks to ensure scientific integrity.<sup>77</sup> A crucial tool is peer review. As the discussion of the U.S. Forest Service's experience below

<sup>69</sup> Louis J. Virelli III, Scientific Peer Review and Administrative Legitimacy, 61 Admin. L. Rev. 723, 724–25, 730–31 (2009).

<sup>&</sup>lt;sup>70</sup> Lars Noah, Scientific "Republicanism": Expert Review and the Quest for Regulatory Deliberation, 49 Emory L.J. 1033, 1072 (2000); Thomas S. Burack, Note, Of Reliable Science: Scientific Peer Review, Federal Regulatory Agencies, and the Courts, 7 Va. J. Nat. Resources 27, 107–08 (1987).

<sup>71</sup> Noah, supra note 70, at 1042-43.

<sup>72</sup> Burack, supra note 70, at 108.

<sup>73</sup> See Stuart Shapiro & David Guston, Procedural Control of the Bureaucracy, Peer Review, and Epistemic Drift, 17 J. of Pub. Admin. Res. & Theory 535, 538-39 (2007).

<sup>74</sup> Id. at 540.

<sup>75</sup> Id. at 544-45.

<sup>76</sup> See id. at 548-49.

<sup>77</sup> See Memorandum on Scientific Integrity, 74 Fed. Reg. 10,671, 10,671 (Mar. 11, 2009).

demonstrates, federal agencies incorporate peer review into their operations as a way to ensure the validity and objectivity of the science they produce.

### A. Peer Review Is Important to Scientific Integrity in Government Research and Policy

At the outset of his first term, President Obama emphasized the importance of science in government decisionmaking.<sup>78</sup> The President specifically recognized the role that peer review plays in conferring legitimacy and integrity on scientific findings and directed agencies to ensure that peer review occurs where appropriate.<sup>79</sup> The Director of the Office of Science and Technology Policy, John Holdren, followed the President's memorandum with a more detailed set of instructions for agencies.80 He, too, made the explicit connection between good science and good policy.81 Holdren wrote: "Scientific and technological information is often a significant contributor to the development of sound policies. Thus it is important that . . . the scientific and technological information and processes relied upon in policymaking be of the highest integrity."82 He also underscored the connection between good science and peer review, observing that it is of "particular importance" that "data and research used to support policy decisions undergo independent peer review by qualified experts."83

President Obama was hardly the first to recognize science as a crucial component of the administrative process. A report issued during the Clinton Administration detailed the use of peer review by twelve government agencies.<sup>84</sup> Additionally, Congress passed the Information Quality Act ("IQA")<sup>85</sup> in 2000. This legislation required, first, that the OMB issue guidelines to agencies to ensure the "quality, objectivity, utility, and integrity" of information disseminated by the agencies and, second, that each agency individually issue guidelines to apply the new OMB regulations in the agency's specific context.<sup>86</sup>

<sup>78</sup> Id.

<sup>79</sup> *Id.* ("When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate . . . .").

<sup>80</sup> Holdren Memo, supra note 1.

<sup>81</sup> Id. at 1.

<sup>82</sup> Id.

<sup>83</sup> Id. at 1-2.

<sup>84</sup> GAO, FEDERAL RESEARCH, supra note 3, at 1-2.

<sup>85 44</sup> U.S.C. § 3516 note (2012).

<sup>86</sup> Id.

In 2002, the OMB issued guidance required under the IQA, declaring that "data and analytic results" which were "subjected to formal, independent, external peer review . . . may generally be presumed to be of acceptable objectivity." In 2005, the OMB finalized an "Information Quality Bulletin" for peer review.8 The Bulletin provided that "important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government." Although no government-wide standards or definition of peer review exists because peer review practices should be flexible depending on the agency's mission and the type of research involved, 90 the OMB did explain generally what the peer review process adds to scientific studies conducted by the government:

The peer reviewer's report is an evaluation or critique that is used by the authors of the draft to improve the product. Peer review typically evaluates the clarity of hypotheses, the validity of the research design, the quality of data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall product.<sup>91</sup>

Federal agencies use peer review in a variety of settings, including in the allocation of federal funds for research, in the evaluation of ongoing research projects, and in the evaluation of various studies that form the basis for rulemaking.<sup>92</sup> Of the federal advisory committees, the GSA deemed roughly a quarter of them "scientific/technical" in nature.<sup>93</sup>

<sup>87</sup> Office of Mgmt. & Budget, Exec. Office of the President, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002).

<sup>88</sup> Office of Mgmt. & Budget, Exec. Office of the President, Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2664 (Jan. 14, 2005).

<sup>89</sup> Id. at 2665.

<sup>90</sup> GAO, FEDERAL RESEARCH, supra note 3, at 4, 5.

<sup>91</sup> OMB, Final Information Quality Bulletin, 70 Fed. Reg. at 2665.

<sup>92</sup> See generally David H. Guston, The Expanding Role of Peer Review Processes in the United States, in Learning from Science and Technology Policy Evaluation: Experiences from the United States and Europe 81 (Philip Shapira & Stefan Kuhlmann eds., 2003) (discussing the history and expansion of peer review).

<sup>93</sup> Id. at 35 n.23 (figure does not include grant review committees).

# B. A Case Study of Peer Review in Agencies: The U.S. Forest Service

As a brief exploration of the role of peer review at the U.S. Forest Service demonstrates, agencies that produce scientific advice have, generally, been responsive to the directives from the White House related to peer review and scientific integrity. The U.S. Department of Agriculture ("USDA"), in which the U.S. Forest Service operates, promulgated "general quality standards" for the constituent units of the Department to use in formulating and disseminating information to the public in accordance with IQA requirements.<sup>94</sup> This policy directs agencies to be guided by the principles of quality, objectivity, utility, and integrity when providing scientific information to the public.<sup>95</sup> The U.S. Forest Service, which has a specific arm dedicated to research and development,<sup>96</sup> adheres to the general USDA Peer Review Implementation Guidelines as well as to its own more particular peer review guidelines.<sup>97</sup>

The USDA Peer Review Implementation Guidelines apply "to influential scientific information and highly influential scientific assessments that contain findings or conclusions that represent the official position of USDA agencies or offices and are officially disseminated to the public at large." The Department has a preference "where appropriate" for "formal, independent, external peer review" to ensure a given piece of scientific information's objectivity and quality. Further, if any agency promulgates a regulation that rests upon "influential scientific information," that information must be subject to peer review. Agencies are required to make public on

<sup>94</sup> Information Quality Activities: General Requirements, U.S. DEP'T OF AGRICULTURE, http://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities (last visited Sept. 28, 2014).

<sup>95</sup> See id.

<sup>96</sup> Research Topics, U.S. Forest Service, http://www.fs.fed.us/research/research-topics/ (last visited Sept. 28, 2014). The research and development arm of the Forest Service focuses on seven priority areas: invasive species; inventory, monitoring and analysis; outdoor recreation; resource management and use; water, air and soil; wildland fire and fuel; and wildlife and fish. Id. The budget for Forest Service research is not inconsequential, totaling over \$275 million in the President's Fiscal Year 2015 Budget. FY 2015 Budget, U.S. Forest Service, http://www.fs.fed.us/research/about/budget/ (last visited Sept. 28, 2014).

<sup>97</sup> See USDA Peer Review Implementation Guidelines, U.S. DEP'T OF AGRICULTURE, http://www.ocio.usda.gov/document/usdas-peer-review-guidelines (last visited Sept. 28, 2014); Quality of Information: Peer Review Agenda, U.S. FOREST SERVICE, http://www.fs.fed.us/qoi/peerreview.shtml (last visited Sept. 28, 2014).

<sup>98</sup> U.S. Dep't of Agriculture, supra note 97, at 1.

<sup>99</sup> Id. at 5.

<sup>100</sup> Id.

their websites an agenda of peer review for influential scientific information and to then provide a peer review plan for each item on the agenda.<sup>101</sup>

On its peer review agenda, the U.S. Forest Service explains: "We require all scientific manuscripts to be reviewed by qualified personnel, including written reviews by at least two peers, competent in the subject matter and with demonstrable objectivity."102 The U.S. Forest Service scientists who receive peer review feedback are required to incorporate the comments of reviewers into their work before publication.103 Peer reviewers for the U.S. Forest Service are asked to evaluate the "factual accuracy, quality of information, clarity, consistency, references, effectiveness, and overall merit" of the research they receive.104 Items of scientific research with listed peer review plans for 2012 include projects such as "Economic impacts of non-native forest insects in the continental United States," "Effects of Federal and State Policies on Family Forest Owners of the United States," and "Trends and causes of severity size and number of fires in northwestern California."105 The individual research plans include a mix of plans that involve a peer review panel selected by an academic journal or a peer review panel selected by the author. <sup>106</sup> In fiscal year 2011, 3,083 U.S. Forest Service articles were published in journals.<sup>107</sup> The scientific advice provided by the U.S. Forest Service allows land and resource managers to utilize "scientific, social, and economic tools," which help them accomplish "the desired outcome to care for the land and [to] serve people."108

The U.S. Forest Service appears to avoid FACA by using three main tactics. First, the U.S. Forest Service utilizes review panels com-

<sup>101</sup> Id. at 4.

<sup>102</sup> U.S. FOREST SERVICE, supra note 97.

<sup>103</sup> Id.

<sup>104</sup> Id.

<sup>105</sup> Id.

Compare Robert G. Haight, Principle Investigator, U.S. Forest Serv., Peer Review Plan: Economic Impacts of Non-Native Forest Insects in the Continental United States, available at <a href="http://www.fs.fed.us/qoi/documents/peer\_review/Economic\_impacts\_of\_non-native\_forest\_insects\_in\_the\_continental\_United\_States.pdf">http://www.fs.fed.us/qoi/documents/peer\_review/Economic\_impacts\_of\_non-native\_forest\_insects\_in\_the\_continental\_United\_States.pdf</a>, with Brett J. Butler, Principle Investigator, U.S. Forest Serv., Peer Review Plan: Effects of Federal and State Policies on Family Forest Owners of the United States, available at <a href="http://www.fs.fed.us/qoi/documents/peer\_review/Effects\_of\_Federal\_and\_State\_Policies\_on\_Family\_Forest\_Owners\_of\_the\_United\_States.pdf">http://www.fs.fed.us/qoi/documents/peer\_review/Effects\_of\_Federal\_and\_State\_Policies\_on\_Family\_Forest\_Owners\_of\_the\_United\_States.pdf</a>.

<sup>107</sup> U.S. FOREST SERVICE, USDA, FOREST SERVICE RESEARCH AND DEVELOPMENT: FY 2011 PERFORMANCE AND ACCOUNTABILITY REPORT 18 (2012) [hereinafter 2011 FOREST SERVICE REPORT], available at http://www.fs.fed.us/research/publications/R&D-PAR-FY11-Reportsmall.pdf.

<sup>108</sup> Id. at 3.

posed exclusively of government personnel because they are exempted from FACA.<sup>109</sup> Second, the U.S. Forest Service seeks reviews from individual external reviewers.<sup>110</sup> Third, by submitting the work for publication to academic journals, the U.S. Forest Service can argue that it is not subject to FACA because it is not "utilizing" the journal committees for advice or recommendation in the sense that the journal's decision to accept or reject a U.S. Forest Service submission would not necessarily inform Forest Service policies.<sup>111</sup>

These three tactics yield some of the benefits of peer review; however, what they trade for efficiency's sake are some of the key benefits of traditional peer review. In composing review panels of exclusively government personnel, the agency by default loses access to the wealth of experience and knowledge possessed by nongovernmental reviewers. Using only individual reviewers suffers from the flaw that these reviewers are unable to collaborate in the provision of comments, which may cause the agency to suffer delay in having to address duplicative, or extremely divergent, comments from reviewers. Finally, although submitting agency work to outside journals for peer review does ensure the basic reliability of the science, the review given by journals would be at the end of the agency's work and may not be timely enough to inform the agency decision-making for which the science was produced.

This overview of announced executive branch policy about the use of science in the formulation of government policy and the specific operation of peer review policies in the U.S. Forest Service demon-

<sup>109 5</sup> U.S.C. app. § 3(2); cf. Forest Service Report, supra note 107, at 11 (providing generalized information concerning the peer review process).

See supra notes 98-100 and accompanying text (discussing similar tactics utilized by the EPA); cf. Forest Service Report, supra note 107, at 17-18 (summarizing the peer review process).

<sup>111</sup> Cf. Forest Service Report, supra note 107, at 17–18 (describing the U.S. Forest Service peer review process). In the past, the U.S. Forest Service tried to avoid FACA by claiming that it was not relying on a committee of outside experts for advice or recommendations. See Cal. Forestry Ass'n v. U.S. Forest Serv., 102 F.3d 609, 611 (D.C. Cir. 1996). When this characterization was challenged, the District of Columbia Circuit held that FACA applied because the U.S. Forest Service used the work of the outside experts in formulating its final recommendations. Id. at 611–12.

<sup>112</sup> See Croley & Funk, supra note 32, at 506-10, 528 (noting the discouragement of peer review stemming from the enactment of FACA).

<sup>113</sup> See WAGNER, supra note 6, at 138.

<sup>114</sup> See Sheila Jasanoff, The Fifth Branch: Science Advisers as Policymakers 78 (1990) ("[S]cientists working to meet policy needs are under constant pressure to deliver results quickly. In the regulatory context, a decision to wait for more data amounts to ... a decision not to act.").

strate the importance of peer review to policymaking.<sup>115</sup> Unfortunately, the administrative burdens of FACA combined with the limitations on the total number of federal advisory committees and the operation of E.O. 12,838, which serves to cap the total number of advisory committees available to each agency, may discourage the use of external peer reviewers by administrative agencies, damaging the integrity and quality of scientific studies conducted by the government.<sup>116</sup>

# III. PEER REVIEW COMMITTEES SHOULD BE EXEMPT FROM CURRENT REGULATIONS PERTAINING TO ADVISORY COMMITTEES

Because of the importance of science in the administrative process and the importance of peer review to the integrity of science, agency-established peer review committees should be exempt from burdens imposed by the current federal advisory committee governance regime. This proposal has two parts. First, President Obama should issue an Executive order exempting peer review panels from the arbitrary caps established by President Clinton in E.O. 12,838.<sup>117</sup> This Executive order would allow agencies to establish new federal advisory committees for the purpose of peer review without forcing the agency to shut down an equivalent number of non-peer review advisory committees.

Second, Congress should amend FACA itself to exempt peer review panels from the establishment, open-meeting, and reporting requirements—all of which arguably deter agency use of peer review panels. The amendment should change section four of FACA to add a new section, 7(d), which should read: "Nothing in this Act shall be construed to apply to any committee or panel whose primary function is the peer review of government-produced scientific studies or findings."

Implementing these changes does not undermine the congressional intent in enacting FACA to increase transparency and guard against industry capture.<sup>119</sup> In the first instance, FACA itself already provides special and less onerous procedures for committees of the

<sup>115</sup> See supra Parts I, II.A-B.

<sup>116</sup> See supra Part I.

<sup>117</sup> See supra notes 20-28 and accompanying text.

<sup>118</sup> See supra Part I.C.

<sup>119</sup> See supra notes 12-13 and accompanying text.

NAS and the National Academy of Public Administration. 120 In part to compensate for the trade off in transparency that results from waiving the requirement that all committee meetings be open to the public, FACA seeks to ensure that members of advisory committees associated with the NAS be free from conflicts of interest and that each committee contains a fair balance of views.<sup>121</sup> FACA allows the NAS to determine its own compliance policies.<sup>122</sup> If there is a compliance breakdown, judicial review—including injunctive relief—may be available to remedy violations.<sup>123</sup> Similarly broad requirements might be imposed on peer review committees under the proposed reform advocated by this Essay, especially because those measures seek to ensure independence and objectivity, two fundamental goals of the peer review process. Thus, the losses in transparency implicit in the proposed reforms can be limited and would be outweighed by the increased ease with which agencies can convene peer review panels. This should lead to the increased use of peer review in the regulatory process and, ultimately because of the ability of peer review to police the reliability of information, to an increase in the legitimacy enjoyed by administrative agencies' decisions.

Although implementing both of these reforms in tandem would do the most to remove barriers to agency use of peer review committees, the proposed Executive order and the proposed FACA exemption are not dependent upon each other. Of the two, the Executive order is both the more critical and the more easily achievable. If agencies must work under advisory committee caps, they must make a choice between establishing a new committee to peer review a project or study and disbanding another one, even if the existing advisory committee is still providing valuable work. Removing the advisory agency caps imposed by E.O. 12,838 could be accomplished—literally—with the stroke of a pen and would alleviate the false choice

<sup>120 5</sup> U.S.C. app. § 15.

<sup>121</sup> *Id.* § 15(b)(1)(A)-(B). Some courts have, however, found the issue of fair balance, when challenged, to be nonjusticiable. *See*, *e.g.*, Fertilizer Inst. v. EPA, 938 F. Supp. 52, 55 (D.D.C. 1996) (noting that the organization lacked standing to bring the case).

<sup>122</sup> See Nat'l Acad. of Scis. et al., Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports (2003), available at http://www.nationalacademies.org/coi/bi-coi\_form-0.pdf (explaining that compliance with the fair balance and conflict of interest provisions of FACA are in the NAS's own best interest because "[c]onclusions by fully competent committees can be undermined by allegations of conflict of interest or lack of balance and objectivity").

<sup>123</sup> See Cargill, Inc. v. United States, 173 F.3d 323, 342 (5th Cir. 1999) (recognizing the appropriateness of injunctive relief); Cal. Forestry Ass'n v. U.S. Forest Serv., 102 F.3d 609, 614 (D.C. Cir. 1996) (same).

agencies currently face between shutting down existing peer review committees and creating new ones.

Implementing these reforms also furthers the policy interests in data quality behind the IQA.<sup>124</sup> Despite the laudable goals of the IQA, some have seen it as an effort to impede agency rulemaking by allowing businesses to delay or thwart regulations against their interests.<sup>125</sup> This proposal does not suffer from the same flaws. First, by removing peer review committees from many of the FACA requirements, it removes one possible avenue through which challenges to agency science could impede rulemaking. Second, by incentivizing peer review, the proposed FACA-exemption for agency peer review panels further promotes the "integrity" and "objectivity" of scientific studies conducted by the government.

#### Conclusion

Science is increasingly important to the decisionmaking of federal agencies. Quality science—science that is objective, useful, and trustworthy—lends legitimacy to the administrative process. Peer review is a process traditionally used by scientists to validate research and is a process embraced by agencies. FACA and E.O. 12,838 impose burdens that constrain agency use of external peer review panels, and both should be amended specifically to exempt scientific peer review panels from their onerous requirements.

<sup>124</sup> See supra Part II.A.

<sup>125</sup> See, e.g., Stephen M. Johnson, Junking the "Junk Science" Law: Reforming the Information Quality Act, 58 Admin. L. Rev. 37, 42–43 (2006) (recounting episodes where business challenges to agency rulemaking under the IQA caused agencies to retreat from precautionary environmental rulemaking); see also Stephen M. Johnson, Ruminations on Dissemination: Limits on Administrative and Judicial Review under the Information Quality Act, 55 CATH. U. L. Rev. 59, 79 (2005) (arguing that judicial review under the IQA outside of rulemaking is generally not available).