No. 14-5226

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

LORILLARD, INC., et al.,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.

Defendants-Appellants.

On Appeal from the United States District Court
For the District of Columbia

BRIEF OF *AMICUS CURIAE* CENTER FOR REGULATORY EFFECTIVENESS IN SUPPORT OF AFFIRMANCE OR REMAND

William G. Kelly, Jr. (D.C. Bar No. 411594)
MULTINATIONAL LEGAL SERVICES, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com

Attorney for *Amicus Curiae*
Center for Regulatory Effectiveness

PARTIES' CONSENT

All parties to this case have consented to the filing of an *amicus curiae* brief on appeal by the Center for Regulatory Effectiveness.

CORPORATE DISCLOSURE STATEMENT

The Center for Regulatory Effectiveness ("CRE") does not have a parent corporation, and no publicly-held corporation holds any of its stock. CRE is a dba of Multinational Business Services, Inc. ("MBS") for administrative purposes, and MBS does not have a parent company and no publicly-held corporation holds any MBS stock. Neither CRE nor MBS has members. MBS is a corporation registered in the District of Columbia.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

For many years one of the main goals of the Center for Regulatory Effectiveness has been to ensure that information that federal agencies disseminate to the public, whether in a rulemaking, on the Internet, or through other means, is of the highest quality, including – as is particularly relevant to this case -- being free of bias.

CRE assisted Members of Congress in developing the Information Quality Act,[1] and commented extensively on OMB's drafting of rules to implement that legislation.

Since then, CRE has actively monitored litigation, legal commentary, and agency activity involving the IQA and its rules, and has participated to express its views on their application, regardless of the subject matter involved.[2]

CRE's interest in this case is in the implications that compliance with the ethics laws and the Federal Advisory Committee Act have for ensuring the success of the IQA prohibitions against bias in government information disseminations.

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[1] Although the legislation does not have an official title, and is considered an implementation directive rather than an amendment to the Paperwork Reduction Act, it is usually referred to by OMB and the courts as the Information Quality Act or IQA; however, it is also often referred to by other parties as the Data Quality Act. We will refer to it here as the IQA.

[2] For example, see the *amicus curiae* brief filed by CRE in *Harkonen v. U.S. Dept. of Justice*, still pending in the Ninth Circuit (No. 13-15197). That case involves interpretation of OMB IQA rules and the issue of APA justiciability of final agency action under the IQA rules.

Non-compliance with such laws can undermine the quality of government information if an agency relies on, or appears to agree with, information developed by an advisory committee that is tainted with various types of non-compliance such that lack of objectivity and bias cannot be readily ascertained from the information itself. This is particularly true where, as here, it appears that there are divergent views on the subject matter issues within the scientific community and selection of committee members and lack of transparency could therefore readily influence the content of a report.

CRE believes that objectivity and absence of bias in advisory committee reports, and in agency rulemakings relying on such reports or other agency disseminations of such reports, can only be ensured if agency adherence to the applicable ethics, committee composition, and open meetings and document disclosure provisions of law are subject to judicial review. We argue that they are in this case.

STATEMENT OF AUTHORSHIP AND FINANCIAL SUPPORT

CRE and its counsel declare, under Fed. R. App. P. 29(c)(5), that no counsel for a party in this case has authored all or any portion of this brief, and that no party, party's counsel, nor any other person other than CRE (or MBS) or its counsel has contributed money that was intended to fund preparation and submission of this brief.

SUMMARY OF ARGUMENT

It is very likely that FDA will rely on, or appear to agree with, the advisory committee report (the Menthol Report) in a rulemaking. If it does so, the report will be considered an agency information dissemination that is subject to the Information Quality Act ("IQA") and OMB's IQA regulations. Those rules require objectivity and prohibit bias in such information disseminations.

If the advisory committee report is so used in a rulemaking, it should be presumed to be biased and to lack objectivity if it was produced by an advisory committee that was convened and overseen by an agency in violation of provisions of law regarding ethics, conflict of interest, fair balance, or open meetings and document disclosure, all of which are aimed largely at ensuring objectivity and eliminating bias.

In order to ensure achievement of the objectives of the IQA and its regulations, it is essential that allegations of bias and lack of objectivity in the advisory committee process be justiciable. An advisory committee report is usually given great weight, and, particularly in the case of scientific/technical issues on which there is a division of opinion within the scientific community, it is unlikely that committee bias will be discernible from the report itself. The IQA and its implementing rules do not address advisory committee bias, and appear to assume that the existing legal and regulatory safeguards applicable to advisory

committees are sufficient for that purpose. Therefore, to guard against bias in a such a report, bias must be guarded against in the advisory committee process. Agencies in the Executive Branch are politically oriented and therefore might have motivation to bias advisory committees through the selection of members and conduct of meetings and disclosures.

While some of the advisory committee provisions at issue allow for considerable agency judgmental discretion, that discretion is not absolute because the laws provide sufficiently manageable principles to allow for judicial review for abuse of discretion under the APA. The agency is arguing for a court ruling that would effectively preclude absolutely any judicial review. There is no evidence of Congressional intent, much less clear and convincing evidence, for such preclusion. This Court should not adopt such a view. On the other hand, there is clearly sufficient law to apply under the APA.

The rebuttable presumption against judicial review in cases seeking to compel agency enforcement actions does not reverse the usual presumption in favor of judicial review because the laws involved here have separate civil and criminal enforcement sanctions which the plaintiffs do not seek to have the agency enforce, and because the presumption against judicial review of enforcement discretion requires an action involving a plaintiff seeking to compel agency enforcement action in the face of an agency's (or official's) refusal to act. Here,

the plaintiffs seek to overturn an agency's affirmative actions in selecting advisory committee members and violating provisions of law for open meetings and document disclosure.

The asserted violations relating to lack of objectivity, bias, and fair and open procedures in this case appear sufficiently serious, particularly in combination, to support the district court's decision to bar agency use of the report. There must be a line somewhere between legitimate exercise of discretion and abuse of discretion that is likely to result in a biased report. While that line is not a bright line, this case involves advisory committee members who have not just been expert witnesses and consultants on a few occasions, but who have virtually made, or clearly will make, what amounts to a living from supporting one side of the controversy consistently, in hundreds of cases for some of them, and are viewed as biased by many observers. In such a case, it was reasonable for the district court to determine that the line has been crossed into abuse of discretion in order to protect the public interest in the integrity of such reports.

Article III standing in this case is premised largely on procedural harm. Non-compliance with the advisory committee provisions results in procedural harm and supplies a basis for standing by putting entities likely to be affected by the report at distinct risk of harm by being subjected to a biased advisory committee report, either in a rulemaking or by use of third parties. This situation is

much like one in which there was a lack of sufficient APA notice and comment in a rulemaking that could harm those entities that are the subject of the rulemaking. In this case, the companies' business is the subject of the advisory committee report. In such cases, this Circuit generally regards standing as self-evident.

Because Congress mandated establishment of the advisory committee and its preparation of the report for the agency's use, it was proper for the district court to require that the advisory committee be reconstituted to be in compliance so that its report can be used by the agency.

The district court did not rule on the issues regarding failure to conduct open meetings and failure to disclose committee documents. Therefore, even if this Court overturns the district court's opinion, it should remand the case for rulings on those issues.

ARGUMENT

I. Information Developed by an Entity Outside the Agency But With Which the Agency Expresses Agreement Is Subject to OMB's Information Quality Act ("IQA") Rules.

The OMB original government-wide IQA rules (67 Fed. Reg. 8452 (Feb. 22, 2002)) define a government information dissemination product to include information that is "initiated or sponsored" by an agency. *Id.* at 8460. The term "initiated" is explained in the preamble as follows:

> [I]f an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines.

Id. at 8454. While the advisory committee report is not covered by the OMB rules at this time, because the agency has not indicated agreement with it, if the agency indicates agreement with it in a rulemaking – which is likely -- the report will be covered by the OMB IQA rules.[3] The report will also be covered by the OMB rules if the agency indicates agreement with it in a dissemination outside a rulemaking.

II. It Is Essential to the Effectiveness of the IQA Prohibition Against Bias in Agency Information Disseminations That the Ethics Laws and FACA Provisions Designed to Prevent Advisory Committee Bias and Promote Transparency and Public Participation Be Subject to Judicial Review.

[3] We refer to them as "rules" even though OMB labeled them "Guidelines" because they clearly are legislative rules under criteria adopted by the Supreme Court and this Circuit. They were issued pursuant to legislation (44 U.S.C. § 3516, note); they went through *Federal Register* notice and comment; and they are written in every respect like legislative rules, particularly in their frequent use of mandatory language (e.g., "shall," "requirements," "must," "comply"), citation of statutory authority for promulgation, and use of the preamble-text format. This Circuit recognized them as legally binding legislative rules in *Prime Time Int'l, Inc. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) (citing the Supreme Court's holding in *United States v. Mead Corp.* that an agency interpretation is entitled to *Chevron* deference "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law ....").

The OMB rules, with which the IQA rules of HHS/FDA and other agencies were required to be consistent, required agencies to adopt basic standards to ensure and maximize the quality and objectivity of the information they disseminate. *Id.* at 8458. "Objectivity" is defined as requiring "a focus on ensuring accurate, reliable, and unbiased information." *Id.* at 8459, 8453. The requirement for objectivity is also expressly contained in the IQA itself. 44 U.S.C.§ 3516, note; 44 U.S.C. §§ 3516, 3504(d)(1), 3501. The HHS/FDA rules issued pursuant to the OMB rules appear consistent with those requirements, as they must be.[4]

Notably, the 2002 OMB rules also emphasize that measures to ensure objectivity and prevent bias need to be more rigorous when the information dissemination is likely to be more important and influential, as appears to be the case here.[5]

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[4] The HHS/FDA rules (called "Guidelines") can be found at http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml (*Guidelines for Ensuring the Quality of Information Disseminated to the Public, F. Food and Drug Administration*, Section V, "Objectivity").

[5] The OMB rulemaking preamble states: "We recognize that some government information may need to meet higher or more specific information quality standards than those that would apply to other types of government information. The more important the information, the higher the quality standards to which it should be held, for example, in those situations involving ''influential scientific, financial, or statistical information'' (a phrase defined in these guidelines)." 67 Fed. Reg. 8452, 8452 (Feb. 22, 2002). This point was reinforced by OMB in its supplemental IQA rules on peer review of agency scientific assessments, which distinguish between "influential" and "highly influential" scientific assessments, and establish more rigorous rules for the latter. It is noteworthy that those rules

FDA is thus obligated to ensure the objectivity (including absence of bias) of all information developed by outside parties if the agency is to rely on that outside information, as Congress contemplated it likely would in the case of the advisory committee report at issue here. Since any bias will likely not be evident on the face of such information (thereby subjecting it to an IQA judicial challenge), the only way that the agency can "ensure and maximize" its objectivity is by conscientious, impartial application of the ethics and advisory committee laws.

This important function should not be left solely to the discretion of the agency, since in many cases it is unlikely that either interested parties or the courts will be able to discern and establish clearly from an advisory committee report itself whether it is significantly biased.[6]

III. Agency Compliance with the Ethics and Advisory Committee Laws Is Not Committed by Law to Agency Discretion and Is Subject to APA Judicial Review for Abuse of Discretion.

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include the need for agencies to take into account conflicts of interest such as consulting arrangements and expert testimony when selecting peer reviewers, as well as requiring a high degree of transparency in the peer review process. 70 Fed. Reg. 2664 (Jan. 14, 2005).

[6] The OMB rules devote considerable attention to the issue of whether information developed outside the agency that has been peer reviewed should be deemed of sufficient quality and objectivity. However, "peer review" does not exactly describe the work of an advisory committee, since the committee is not reviewing a document drafted by another party, as peer reviewers typically do. The OMB rules also do not specifically address advisory committee reports. It appears that OMB was relying on ethics and FACA provisions designed to prevent bias to be sufficient to prevent bias in advisory committee reports.

The agency argues that decisions regarding selection of advisory committee members should be left to its unreviewable discretion. Because there is clearly sufficient law to apply, or judicially manageable standards, that argument must fail.

As is the case with many statutes and regulations, the agency is provided with some judgmental discretion in determining whether conflicts of interest should disqualify a particular expert from serving on a particular advisory committee. But the existence of some discretion, even very substantial discretion, does not commit such decisions to agency discretion and prevent judicial review under the APA. *See, e.g., Menkes v. Dep't of Homeland Security.*, 486 F.3d 1307, 1313 (D.C. Cir. 2007) (and cases cited therein); *Arent v. Shalala*, 70 F.3d 610, 614 (D.C. Cir. 1995) (and cases cited therein). The relevant statutes and regulations in this case provide standards that are considerably more definite than those that have been found adequate to guide judicial review in many cases.

The agency appears to concede this and instead argues that its advisory committee member selection action should be immune from judicial review because the agency action at issue is "enforcement" action for which it has absolute discretion.

This argument is not supportable. The relevant statutes on advisory committees and conflict of interest have very specific provisions for civil and

criminal penalties. Those provisions clearly involve enforcement decisions, but they are not at issue here. The case law regarding enforcement discretion derives principally from *Heckler v. Chaney*, which distinguished enforcement cases from reviewable *Overton Park* cases on the basis that "*Overton Park* did not involve an agency's refusal to take requested enforcement action. It involved an affirmative act of approval under a statute that set clear guidelines for determining when such approval should be given." 470 U.S. 821, 831 (1985). The case at hand is analogous to *Overton Park*, involving an affirmative act of approval of advisory committee members, and not an alleged failure to take necessary civil or criminal enforcement action.[7] Even if this could be considered an action to compel an enforcement action, the *Heckler v. Chaney* presumption in favor of non-reviewability of enforcement decisions is a rebuttable presumption, which could be rebutted by the evident law to apply in the ethics and advisory committee statutes and rules.

IV. The Companies' Standing is "Self-Evident" Because Their Business Is the Subject of the Advisory Committee Report. If They Do Not Have Standing to Challenge Advisory Committee Defects, No One Does.

[7] To the extent the agency's reliance on the judicial review disclaimer in 5 C.F.R. § 2635.106 might be construed as extending beyond enforcement/disciplinary discretion, the disclaimer would run afoul of *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022-23 (D.C. Cir. 2000) (holding that a judicial review disclaimer in a legislative rule – labeled "guidance"-- did not have any effect and was mere "boilerplate"). An agency's attempt to self-immunize itself from judicial review would raise a serious Constitutional separation-of-powers issue.

A. A Suit Alleging a Procedural Defect, As Here, Need Only Rely on a Distinct Risk of Harm, Not Actual Harm.

The agency argues that the actions of the agency in selecting advisory committee members, overseeing the committee process, and violating open meetings and document disclosure requirements has not resulted in any actual harm to the companies, and that therefore they lack standing. But actual harm does not apply in the case of alleged procedural defects and injuries such as those involved here; the test is "distinct risk" of harm to the plaintiffs' concrete interests that the procedures were designed to protect. *Shays v. Fed. Election Comm'n*, 414 F.3d 76, 91 (D.C. Cir. 2005); *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 51 (D.C. Cir. 1999).

B. The Distinct Risk Faced by the Companies is Self-Evident.

The advisory committee report at issue in this case addresses directly the companies' business. This is closely analogous to a case in which standing is upheld based on the fact that a challenged regulation would apply to the plaintiff. As this Circuit stated in *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002):

> In many if not most cases the petitioner's standing to seek review of administrative action is self evident; no evidence outside the administrative record is necessary for the court to be sure of it. In particular, if the complainant is "an object of the action (or forgone action) at issue". . . there should be "little question that the [agency] action or inaction has caused him injury and that judgment preventing

> or requiring the action will redress it." [Quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992).]

In the case at hand, the companies' business is the object of the advisory committee report. It is difficult to imagine parties more likely to be directly affected by the agency action and the report. If this Court were to find that the companies lack standing, it would essentially have the same effect as finding that agency discretion with regard to the challenged actions is absolute and unreviewable, something we oppose.

V. The Agency Violations Alleged Here, Whether Considered Separately or in Combination, Are Sufficiently Serious to Support Judicial Intervention and Affirmance.

The agency clearly has some significant degree of discretion in making judgments regarding selection of advisory committee members, but that discretion is not absolute because there is law to apply in judging whether there has been an abuse of discretion. In judging whether there has been an abuse of discretion here, there is no bright line. Certainly the agency has discretion to select committee members who have, or will, testify as expert witnesses in some cases, and who have done some consulting work with companies likely to be affected by the report, but whether they have a conflict requiring disqualification should be a matter of degree. There is a big difference between a scientist who has testified as an expert witness in several, or even a dozen cases, and one who has testified, and is scheduled to testify, as an expert witness on one side of a disputed issue in

hundreds of cases, virtually making their living at it. In such a case, their finances are surely directly affected if the subject matter of the report they are selected to prepare would very likely assist those finances. And when the same person has also been engaged in possibly conflicting consulting, the cumulative effect of their ties along with their expert testimony commitments should also be taken into account.

The agency appears to contend that disqualifying the three scientists involved here, or even one or two of them, would interfere with its ability to empanel a committee with sufficient expertise. There appears to be no evidence that this is the case here, and the fact that the agency (or its agent) has recently had no trouble in finding presumably qualified experts to peer review its own preliminary scientific assessment demonstrates that there was no need to select the three challenged experts involved in this case.

It was clear to the district court that the abuse-of-discretion line had been crossed in this case, and that opinion appears to be supported.

VI. If This Court Should Reverse the District Court, It Should Remand the Case to the District Court for Consideration of the Issues of Violation of FACA Requirements for Open Meetings and Release of Meeting Documents.

Violations of open meetings and document disclosure requirements appeared to be important, if not primary, allegations of agency action as arbitary and capricious, an abuse of discretion, or otherwise contrary to law; however, those

issues are still outstanding because the district court relied solely on the allegations of conflict of interest and appearance of conflict of interest. Whether it should have done so is debatable, since the issues regarding open meetings and document disclosure could be considered part of a pattern or matrix of agency behavior encompassing the conflict of interest and appearance of conflict claims as well as those issues that were not ruled on. In any event, if this Court were to decide that those claims relied on by the district court are inadequate to support its opinion, it should remand to the district court on the remaining issues, particularly because they appear to be so fact-intensive.

CONCLUSION

The district court opinion should be affirmed. If it is not affirmed, the case should be remanded for consideration of the open meetings and document disclosure issues.

Dated: April 15, 2015

/s/ William G. Kelly, Jr.

MULTINATIONAL LEGAL SERVICES, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com

Attorney for *Amicus Curiae*
Center for Regulatory Effectiveness

CERTFICATE OF COMPLIANCE

I hereby certify that this *amicus curiae* brief (1) complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 3,218 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii), as computed by Microsoft Word 7; and (2) complies with the typeface requirements of Fed. R. App. P. 32 (a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Word 7 in 14-point Times New Roman font.

Dated: April 15, 2015

/s/ *William G. Kelly, Jr.*
William G. Kelly, Jr.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing *amicus curiae* brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit on April 15, 2015, by using the appellate CM/ECF system. I certify that all attorneys of record in this case are registered CM/ECF users and that service on them will be accomplished by using the appellate CM/ECF system.

I also herby certify that I will cause the Clerk of the Court to be served with 8 paper copies of the brief by First-Class Mail, or other class of mail that is at least as expeditious, postage prepaid, by mailing the copies within two business days of the electronic filing.

Dated: April 15, 2015

/s/ *William G. Kelly, Jr.*

William G. Kelly, Jr.
MULTINATIONAL LEGAL SERVICES, PLLC
1850 Fall Line Dr.
Driggs, ID 83422
(208) 354-3050
wgkelly@silverstar.com

Attorney for *Amicus Curiae*
Center for Regulatory Effectiveness