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June 28, 2011

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Citizen Petition Regarding Use of Advice from IOM Committee That Fails to Comply with FACA's Fair Balance Requirement

CITIZEN PETITION

The Washington Legal Foundation (WLF) hereby submits this petition under 21 C.F.R. § 10.30, to request the Food and Drug Administration (FDA) not to use any advice or recommendations provided by the Institute of Medicine (IOM) committee (the " IOM Committee") recently assembled for the purpose of assessing the 510(k) program. Use of such advice or recommendations would violate the Federal Advisory Committee Act of 1972 (FACA).

A significant percentage of new medical devices are approved by FDA through the 510(k) clearance process. Since 2009, FDA has been undertaking a comprehensive review of the 510(k) program. In January 2011, FDA published a Plan of Action, which reported 25 actions that it is considering for improving the 510(k) program. In connection with that review, FDA referred seven controversial questions to the IOM Committee for analysis and recommendation. Press reports indicate that the IOM Committee is expected to issue its report in the very near future.

FACA establishes rules governing both the conduct/composition of federal advisory committees and the appropriate use of recommendations from those committees. Section

15(b)((1) of FACA requires that the membership of the IOM Committee be "fairly balanced." Section 15(a) of FACA prohibits FDA from "us[ing] any advice or recommendation provided by" any IOM committee that is not "fairly balanced." WLF submits that the IOM Committee is not "fairly balanced" under any plausible definition of that term. In particular, the IOM Committee's membership includes *no one* with any experience in seeking to use the 510(k) process to obtain FDA marketing approval for a new medical device. Nor does it include any representatives of patients, who have a strong interest in ensuring that the 510(k) program continues to permit the speedy approval of new, life-saving medical products. Accordingly, FACA § 15(a) prohibits FDA from "us[ing] any advice or recommendation" provided to it by the IOM Committee.[1]

WLF submits that the problem of unbalanced advisory committees will persist unless and until FDA provides guidance to the IOM and others regarding FDA's obligations under FACA § 15. Accordingly, WLF requests that FDA issue a document for the purpose of providing such guidance.

A. ACTION REQUESTED

At the request of FDA, the IOM established an advisory committee to review the 510(k) program and, in particular, to analyze and provide recommendations regarding nine issues regarding potential changes in the 510(k) program. The IOM Committee is expected to issue its report and recommendations in the near future. WLF requests FDA to issue a determination that

[1] WLF's Citizen Petition borrows heavily from an analysis of the IOM Committee contained in a recently published law review article. *See* Ralph F. Hall & Eva Stensvad, *Failure to Comply: An Initial Assessment of Gaps in IOM's Medical Device Sudy Committee*, Minn. J.L. Sci. & Tech. 2011:12(2):E1-E-18. WLF wishes to thank the authors for their excellent article and (with their permission) incorporates it herein by reference.

it is barred by FACA from using any advice or recommendation from the IOM Committee as currently constituted – because the Committee's composition does not comply with FACA's "fair balance" requirement. WLF requests that FDA either proceed with its comprehensive review of the § 510(k) program without obtaining any input from IOM, or else request that IOM reconstitute its committee so as to come into compliance with the "fair balance" requirement.

WLF further requests that FDA issue a guidance document explaining FDA's obligations under FACA, and what advisory committees must do in order to permit FDA to make use of any advice or recommendations provided to the agency.

C. INTERESTS OF PETITIONER

WLF is a public interest law and policy center with members and supporters in all 50 states. It devotes a substantial portion of its resources to supporting the rights of patients to gain access to safe and effective medical products. To that end, it often represents patients who turn to administrative appeals and the courts in an effort to remove unwarranted FDA barriers to access to such products. *See, e.g., Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 552 U.S. 1159 (2008). WLF also litigates in support of the free flow of truthful information regarding FDA-approved drugs and medical devices, to ensure that doctors and patients are fully informed regarding their treatment options. *See, e.g., Washington Legal Found. v. Henney*, 56 F. Supp. 81 (D.D.C. 1999), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF also litigates in support of efforts to ensure that the requirements of FACA are adequately enforced. *See, e.g., Washington Legal Found. v. U.S. Dep't of Justice*, 491 U.S. 440 (1989).

D. STATEMENT OF GROUNDS

Congress adopted the Federal Advisory Committee Act of 1972, 86 Stat. 770, 5 U.S.C. Appx., to govern the creation and operation of committees that provide advice to federal agencies. One of Congress's stated purposes was to ensure that "standards and uniform procedures" would "govern the establishment, operation, administration, and duration of advisory committees." 5 U.S.C. Appx. § 2(b)(4).

1. Section 15 of FACA

Section 15 of FACA (added to FACA in 1997) governs advisory committees set up under the auspices of the U.S. National Academy of Sciences (the Academy), of which the IOM is a part.[2] In particular, § 15(b)(1) governs the composition of any such advisory committee:

> The Academy shall make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable, (B) the committee membership is *fairly balanced* as determined by the Academy to be appropriate for the functions to be performed, and (C) the final report of the Academy will be the result of the Academy's independent judgment.[3]

Courts examining FACA have concluded that the "'fairly balanced' requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee

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[2] *See* Web site for the National Academy of Sciences at http://www.nasonline.org/site/PageServer?pagename=ABOUT_main_page. The IOM is a highly respected authority in its areas of expertise.

[3] FACA § 15(b)(1) (emphasis added). FACA also sets forth requirements governing the creation and operation of all other federal advisory committees. Section 5 includes a provision that largely mirrors § 15(b)(1)'s "fairly balanced" requirement: it provides that the membership of *any* advisory committee must be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." 5 U.S.C. Appx., § 5(b)(2).

would have some representation on the committee."[4]

Section 15(a) imposes obligations on any agency (such as FDA) that contemplates making use of the advice or recommendations of an advisory committee established by the Academy. Section 15(a) states, "An agency may not use any advice or recommendation provided by the National Academy of Sciences or National Academy of Public Administration that was developed by use of a committee created by that academy under an agreement with an agency," unless the academy and the committee have complied with all the requirements of § 15 (including § 15(b)(1)'s requirement that the committee membership be "fairly balanced").

2. FDA Requests to IOM

In 2009, FDA commissioned the IOM to conduct a detailed analysis of the 510(k) system.[5] In response, the IOM established the IOM Committee, whose formal title is the Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process. Earlier this year, FDA referred seven controversial questions (from among 25 actions listed in its January 2011 Plan of Action) to the IOM Committee for analysis and recommendation.[6] The questions sought general policy recommendations rather than detailed answers to technical scientific

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[4] *Nat'l Anti-Hunger Coalition v. Exec. Comm. of President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983).

[5] *See* Press Release, U.S. Food & Drug Admin., FDA: Institute of Medicine to Study Premarket Clearance Process for Medical Devices (Sept. 23, 2009), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM183497.pdf. The Committee was initially requested to consider two broad questions: (1) whether the current § 510(k) process optimally protects patients; and (2) whether it promotes innovation in support of public health.

[6] U.S. Food & Drug Admin., Center For Devices and Radiological Health, *Plan of Action for Implementation of 510*(*k*) *and Scientific Recommendation* (2011), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf.

questions. FDA asked the IOM Committee:

1. To consider defining the scope and grounds for the exercise of the Center's authority to fully or partially rescind a 510(k) clearance.

2. To seek greater authority to require post market surveillance studies as a condition of clearance of certain devices.

3. To develop guidance defining "Class IIb" devices for which clinical information, manufacturing information or, potentially, additional evaluation in the post-market setting would typically be necessary to support a substantial equivalence determination.

4. To clarify when a device should no longer be available for use as a predicate.

5. To consolidate the concepts of "indication for use" and "intended use" into a single term, "intended use."

6. To consider the possibility of requiring each 510(k) submitter to keep at least one unit of device under review available for CDRH to access upon request.

7. To explore the possibility of pursuing a statutory amendment that would provide the agency with the express authority to consider an off-label use when determining the "intended use" of a device.

FDA has made clear that it intends to act upon any advice and recommendations it receives from the IOM Committee. It should be noted that after these seven additional questions were posed to the Committee, FDA has sought no further input from the medical device industry or patient groups regarding the questions posed. Nor have any of the IOM Committee meetings conducted during this time period been open to the public.

3. Selection of the IOM Committee

The IOM Committee has 12 members, consisting of five physicians, three lawyers, and several academics with a variety of technical backgrounds. While the qualifications of the individual members within their particular areas of expertise cannot be questioned, noticeably absent from the IOM Committee is anyone with backgrounds in several areas of critical

importance to the Committee's work. In particular, no member has experience in the critical area of using the § 510(k) program to gain FDA approval for the marketing of innovative products. For example: there are no innovators or inventors who have created new medical devices under the current FDA clearance process, or any product developers who have navigated the clearance process to bring products from concept to market. There are no entrepreneurs, venture capitalists, investment bankers, or angel investors with experience financing medical device innovations, even though one current controversy surrounding the § 510(k) program is its effect on investment in new companies, and even though the second of FDA's initial two questions to IOM related to the program's effect on innovation.

Nor does the IOM Committee include any individuals who routinely prepare § 510(k) applications, or any professionals from the medical device industry. Perhaps most surprisingly, the Committee has no representatives of patients and patient advocacy groups that have benefitted from the development of innovative medical devices and that have a vested interest in ensuring that any changes in the § 510(k) program do not stifle innovation.

In addition to the absence of members with the expertise/backgrounds enumerated above, the IOM Committee does not appear to include members from a wide variety of policy perspectives. The § 510(k) program has been criticized from all sides of the ideological spectrum. Some view the program as too lax from a safety perspective; they charge that the program has allowed medical devices to be marketed with insufficient attention being paid to whether the product is safe for its intended use. Others view the program as overly bureaucratic and one that unnecessarily delays the marketing of innovative products. The former perspective is well-represented on the Committee. Indeed, one member has worked for 20 years at Public

Citizen Litigation Group, a public interest law firm that has been highly critical of the § 510(k) process and has asserted that dangerous medical devices have been allowed to enter the market because devices are approved too quickly.[7] But no member of the Committee is publicly identified with the latter perspective.

The absence of any Committee members with the backgrounds enumerated above is not an accident. The IOM does not contest that such an absence exists. Rather, the IOM evidently takes the position that inclusion of individuals with meaningful experience in the development of innovative medical devices and/or navigating the § 510(k) process would risk violating FACA's conflict-of-interest requirements.[8]

Numerous interested parties have contacted the IOM to express their dismay over the unbalanced nature of the IOM Committee and to urge the IOM to broaden the Committee's composition. For example, in a February 17, 2010 letter to the IOM, the Medical Device Manufacturers Association (MDMA) stated that "the current makeup of the committee does not adequately reflect all relevant stakeholders in the process" and urged the IOM to "take the necessary steps to ensure the committee's review of the 510(k) process is fair, balanced and inclusive by including representatives of key stakeholder groups to participate as members of the

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[7] Public Citizen's motto is, "Defending Democracy. Resisting Corporate Power." Its published critiques of the 510(k) program include Press Release, Sidney Wolfe, *FDA Dodges Responsibility Regarding Medical Device Approval, Defers to IOM* (Jan. 19, 2011), *available at* http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3261.

[8] FACA requires the IOM to make its best efforts to ensure that "no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable." FACA § 15(b)(1)(A).

committee."[9] Despite such entreaties, the IOM took no steps to balance the IOM Committee's membership by adding members with backgrounds not represented on the Committee.

4. FDA's Obligation to Comply with FACA

FDA does not, of course, possess the authority to tell the IOM who should be included as members of advisory committee's established by the IOM, even when (as here) the committee was created at the request of FDA. *See* FACA § 15(a)(1). The IOM is an independent body and possesses ultimate authority to determine who should serve on its committees. However, FACA strictly regulates FDA's authority to use advice or recommendations submitted to it by an IOM committee. In particular, FACA § 15(a) provides that FDA may not make use of such advice or recommendations unless the committee has adhered to all of the requirements imposed by FACA § 15, including § 15(b)(1)'s "fairly balanced" requirement.

Accordingly, before it makes use of any advice or recommendation issued by the IOM Committee, FDA has an independent obligation to ensure that the IOM Committee did, indeed, comply with the "fairly balanced" requirement.[10] It does not suffice for FDA simply to say, "It is up to the IOM to determine the membership of its committees, and we rely on the IOM's assurances that membership on the IOM Committee met the 'fairly balanced' requirement." Rather, because the obligations created by § 15(a) are directed at FDA and not at the IOM, FDA has no authority to abdicate to others its responsibility for determining whether FACA permits it

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[9] Letter dated February 17, 2010 to Katie McGraw of the IOM from Mark Leahey, President and CEO of MDMA.

[10] *See Cargill, Inc. v. United States*, 173 F.3d 323, 341 n.36 (5th Cir. 1999) ("While some of FACA's requirements may seem 'nit-picky,' it is not the court's place to loosen the statute's requirements. If the straightjacket is too tight, Congress is free to loosen it.") Neither courts nor FDA have the authority to ignore the requirements of FACA § 15(a).

to rely on advice or recommendations received from the Committee.

A regulation issued by the General Services Administration provides that when an advisory committee created under the auspices of the Academy delivers to a federal agency a report containing advice or recommendations, it must simultaneously provide written certification to the agency that: (1) it has adopted policies and procedures that comply with the requirements of FACA § 15; and (2) the committee has undertaken its work in compliance with those policies and procedures. 41 C.F.R. § 102-3.185(c). The regulation further provides that the agency "may" rely upon any such written certification. That regulation makes sense as a practical matter in the run-of-the-mill case; FDA and other federal agencies cannot be expected to undertake a detailed review of the work of *every* advisory committee created under the auspices of the Academy. In the absence of evidence that any such advisory committee has not complied with FACA § 15, it makes sense to permit agencies (when policing their own compliance with FACA § 15(a)) to rely on a certification from the Academy that it has complied. But the regulation cannot be allowed to override FACA § 15(a)'s statutory mandate, nor is there any evidence that the GSA intended such an override when it adopted its regulations. Rather, when (as here) substantial evidence has been provided to FDA that an Academy advisory committee has not complied with the "fairly balanced" requirement, it is incumbent upon FDA to examine the matter and to determine for itself whether FACA § 15(a) permits the agency to use any advice or recommendations provided by the committee.

5. Membership of the IOM Committee Is Not "Fairly Balanced"

WLF recognizes that the term "fairly balanced" is not susceptible of a precise definition. Nonetheless, it is demonstrably untrue that Congress intended the "fairly balanced" requirement

to be a mere aspirational goal that FDA is free to overlook at its discretion. Rather, Congress intended that FDA and other federal agencies should take their FACA obligations seriously, including their obligation not to use the advice or recommendations of advisory committees that are not "fairly balanced." WLF submits that under any plausible definition of that term, the IOM Committee is not "fairly balanced."

a. FACA Is Not "Toothless"

Congress envisioned that the "fairly balanced" provision would prohibit an agency from using advice from a committee that lacked balanced representation of different points of view.[11] The primary impetus for enforcing that prohibition must come from the agency itself.[12] Indeed, unless an agency takes its enforcement responsibilities seriously, there is likely to be no enforcement whatsoever, because courts have tended to be highly deferential in their review of agency compliance with FACA.[13] Accordingly, the judiciary's generally deferential approach to FACA issues makes it all the more important that FDA *itself* undertake meaningful steps to ensure that it is complying with Congress's mandate. Courts have warned that unless agencies take steps to ensure that advisory committees are properly constituted, there is a danger that FACA will be transformed – contrary to Congress's intent – into toothless, merely aspirational legislation.[14]

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[11] H.R. Rep. 92-1017, 3496 (1972).

[12] *See, e.g., Fertilizer Inst. v. EPA*, 938 F. Supp. 52, 53 (D.D.C. 1996).

[13] *See, e.g., Cargill*, 173 F.3d at 338 ("While the functional balance requirement [is] justiciable, [it is] subject to highly deferential review.")

[14] *Alabama-Tombigbee Rivers Coalition v. Dep't of Interior*, 26 F.3d 1103, 1106 (11th Cir. 1994). *See also Cargill*, 173 F.3d at 341 ("If the Courts do not enforce FACA by enjoining the work product of improperly constituted committees, FACA will be toothless, merely

b. What Constitutes a "Fairly Balanced" Committee

In adopting the "fairly balanced" requirement, Congress emphasized the need "to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee."[15] It cannot be seriously disputed that the numerous persons/groups identified above as lacking representation on the IOM Committee (*e.g.*, patients and individuals with experience in navigating the §510(k) process) are "directly affected by the work of" the IOM Committee.

Congress provided a fair degree of guidance regarding what a "fairly balanced" committee entailed and what it hoped to accomplish by requiring fair balance. It stated, for example, that:

- advisory committees should avoid "the charge of favoritism" by ensuring that "a particular region, university, industry, company, or discipline" are not "overrepresented";
- Rather than relying on "personal acquaintances," agency "clientele," or individuals who are "close" to the agency, an agency should broaden advisory committee membership to include "[i]ndividuals with ideas, knowledgeable people, and *affected individuals*" (emphasis added);
- Committee members should "be representative of *a broader range of interests* . . . than has been the case"; and
- Agencies should avoid the pre-FACA state of affairs, under which many agencies were "receiving their advice from sources which have special or limiting viewpoints."[16]

Congress was particularly concerned with the requirement that a broad range of

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aspirational legislation.").

[15] *Nat'l Anti-Hunger Coalition*, 711 F.2d at 1074 n.2.

[16] H. Rep. 91-1731, 91st Cong., 2d Sess. (1970).

viewpoints be included on advisory committees, even (and especially) unpopular viewpoints.[17] Such diversity of viewpoints is especially important when (as here) the issues being considered by a committee are policy-oriented. When a committee is tasked with a addressing highly technical, scientific issues, ensuring maximum viewpoint-diversity on the committee may be of lesser importance because the highest priority is likely to be recruitment of individuals with an extremely high level of relevant technical skills. But addressing policy issues of the sort being considered by the IOM Committee does not require mere technical expertise; it also requires a committee membership that is sufficiently diverse to permit the committee to knowledgeably weigh the competing interests that go into adoption of an optimal government regulatory policy.

Courts have established precisely that approach – an examination of the specific function of the committee in question – when determining whether an advisory committee meets the "fairly balanced" requirement of FACA § 5. When a committee is charged with a narrow, scientific, or highly technical mandate, fewer viewpoints and areas of expertise may be required on the committee.[18] Where the functions to be performed are not "narrow and explicit,"[19] but instead involve "diverse and far-reaching issues that affect others," broader representation on the committee is required.[20] This is especially true of committees whose purpose is "to study the

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[17] *See Cummock v. Gore*, 180 F.3d 282, 291 (D.C. Cir. 1999) ("[A]n interpretation of FACA that permitted a given advisory committee to exclude a disfavored member would fly in the face of the principles established by these requirements.").

[18] *See, e.g.*, *Cargill*, 173 F.3d 323; *Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 708 F. Supp. 359 (D.D.C. 1988).

[19] *Nat'l Anti-Hunger Coalition*, 711 F.2d at 1074.

[20] *Nw. Ecosystem Alliance v. Office of U.S. Trade Representative*, No. C99-1165R, 1999 WL 33526001, *7 (W.D. Wash. 1999).

effects of a particular type of regulation . . . on the public."[21] The key issues in evaluating compliance with FACA, then, are first determining the committee's function, and then figuring out what areas of expertise are required on the committee to fulfill that function. Importantly, the statutory requirement of fair balance applies specifically to committee membership. The IOM cannot satisfy this requirement through other input mechanisms. For example, a lack of balance on the committee cannot be remedied simply by allowing missing stakeholders to submit data, make presentations, or serve as peer reviewers. If these were acceptable alternatives to fair balance on the committee, then the statute would not explicitly require such balance on IOM committees themselves. Inclusion of necessary experts and viewpoints during the data-gathering and reviewing processes is important, but cannot substitute for balance within the committee membership. Since each committee meets in private to decide the content its final report and recommendations, balance and expertise is required on the committee. Anything less violates the statutory requirements.

c. The IOM Committee Is Not "Fairly Balanced" Because Its Membership Is Not "Appropriate for the Functions to Be Performed"

The IOM Committee has not been charged with a narrow, scientific, or highly technical mandate. To the contrary, it has been asked to address extremely broad policy questions regarding the future direction of the § 510(k) program. Its mandate requires it to determine whether the program "optimally protects patients," to determine whether it "promotes innovation in support of public health," and to determine the proper balance between protecting patients and promoting development of innovative, life-saving products. Those policy questions have no

[21] *Pub. Citizen*, 708 F. Supp. at 364.

inherently "correct" answers. Moreover, an informed decision regarding the trade-off between safety and innovation requires meaningful input from individuals possessing an extremely wide array of backgrounds. At the very least, it requires that "persons or groups directly affected by the work of [the IOM Committee] have some representation on the committee."[22]

As discussed above, the IOM Committee falls woefully short in this regard. Absent from its membership are individuals whose backgrounds render them "directly affected" by the Committee's work and that are likely to possess crucial information relevant to the Committee's charge. The IOM Committee includes no members with experience in using the § 510(k) program to gain FDA approval for the marketing of innovative products (*e.g.*, innovators or inventors who have created new medical devices under the current FDA clearance process, or product developers who have navigated the clearance process to bring products from concept to market); no members who are entrepreneurs, venture capitalists, investment bankers, or angel investors with experience financing medical device innovation; no members who have routinely prepared § 510(k) applications or who are professionals from the medical device industry; and no members who are patient advocates or patients whose well-being depends on the development of innovative, life-saving medical devices. Under those circumstances, there is no plausible case to be made that the IOM Committee is "fairly balanced." Its membership cannot be deemed "appropriate to the functions to be performed," FACA § 15(b)(1)(B), when it lacks membership input from such a significant proportion of those most knowledgeable about how the § 510(k) program functions and how changes in the program are likely to affect safety and innovation. Under those circumstances, FDA is barred by FACA § 15(a) from using any advice or

[22] *Nat'l Anti-Hunger Coalition*, 711 F.2d at 1074 n.2 (D.C. Cir. 1983).

recommendation submitted to it by the IOM Committee.

d. Fairly Balanced vs. Conflict-of-Interest Requirements

In addition to requiring that Academy advisory committees be "fairly balanced," FACA § 15(b)(1) also requires the Academy to avoid appointing committee members with conflicts of interest. WLF understands that the IOM's failure to appoint individuals possessing practical experience with the § 510(k) process was based at least in part on a desire to avoid appointing members with potential conflicts of interest because they might stand to benefit or suffer financially from the Committee's advice or recommendations. But nothing in FACA authorizes the Academy to ignore the "fairly balanced" requirement in order to avoid conflicts of interest among committee members. Indeed, FACA § 15(b)(1) indicates that in the event of a direct conflict between these two provisions, it is the conflict-of-interest provision that is to give way.[23]

The Academy's own internal policies regarding committee selection recognize the need to include individuals with diverse points of view. Those policies explicitly permit committees to include members who are biased or have expressed a strong opinion on a particular issue of interest. According to the Academy guidelines governing the committee appointment process, "[a] point of view or bias is not necessarily a conflict of interest.[24] The IOM recognizes that member bias is not only permissible, it is sometimes necessary. According to the NAS Policy on Committee Composition and Balance, "[f]or some studies . . . it may be important to have an

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[23] *See* FACA § 15(b)(1) (A) (conflict-of-interest rules can be waived where any conflict "is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable.").

[24] *See Committee Appointment Process*, NAT'L ACADS, http://www8.nationalacademies.org/cp/information.aspx?key=Committee_Appointment.

'industrial' perspective" if such a perspective is "vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee."[25] However, the IOM must balance these perspectives to produce an overall objective committee and avoid bias or the perception of bias. If these individuals have conflicts of interest, they may nevertheless be included on the committee to provide needed expertise, knowledge, balance, or perspective. In such cases, the conflict of interest is "unavoidable" and simply must be disclosed.[26]

Conflict-of-interest rules have not prevented numerous other committees established by the IOM at the behest of FDA from including industry representatives and others from far more diverse backgrounds than IOM Committee members. Out of ten current or recent FDA-sponsored IOM activities, at least half contain members with industry background and at least three committees contain members with disclosed conflicts of interest.[27] For example, the IOM committee on Qualification of Biomarkers and Surrogate Endpoints in Chronic Disease includes a Vice President at Merck & Co.[28] The committee on Accelerating Rare Diseases Research and

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[25] NAT'L ACADS., *Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports* 3 (2003), *available at* http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

[26] *Id.*

[27] *About Activities*, INST. MED., http://www.iom.edu/Activities.aspx?search=%22food%20and%20drug%20administration%22. Disclosures of committee member conflicts of interest are only available for current projects, but not recently completed projects, so there may have in fact been more than three recent committees involving disclosed conflicts of interest.

[28] See *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease,* INST. MED., http://iom.edu/Reports/2010/Evaluation-of-Biomarkersand- Surrogate-Endpoints-in-Chronic-Disease.aspx, for list of committee members.

Orphan Product Development includes a former Vice President of Medtronic, Inc., and a former Senior Vice President of Pfizer.[29] The committee on Review of the Food and Drug Administration's Role in Ensuring Safe Food includes the Senior Vice President and Chief Scientific and Regulatory Affairs Officer of the Grocery Manufacturers Association.[30] Clearly, individuals with industry background or connections are frequently deemed valuable and necessary for IOM committees to fulfill their functions, despite obvious conflicts of interest. Thus, it is not unusual that individuals with "unavoidable" conflicts of interest are included on IOM committees.

Moreover, as noted above, the IOM Committee includes among its members an attorney who has worked for 20 years for Public Citizen Litigation Group. His inclusion raises conflict-of-interest concerns, both because of Public Citizen's institutional commitment to ending the current § 510(k) program and because of its close financial ties to the plaintiffs' bar. The IOM's decision nonetheless to include him on the Committee demonstrates its understanding in this very case that the conflict-of-interest roles must be applied flexibly in order to ensure the optimal mix of members on an advisory committee. The inclusion of a Public Citizen lawyer makes all the more inexplicable the IOM's failure to include an industry representative or anyone else with practical experience in navigating the § 510(k) program.

In sum, the IOM has explicitly recognized – both in its own internal policies and in its

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[29] See *Accelerating Rare Diseases Research and Orphan Product Development*, INST. MED., http://iom.edu/Activities/Research/OrphanProductResearch.aspx, for list of committee members.

[30] See *Review of the Food and Drug Administration's Role in Ensuring Safe Food*, INST. MED., http://iom.edu/Activities/Nutrition/FDARoleReview.aspx, for list of committee members.

past committee appointment practices – that conflict-of-interest rules do not prevent the appointment of committee members with ties to firms doing business in the field, where such individuals' backgrounds will provide the committee with expertise in areas that would otherwise be absent. In light of that recognition, the IOM cannot plausibly maintain that conflict-of-interest rules justified its failure to appoint a "fairly balanced" committee in this instance.

Nor can the IOM claim to have cured its noncompliance with the "fairly balanced" requirement by seeking the input of outside groups at three public meetings held during 2010. FACA's "fairly balanced" requirement applies to the *membership* of advisory committees, not to the manner in which committees conduct their business. Nothing in the language of FACA § 15 suggests that Congress intended to tolerate a committee's unbalanced membership provided that the committee conducts "balanced" meetings. Moreover, given the IOM Committee's failure to conduct a single open meeting since FDA's referral of seven additional questions in January 2011, it has forfeited any right to claim that it has solicited advice on those questions from broadly diverse sources.

6. FDA Guidance to Advisory Committees

WLF respectfully suggests that FDA take steps to ensure that this fiasco is not repeated. Because FDA is barred from considering any advice or recommendations from the IOM Committee, a great deal of energy has been wasted, and FDA's consideration of revisions to the § 510(k) program will likely be delayed. The only way that FDA can assist the Academy and others in understanding FDA's obligations under FACA § 15(a) is for FDA to issue a guidance document that spells out when a committee's composition is sufficiently balanced to permit FDA

to consider the committee's advice and recommendations.

FDA is not, of course, permitted to exercise "any actual management or control" of an Academy advisory committee. FACA § 15(a)(1). Thus, the FDA guidelines should not attempt to dictate to the Academy the precise membership of any of its advisory committees. Moreover, the guidelines should acknowledge that FDA is willing to defer to some extent to the Academy's determinations regarding what constitutes "fair[ ] balance" in the membership of an Academy advisory committee.[31] Nonetheless, such guidelines would serve an important function by making clear to the Academy and others that FDA has an independent statutory duty to ensure that it is not using advice or recommendations from advisory committees that are not "fairly balanced." By providing guidance regarding what FDA deems the essential characteristics of any "fairly balanced" committee, FDA can assist the Academy and others to avoid the appointment of committees that, like the IOM Committee, so obviously do not meet any plausible definition of "fairly balanced."

7. Conclusion

It was entirely appropriate for FDA to seek the advice and recommendations of the IOM with regard to the 510(k) program. The IOM is highly respected and could provide valuable insight as to the effect of the 510(k) program on public health. Implementation of that request, however, has resulted in a committee that lacks fair balance. The IOM has made an effort to include an "anti-industry" perspective by including a long-time industry critic. However, the IOM ignored its own policy by not including those with offsetting viewpoints or anyone with

[31] *See* FACA § 15(b)(1)(B) (committee membership is to be fairly balanced "*as determined by the Academy* to be appropriate for the functions to be performed") (emphasis added).

backgrounds necessary to ensure a sufficiently broad range of inputs from affected groups.

The individuals on the panel each are unquestionably valuable participants. However, the IOM Committee was charged with policy questions for which it did not select members with appropriate ranges of experience. The IOM employed a strained definition of the conflict of interest requirements of FACA § 15(b)(1), while ignoring that subsection's "fairly balanced" requirement. Public meetings under § 15 are appropriate but do not substitute for compliance with the "fairly balanced" requirement. It was within the IOM's statutory authority and internal policies to satisfy both conflict-of-interest and fairness criteria. However, the IOM ignored fairness.

While it is unfortunate that IOM has gone forward with this process while being on notice of the lack of fair balance, it is a violation of FACA for FDA now to rely on the advice or recommendations of the Committee.

E. ENVIRONMENT IMPACT

WLF claims a categorical exclusion under 21 C.F.R. § 25.24(a)(1).

F. ECONOMIC IMPACT

WLF will submit information upon request of the Commissioner. WLF believes that if FDA ignores its responsibilities under FACA § 15(a) and considers the advice and recommendations of an advisory committee whose membership so clearly is not "fairly balanced," it risks adopting ill-considered changes in the § 510(k) process that could result in increased health care costs and in adverse economic impact on patients.

G. CERTIFICATION

The undersigned certify that, to the best of the knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies. And that it includes all representative data and information known to the Petitioner which are unfavorable to the Petition.

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