AUTHORS' SUBMITTED DRAFT—THIS ARTICLE HAS BEEN ACCEPTED FOR PUBLICATION IN *MJLST* VOL.13(1), BUT HAS NOT YET BEEN EDITED

Left to Their Own Devices: IOM's Medical Device Committee's Failure to Comply

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INTRODUCTION

The U.S. medical device market is the largest in the world.[3] It has been estimated at $ 94.9 billion in 2010, and seven of the world's ten largest device manufactures are U.S. companies.[4] However, the industry is in the midst of major change. In 2009, the U.S. Food and Drug Administration (FDA) launched a comprehensive review of one of its major pathways for devices to enter the market—the 510(k) clearance process.[5] As part of this review, it assembled a number of internal working groups, held public meetings and also commissioned the Institute of Medicine (IOM) to assemble a committee to conduct its own independent evaluation of the 510(k) system.[6] In early 2011, the FDA released its recommendations for approximately twenty-five changes it plans to implement.[7] There were seven additional issues, however, that FDA recognized as being especially problematic.[8] The FDA deferred taking actions on these particular issues, instead referring them to the IOM committee for evaluation.[9]

The IOM is the "health arm of the National Academy of Sciences," which together with the National Academy of Engineering and National Research Council, form the National Academies.[10] Its mission is to serve as an advisor to the federal government.[11] As such, it is heavily involved in policy analysis and recommendations. In fact, most of its work comes from Congress or federal agencies.[12] Because of IOM's reputation for distinguished experts, robust analyses, and fair processes, its recommendations are heavily relied upon by government officials and other stakeholders. Thus, the IOM is highly influential in shaping public policy.

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[3] EPSICOM HEALTHCARE INTELLIGENCE, THE MEDICAL DEVICE MARKET: USA (2011), *available at* http://www.marketresearch.com/product/display.asp?productid=6134830&SID=60434945-509248120-499165305&curr=USD.

[4] *Id.*

[5] FDA, 510(K) AND SCIENCE REPORT RECOMMENDATION: SUMMARY AND OVERVIEW OF COMMENTS AND NEXT STEPS 1 (2011) [hereinafter FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS], *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf.

[6] *Id.*

[7] *Id.* at 3; *see also* FDA, PLAN OF ACTION FOR IMPLEMENTATION OF 510(K) AND SCIENCE RECOMMENDATIONS 1 (2011) [hereinafter FDA, PLAN OF ACTION], *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf.

[8] FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS, *supra* note 5, at 2.

[9] *Id.*

[10] *About the IOM*, INST. MED., http://www.iom.edu/About-IOM.aspx (last visited May 2, 2011).

[11] *See* COMM. ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: BALANCING PATIENT SAFETY AND INNOVATION: WORKSHOP REPORT, at iv (Theresa Wizemann ed. 2010), *available at* http://books.nap.edu/openbook.php?record_id=12960&page=R1 ("The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government . . . .").

[12] *See About the IOM*, *supra* note 10.

IOM's powerful status creates a responsibility to ensure that its processes are fair, objective, and inclusive. Unlike traditional federal advisory committees, IOM committees that advise federal agencies have few legal requirements.[13] For example, they do not have to publish notice of meetings in the Federal Register, may deliberate in private, do not require monitoring by federal officials, and do not need to release for public comment their recommendations before issuing them in final form.[14] Additionally, IOM alone determines who is appointed to each committee.[15] However, like advisory committees, IOM committees are required to be "fairly balanced . . . for the functions to be performed."[16]A committee that is not fairly balanced lacks essential expertise and perspectives to adequately fulfill its function. Such a committee's recommendations may thus be incomplete or ill-informed. Additionally, the committee risks actual or perceived bias, threatening stakeholder acceptance of its recommendations. To avoid relying on such an unbalanced committee, federal law prohibits FDA from using any report issued by a committee that lacks fair balance.[17]

This Article[18] contends that, while the IOM is generally an invaluable policy resource, its Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process ("510(k) Committee")[19] is not fairly balanced. The committee's primary function is to evaluate the 510(k) system's effect on patient safety and innovation,[20] yet the committee lacks patients, patient advocates, inventors and innovators who are familiar with the 510(k) system, product developers, entrepreneurs, financiers, manufacturers, and medical device industry professionals. These critical omissions in committee membership render the committee unbalanced, and thus unable to fairly and accurately perform its duties. Additionally, the committee also does not contain a balance of perspectives, subjecting it to possible bias, or at least the appearance of bias. For these reasons, FDA is legally prohibited from using "any advice or recommendation provided by" this committee.[21] Furthermore, it is in IOM's best interest not to release any report from this committee until these issues are resolved, or else the IOM risks damaging its well-deserved reputation for quality and objectivity.

This Article proceeds in five parts. Part I introduces the FDA's 510(k) clearance process and discusses some of the controversy regarding the adequacy of that process. Part II reviews the federal law that applies to advisory committees, generally, as well as the specific provisions that pertain to IOM committees. This Part discusses the requirement that IOM committees be "fairly balanced" and suggests how courts might interpret that requirement. Part III presents the National Academies' policies regarding committee member selection and committee operation. It focuses on the Academies' policies regarding balance, bias, and conflicts of interest. Part IV closely examines the 510(k) Committee's purpose and composition, concluding that the

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[13] Federal advisory committees are governed by the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2 § 5–14 (2006). IOM committees are only governed by FACA section 15. *Id.* § 15.
[14] *Compare* 5 U.S.C. app. §§ 5–14, *with id.* § 15.
[15] *Id.* § 15(b)(1).
[16] *Id.* § 15(b)(1)(B).
[17] *Id.* § 15(a).
[18] This Article is an expansion of an earlier piece on this subject by the authors. *See* Ralph F. Hall & Eva Stensvad, Recent Development, *A Failure to Comply: An Initial Assessment of Gaps in IOM's Medical Device Study Committee*, 12 MINN. J.L. SCI. & TECH. (forthcoming 2011), *available at* http://mjlst.umn.edu/uploads/1e/92/1e92255ff467d2f19d306f6d7cd836d6/122_hall.pdf.
[19] *Activity: Public Health Effectiveness of the FDA 510(k) Clearance Process*, INST. MED., http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx (last updated Jan. 28, 2011).
[20] *Id.*
[21] 5 U.S.C. app. 2 § 15(a) (2006).

committee lacks the balance of expertise or perspectives necessary to fulfill its function. Finally, Part V addresses other policy considerations that dictate a balanced committee. The Article concludes that given the IOM Committee's current composition, FDA is statutorily barred from using the committee's report. Furthermore, it is in both FDA and IOM's best interest that IOM not release its report until these serious issues can be resolved.

The issue presented by this Article is a matter of fair process—it does not matter what the final report recommends, or whether the authors of this Article agree or disagree with the IOM's final recommendations.[22] If federal agencies intend to rely on IOM committees when making major policy and regulatory decisions, those IOM committees must follow good process and contain fair balance. At the very least, they must comply with the few statutory requirements that apply to them.

I. FDA's 510(k) Clearance Process for Medical Devices

The FDA is an agency within the Department of Health and Human Services. It has two primary goals with respect to medical devices. First, it is "responsible for protecting the public health by assuring the safety, efficacy, and security" of medical devices.[23] Second, it is "responsible for advancing the public health by helping to speed innovations."[24] Given the inherent tension between thoroughly ensuring that devices are safe and effective and optimally promoting innovation, FDA attempts to balance these goals through its device approval and clearance mechanisms. In particular, the 510(k) process aims to make safe and effective devices available to consumers faster and less expensively, thus promoting innovation in the device industry.[25]

Before a manufacturer can market a medical device in the United States, the medical device is first classified into one of three regulatory classes, based on the level of regulatory control that is necessary to assure the device's safety and effectiveness.[26] Classification is essentially risk-based, with Class I devices being the lowest risk and Class III the highest risk.[27] For non-exempt devices,[28] manufacturers must obtain FDA approval or clearance through one of

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[22] At the time this Article was written, IOM recommendations has not yet been released to the public, so the authors do not know what the IOM might recommend.

[23] *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last updated 11/18/2010).

[24] *Id.*

[25] *Project Information*, NAT'L ACADS., http://www8.nationalacademies.org/cp/projectview.aspx?key=IOM-BPH-09-03 (last visited Apr. 18, 2011).

[26] *Device Classification*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ (last updated Apr. 27, 2009).

[27] *Id.*

[28] Most low-risk medical devices, such as crutches, heating pads, thermometers, tongue depressors, and bandages, are specifically exempt from any premarket notification or review. *See* 21 C.F.R. pts. 862–892. This exemption includes almost all Class I devices and some Class II devices. *See Medical Device Exemptions 510(k) and GMP Requirements*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm (last updated May 13, 2011). Class I devices are those low-risk devices for which general controls (such as good manufacturing practices) are sufficient to ensure safety and effectiveness. 21 C.F.R. § 860.3(c)(1). Class II devices are moderate-risk devices for which both general and special controls (such as postmarket surveillance, patient registries, or specific FDA guidance) are required. 21 C.F.R. § 860.3(c)(2).

two main pathways.[29] The first pathway, for higher-risk or Class III devices,[30] is Premarket Approval (PMA).[31] This is the most stringent type of device application required by FDA, requiring extensive scientific and regulatory review to ensure the device's safety and effectiveness prior to marketing.[32] Although FDA regulations provide 180 days to review the PMA and make a determination, actual review usually takes a lot longer.[33] Approval is based on the strength of the scientific and clinical data, as well as inspections of the manufacturing facility, processes, and regulatory compliance.[34]

The second pathway to market is the 510(k) clearance process, or premarket notification, pursuant to section 510(k) of the Food, Drug and Cosmetic Act.[35] This process can be used for moderate-risk devices (generally Class II devices) which do not require a PMA and for which a "predicate" device exists.[36] It can also be used when a manufacturer seeks a new indication or "intended use" for an already-marketed device, or when the manufacturer has changed the design or characteristics of a device such that it might affect its performance, safety, or effectiveness.[37] The manufacturer must submit a 510(k), which is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, i.e. substantially equivalent, to a legally marketed device, or "predicate" device.[38] A predicate device is: one that was legally marketed prior to May 28, 1976, for which a PMA is not required; a device which

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[29] Investigational Device Exemptions (IDE) allow investigational devices to be used in a clinical study to collect the safety and effectiveness data required for a Premarket Approval (PMA) or 510(k) submission. *See Overview of Medical Devices and Their Regulatory Pathways*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm203018.htm (last updated May 19, 2010). There is also the Humanitarian Device Exemption (HDE) for situations involving less than 4000 products, which will not be discussed here. *Id.*

[30] "Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury." *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm (last updated Sept. 3, 2010); *see also* 21 C.F.R. § 860.3(c)(3). Classification regulations can be found at 21 C.F.R. pts. 868–92. Examples of Class III devices include heart valves, defibrillators, and various implantable materials such as prostheses, cochlear implants, and breast implants. *See Product Classification*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm (last updated May 13, 2011).

[31] 21 U.S.C. § 360e (2006).

[32] *Premarket Approval (PMA)*, *supra* note 30.

[33] *Id.*

[34] *See* MICHELE SCHOONMAKER, THE U.S. APPROVAL PROCESS FOR MEDICAL DEVICES: LEGISLATIVE ISSUES AND COMPARISON WITH THE DRUG MODEL 16 (2005).

[35] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(k) (2006).

[36] Examples of Class II devices include infusion pumps, blood pressure cuffs, ventilators, x-ray systems, and various surgical materials. *See Product Classification*, *supra* note 30. Where a predicate device does not exist, applicants may use the "de novo" process to seek reclassification based upon a risk assessment of the product, possibly enabling them to utilize the 510(k) system rather than the default PMA pathway. *See* 21 U.S.C. § 360c(f)(2) (2006); Special Considerations, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134578.htm (last updated Sept. 3, 2010).

[37] *Premarket Notification (510k)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last updated Sept. 3, 2010).

[38] *Id.* A finding of substantial equivalence does not mean that the devices are identical—it means that when looking at the intended use of the device and its technological characteristics, there are no new questions raised as to the device's safety and effectiveness. *Id.*

has been reclassified from Class III to Class II or I; or a device which has been found substantially equivalent through the 510(k) process.[39] Once the manufacturer makes its 510(k) submission, the Center for Devices and Radiological Health (CDRH) within the FDA has ninety days to determine whether the device is, in fact, substantially equivalent.[40] Once the FDA declares a device substantially equivalent, the manufacturer may immediately market the device.[41]

Compared to the PMA process, the 510(k) process is different in three key ways. First, it is generally less stringent—PMAs require scientific and clinical studies and more thorough FDA review, including inspection of manufacturing facilities, whereas substantial equivalence for 510(k)s is usually based on device descriptions and technical data.[42] Second, it is usually much faster than the PMA process—FDA generally makes 510(k) decisions faster than it does PMA decisions.[43] Third, 510(k)s are significantly less expensive than PMAs. For example, in fiscal year 2011, the standard fee for a PMA was $236,298.[44] In contrast, the standard 510(k) fee was only $4,348.[45] For these reasons, and since most new medical devices are similar to products already on the market, do not present any new safety or technical questions, and do not represent a significant health risk,[46] the 510(k) process is heavily utilized by the medical device industry. In 2009, FDA received 3597 510(k)s, and only 20 original PMAs and 1394 PMA supplements.[47] In 2010, 2766 medical devices were cleared through the 510(k) process.[48] Between January and March 2011, 776 devices had already been cleared.[49]

Despite the advantages of the 510(k) process, it has recently come under attack. Stakeholders on both sides have criticized the process as inadequately protecting public health—either by insufficiently ensuring patient safety or by unnecessarily hindering innovation.[50] For example, Public Citizen, a national, nonprofit organization, fervently argues that the 510(k)

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[39] 21 C.F.R. 807.92(a)(3).
[40] *Premarket Notification (510k)*, *supra* note 37. Alternatively, FDA can find the device not substantially equivalent (NSE), or can request additional information giving the manufacturer an additional thirty days. *See* SCHOONMAKER, *supra* note 34, at 14.
[41] *Id.*
[42] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 14–15 (2009).
[43] *Id.* at 15.
[44] *PMA Review Fees*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm048161.htm (last updated Sept. 30, 2010).
[45] *Premarket Notification [510(k)] Review Fees*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm (last updated Oct. 25, 2010).
[46] *OCD FY2006: FDA Goal 2—Increasing Access to Innovative Products and Technologies to Improve Health*, U.S. Food & Drug Admin., http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129301.htm (last updated Aug. 19, 2010).
[47] OFFICE OF DEVICE EVALUATION, ANNUAL PERFORMANCE REPORT: FISCAL YEAR 2009, at 4, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM223893.pdf.
[48] *See Devices Cleared in 2010*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm199998.htm (last updated Jan. 6, 2011).
[49] *See Devices Cleared in 2011*, U.S. Food & Drug Admin., http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm242632.htm (last updated Apr. 5, 2011).
[50] *Project Information*, *supra* note 25.

process clears devices too easily and "has failed to keep dangerous and ineffective medical devices from the market."[51] To support this assertion, a Government Accountability Office (GAO) study found that between 2003 and 2007, FDA reviewed 13,199 510(k) submissions for Class I and II devices and cleared 90 percent for marketing.[52] It also found that FDA reviewed 342 submissions for class III devices and cleared 67 percent for marketing.[53] In 2010, 73 percent of 510(k) submissions resulted in a substantially equivalent determination, and in the first eight months of 2011, that number rose again to 77 percent.[54]

Conversely, other groups argue that the 510(k) is overly burdensome, unpredictable, and inconsistent such that it actually inhibits innovation.[55] A survey of over 200 medical technology companies found that the inefficient, prolonged premarket regulatory process resulted in devices being available in the U.S. a full two years later than in other countries, having a significant effect on patient health in the U.S.[56] As a result of the perceived flaws of the regulatory system, fewer medical device start-ups are being launched in the U.S. and innovators are relocating to other countries.[57] In addition, although FDA clears a significant percentage of devices, at least one analysis has shown that the vast majority of 510(k) clearances do not result in a Class I safety recall[58] over a five-year period.[59]

Because of the widespread criticism of the premarket regulatory process, FDA launched a review of the 510(k) system. In September 2009, FDA established two staff committees—the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making—to review and address concerns regarding the 510(k) program.[60] In August 2010, the two internal working groups issued fifty-five recommendations, and after reviewing public comment, FDA announced in January 2011 the twenty-five actions it plans to take to improve the 510(k) program.[61]

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[51] *Comments on FDA 510(k) Medical Devices Working Group Preliminary Report and Recommendations*, PUB. CITIZEN (Oct. 4, 2010), http://www.citizen.org/Page.aspx?pid=4535.

[52] U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 42, at 6. This study did not look at all 510(k) submissions—for specific study methodology, see *id.* at 30.

[53] *Id.* at 6.

[54] FDA, INITIAL RESULTS OF 510(K) AUDIT—ANALYSIS OF NOT SUBSTANTIALLY EQUIVALENT (NSE) DETERMINATIONS 2 (2011), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM259187.pdf.

[55] *See, e.g.*, JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION 6–7 (2010) (surveying over 200 medical technology companies and finding that most respondents found the regulatory process to be unpredictable, prolonged, inefficient, and expensive).

[56] *Id.* at 7. "Under current FDA processes, millions of U.S. patients are being denied or delayed access to leading medical devices that are first (or exclusively) brought to market in other countries." *Id.* at 8.

[57] *Id.* at 8.

[58] Class I recalls are the most serious recalls, in which "there is a reasonable probability that the use of . . . a violative product will cause serious adverse health consequences or death." *Background and Definitions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Safety/Recalls/ucm165546.htm (last updated June 24, 2009).

[59] Ralph F. Hall, Univ. of Minn., Using Recall Data to Assess the 510(k) Process (July 28, 2010), *available at* http://www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/510kProcess/2010-JUL-28/06%20Hall.pdf. This study found that 99.55% of all devices cleared through the 510(k) process over a five-year period did not result in a Class I recall for any reason, and 99.78% the devices did not experience Class I safety recalls related to any premarket issue. *Id.* In sum, only 0.22% of cleared devices resulted in a recall related to premarket issues. *Id.*

[60] Press Release, FDA, FDA to Improve Most Common Review Path for Medical Devices (Jan. 19, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm.

[61] *Id.*; *see also* FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS, *supra* note 5, at 1–3; FDA, PLAN OF ACTION, *supra* note 7.

In addition to its internal working groups, FDA also commissioned the Institute of Medicine (IOM) to conduct a detailed external review of the system.[62] This IOM committee was formed in early 2010 and held three public meetings in March, June and July 2010.[63] In FDA's January 2011 work plan, it specifically referred seven important questions to this IOM committee.[64] However, the IOM committee has held no public meetings since FDA referred these questions to it.[65] The IOM committee is expected to release its report in the summer of 2011,[66] following a peer review process without any public discussion of proposed recommendations.[67]

II. The Federal Advisory Committee Act

IOM committees do not operate in a legal vacuum—they are governed by section 15 of the Federal Advisory Committee Act (FACA). This next section discusses FACA's history and application to IOM committees. It then examines the requirements imposed by section 15 on IOM committees. Finally, it discusses whether judicial review of IOM committees is possible, and if so, what such review might entail.

A. Federal Advisory Committee Act and Amendments

FACA was originally enacted in 1972 in order to address concerns that advisory committees[68] were disorganized, duplicative, lacked oversight, and lacked public involvement.[69] The goals of the Act were "to reduce wasteful expenditure on advisory committees and make such committees more accountable to the public,"[70] by "provid[ing] standards for the

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[62] *See Project Information*, *supra* note 25.
[63] *Id.*
[64] FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS, *supra* note 5, at 2.
[65] *See Project Information*, *supra* note 25 (indicating that the last public meeting was held in July 2010, and the seven subsequent meetings were all closed to the public).
[66] *See id.* ("A report will be issued at the end of the project in approximately 22 months.").
[67] Drafts of IOM reports remain confidential until after the report is independently reviewed. *See* NAT'L ACADS., OUR STUDY PROCESS: ENSURING INDEPENDENT, OBJECTIVE ADVICE 4 (n.d.) [hereinafter NAT'L ACADS., OUR STUDY PROCESS], *available at* http://www.nationalacademies.org/studycommitteprocess.pdf. Only after all committee members and appropriate officials sign off on the final report is the report released to the public. *Id.*
[68] Advisory committees are generally "entities created to provide the Government with expert advice and collective recommendations from the private sector." Virginia A. McMurtry, *Introduction and Legislative History of the Federal Advisory Committee Act (Public Law 92-463)*, *in* VIRGINIA A. MCMURTRY, CONG. RESEARCH SERV., 95TH CONG., FEDERAL ADVISORY COMMITTEE ACT (PUBLIC LAW 92-463): SOURCE BOOK: LEGISLATIVE HISTORY, TEXTS, AND OTHER DOCUMENTS 3, 3 (Comm. Print 1978). FACA defines "advisory committees" as "any committee, board, commission, council, conference, panel, task force, or other similar group . . . which is (a) established by statute or reorganization plan, or (b) established or utilized by the President, or (c) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government." 5 U.S.C. app. 2, § 3(2) (2006). The current definition specifically excludes any committee created by the National Academy of Sciences. *Id.*
[69] Kurtis A. Kemper, *Construction and Application of Federal Advisory Committee Act*, 160 A.L.R. FED. 483 (2000).
[70] *Id.*; *see also* Federal Advisory Committee Act, Pub. L. No. 92-463 (1972). FACA's purpose was "to control the advisory committee process and to open to public scrutiny the manner in which government agencies obtain advice from private individuals." Food Chem. News, Inc. v. Davis, 378 F. Supp. 1048, 1052 (D.D.C. 1974); *see also* Pub. Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 459 (1989) ("FACA's principal purpose was to enhance the public accountability of advisory committees.").

establishment, operation, termination, and control of advisory committees"[71] It imposed a number of requirements on advisory committees, including fair balance on committees, filing of committee charters, notice and publication of meetings in the Federal Register, public access to meetings and records, monitoring of meetings by federal officials, and limited committee duration.[72] It also provided for Office of Management and Budget (OMB) oversight.[73]

FACA applies to advisory committees that are "established" or "utilized" by federal agencies.[74] As originally enacted, FACA was not intended to apply to committees formed by the National Academy of Sciences (NAS),[75] of which IOM is a part.[76] NAS is a private, independent organization of scientists and academics, chartered by Congress in 1863 to "investigate, examine, experiment, and report upon any subject of science."[77] Its original purpose was to provide the government with independent advice on scientific matters.[78] It "consists of members elected by peers in recognition of distinguished achievement in their respective fields."[79] NAS has about 2100 members, and IOM has about 1600 members.[80] While NAS and IOM are technically independent and do not receive "direct appropriations from the federal government, . . . many of [their] activities are mandated and funded by Congress and federal agencies."[81] In fact, approximately ninety percent of NAS reports are requested by government agencies and/or legislative committees of Congress.[82] NAS and IOM are highly influential organizations, due to the wealth of expertise among their membership, the high quality of their work, and their well-earned "solid reputation[s] as the nation's premier source of independent, expert advice on scientific, engineering, and medical issues."[83]

For twenty-five years, FACA was not applied to NAS—it was only applied to committees "subject to actual management and control by a Federal agency."[84] However, in 1997, the United States Court of Appeals for the District of Columbia in *Animal Legal Defense*

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[71] Exec. Order No. 11,686, 37 Fed .Reg. 21,421 (Oct. 9, 1972).
[72] 5 U.S.C. app. 2 §§ 5–14 (2006); *see also* S. Rep. No. 92-1098 (Sept. 7, 1972).
[73] OMB's oversight was later transferred to the General Services Administration. 5 U.S.C. app. 2 § 12.
[74] 5 U.S.C. app. 2, § 3(2).
[75] "The concept of extending FACA to privately managed and controlled organizations outside the Federal government such as the National Academy of Sciences was discussed and rejected when the FACA legislation was adopted by the House of Representatives." 143 CONG. REC. 25,844 (1997) (citing 118 CONG. REC. 31,421 (1972)).
[76] NAS established the IOM in 1970. *History of the National Academies*, NAT'L ACADS., http://www.nationalacademies.org/about/history.html (last visited Apr. 21, 2011). Over the years, NAS has evolved to incorporate not only IOM, but also the National Academy of Engineering and the National Research Council. NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS 2 (2005). Together, these organizations are collectively known as the National Academies. *Id.*
[77] *Who We Are*, NAT'L ACADS., http://www.nationalacademies.org/about/whoweare.html (last visited Apr. 21, 2011).
[78] *Id.*
[79] *History of the National Academies*, *supra* note 76.
[80] *Id.*
[81] *Who We Are*, *supra* note 77.
[82] 143 CONG. REC. 25,844 (1997) (statement of Rep. Stephen Horn). "Federal agencies are the primary financial sponsors of the Academies' work." NAT'L ACADS., OUR STUDY PROCESS, *supra* note 67.
[83] *Our Reputation*, NAT'L ACADS., http://www.nationalacademies.org/about/reputation.html (last visited Apr. 21, 2011). NAS has an entire webpage of quotes extolling the prestige, reputation, credibility, and influence of the NAS. *Id.*
[84] 143 CONG. REC. 25,844 (1997). Analysis of cases prior to 1997 is irrelevant when analyzing current FACA requirements for NAS committees because of the specific FACA amendment concerning NAS in 1997. *See* Federal Advisory Committee Act Amendments of 1997, Pub. L. No. 105-153, 111 Stat. 2689.

Fund, Inc. v. Shalala[85] held that FACA should apply to committees formed by NAS, since NAS was a "quasi-public" organization which received public funds, was formed by the government, and generally operated for the government's benefit.[86] The court found the NAS committee was "utilized" by the U.S. Department of Health and Human Services, and thus subject to FACA's many requirements.[87]

Congress became concerned that the District Court's decision could "impose significant burdens on the Federal government"[88] and interfere with the independence and quality of NAS studies. In response, it passed the Federal Advisory Committee Act Amendments of 1997,[89] including the now-numbered section 15, in order to "clarify public disclosure requirements that are applicable to the National Academy of Sciences."[90] The purpose of the amendments was twofold. First, it sought to make it clear that the "academy should not be subject to the full process of the Federal Advisory Committee Act."[91] Congress considered the Academies "valuable to America precisely because they are independent of agency influence" and because they include the "best professionals and experts" and "derive their recommendations from multiple perspectives."[92] FACA imposed rigorous procedural requirements which could potentially affect NAS's independence.[93] For those reasons, Congress wanted to ensure NAS's independence from the government to "preserve their high quality, objective, independent studies."[94]

Second, the amendments "require[d] more openness when Federal agencies utilize the academies."[95] Congress recognized that NAS often provided the government with advice, and needed to balance NAS's need for independence with "the public's right to know about the advisors and procedures used to produce technical or policy advice for the government."[96] These openness and accountability requirements included that NAS "post for public comment the names, biographies, and conflict of interest disclosures when committee members are nominated."[97] It also required open data-gathering meetings, posting for public comment the names of reviewers of draft committee reports, and making summaries available to the public of any closed committee meetings.[98] Importantly, the amendments required that NAS committee membership be fairly balanced "for the functions to be performed."[99]

B. NAS "Fair Balance" Requirements Under FACA Section 15

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[85] 114 F.3d 1209 (D.C. Cir. 1997).
[86] *Id.* at 1209–10; *see also* Animal Legal Def. Fund, Inc. v. Shalala, 104 F.3d 424, 428–29 (D.C. Cir. 1997).
[87] 114 F.3d at 1209–10.
[88] 143 CONG. REC. 25,844 (1997). It would have nearly "double[d] the number of discretionary committees subject to the FACA chartering requirements, almost double[d] the number of discretionary committees that must be monitored by Federal officials, and significantly increase[d] the administrative burdens on OMB and GSA in overseeing FACA committees." *Id.*
[89] Federal Advisory Committee Act Amendments of 1997, Pub. L. No. 105-153, 111 Stat. 2689.
[90] 143 CONG. REC. 25,842 (1997) (statement of Rep. Stephen Horn).
[91] *Id.* at 25,843.
[92] *Id.* at 25,845.
[93] *Id.* (statement of Rep. Henry Waxman).
[94] *Id.*
[95] *Id.* at 25,843 (statement of Rep. Stephen Horn).
[96] *Id.* at 25,845 (statement of Rep. Henry Waxman).
[97] *Id.* (statement of Rep. Stephen Horn).
[98] *Id.*
[99] 5 U.S.C. app. 2 § 15(b)(1)(B) (2006).

Section 15 was intended to make NAS committees more open and accountable, without sacrificing their independence and objectivity.[100] Among the other requirements previously discussed, section 15 provides that "[NAS] shall make its best efforts to ensure that . . . the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed."[101] This "fair balance" requirement serves two important purposes. First, it ensures that the committees upon which federal agencies rely are objective and unbiased. Second, it guarantees that these committees include the variety of perspectives and expertise necessary to fulfill the committees' functions. If a committee lacks balance, it may be inadequate to competently accomplish its task. Even if the range of expertise is adequate, the committee's work and agency's reliance on it may still be undermined as biased.

Additionally, individuals with conflicts of interest should not serve on the committee unless the conflict is "unavoidable" and "is promptly and publicly disclosed."[102] The statute itself does not define when a conflict of interest is "unavoidable," and there is no useful discussion of this issue contained in the legislative history. But a plain reading of the statute, as well as IOM's practice in past committees,[103] indicates that this is not a statutory bar to including members with conflicts of interest, but merely a discouragement of such a practice unless the individuals are needed to provide a necessary perspective or area of expertise. NAS and IOM have definitions and policies of their own regarding such conflicts, which will be discussed later in this Article.

Section 15 sets forth this "fair balance" requirement as a separate, additional requirement from public notice of meetings,[104] open data-gathering meetings,[105] public accessibility to materials,[106] public availability of final reports,[107] and public availability of reviewers' names.[108] Therefore, while public input and access to other parts of the committee's work and data-gathering are valuable, these other mechanisms for public participation cannot compensate for a committee's failure to meet the fair balance requirement. Importantly, the statute specifically requires fair balance among the *committee membership*, so fair balance during the peer review process alone also fails to satisfy FACA section 15. The NAS committee itself must have fair balance, regardless of how much public input and balance is present throughout the rest of the process.

Importantly, if a NAS committee fails to comply with the statute—for example, by not being fairly balanced—then "[a]n agency may not use any advice or recommendation" provided by that committee.[109] Therefore, while NAS is free to include whomever it wants on its committees, if that committee composition does not comply with FACA requirements, then FDA, a federal agency, is legally prohibited from using that committee's work.

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[100] Section 15 applies to "the National Academy of Sciences as a corporation, and therefore to the *National Academies* as a whole, including the National Academy of Engineering, the Institute of Medicine, and the National Research Council." NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION AND BALANCE AND CONFLICTS OF INTEREST FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS 2 (2003) [hereinafter NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION], *available at* http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.
[101] 5 U.S.C. app. 2 § 15 (b)(1)(A).
[102] *Id.* § 15(b)(1)(A).
[103] *See infra* notes 185–204 and accompanying text.
[104] 5 U.S.C. app. 2 § 15 (b)(2).
[105] *Id.* § 15 (b)(3).
[106] *Id.* § 15 (b)(3), (4).
[107] *Id.* § 15 (b)(5).
[108] *Id.* § 15 (b)(6).
[109] *Id.* § 15(a).

C. Judicial Review of Committee Balance[110]

FACA section 15 grants IOM a great deal of discretion in committee membership—for example, IOM has almost complete discretion as to which specific individuals it appoints to serve on its committees.[111] Additionally, IOM can determine when a conflict of interest is unavoidable.[112] However, IOM's discretion is not absolute. The statute dictates the committee membership be fairly balanced for its given functions—IOM may only decide how to achieve this balance, not whether to achieve this balance.[113] And while balance need not be perfect, IOM must make its "best efforts" to ensure that such balance on the committee is present. Thus, while IOM has discretion as to how to achieve fair balance, an utter failure to comply, or even attempt to comply, with this statute, could result in judicial review of the FDA's use of an IOM committee's advice.

There is currently no existing case law in which an IOM committee's composition was challenged under FACA section 15. However, case law under section 5 of FACA may provide useful guidance as to when and how a court might evaluate an IOM committee's balance. Section 5 deals with official federal advisory committees (not IOM committees), but it contains similar language as section 15. Section 5 requires that "the membership of the advisory committee [] be fairly balanced in terms of the . . . functions to be performed."[114] Courts examining section 5 have concluded that this "'fairly balanced' requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee."[115] Furthermore, "[u]nder FACA, agencies

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[110] There are a number of avenues through which committee composition may be reviewed and challenged and judicial review is just one option. For example, any person can submit a Citizen Petition, requesting the FDA to refrain from taking any administrative action. 21 C.F.R. pt. 10.30 (2010). The different mechanisms of challenging agency regulations are beyond the scope of this Article.

[111] 5 U.S.C. app. 2 § 15(b)(1).

[112] *Id.* § 15(b)(1)(A).

[113] While the statute says that fair balance must be "determined by the Academy," *id.* § 15(b)(1)(B), this phrase cannot be read so as to confer upon NAS unfettered discretion by removing a court's authority to review statutory compliance. Otherwise, NAS could theoretically appoint anyone to a committee—for example, it could select a committee comprised entirely of industry representatives—and sprinkle the magic words "fairly balanced" over it. Without any possibility of reviewing NAS's fair balance determination, there would be no means to challenge NAS or any federal agency using the NAS committee under this statute. Such a reading would render the entire statutory provision meaningless. It is well accepted that statutes should be read as to "give effect, if possible, to every clause and word . . . ." Montclair v. Ramsdell, 107 U.S. 147, 152 (1883). Furthermore, there is a "strong presumption that Congress intends judicial review of administrative action." Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667, 670 (1986); *see also* McNary v. Haitian Refugee Ctr., 498 U.S. 479, 496 (1991) ("[I]t is most unlikely that Congress intended to foreclose all forms of meaningful judicial review . . . ."). The Administrative Procedure Act, which governs the FDA, provides that "final agency action for which there is no other adequate remedy in a court [is] subject to judicial review." 5 U.S.C. § 704 (2006). Therefore, there must be some form of meaningful judicial review of FDA's compliance with this statute—which entails some evaluation of NAS's determinations of fair balance. NAS's discretion cannot be entirely beyond review.

[114] 5 U.S.C. app. 2 § 5(b)(2).

[115] Nat'l Anti-Hunger Coal. v. Exec. Comm. of the President's Private Sector Survey on Cost Control, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983) (citing S. REP. NO. 92-1098 (1972) and H.R. REP. NO. 92-1017 (1972)). The Senate Report states that section 5 "require[s] that membership of the advisory committee shall be representative of those who have a direct interest in the purpose of such committee." S. REP. NO. 92-1098, at 9 (1972).

should not be permitted to assign advisory committees functions that the committee members do not have the expertise to perform."[116]

This language is strikingly similar to the fair balance requirement in section 15, and it may be fair to presume that Congress intended the same meaning and application of this phrase within the statute when it enacted section 15.[117] Section 5 also requires fair balance with respect to points-of-view represented on the committee.[118] While section 15 does not explicitly require point-of-view balance, such balance may nevertheless be necessary for an IOM committee to adequately fulfill its function—a biased IOM committee may be unable to competently address the issues with which it has been tasked.[119] Therefore, committee members' points-of-view must be considered when evaluating whether the committee is fairly balanced to perform its functions.

Courts reviewing committees' compliance with section 5's fair balance requirement[120] are generally deferential to agencies' determinations that a committee is fairly balanced to perform its functions.[121] However, on occasion, courts have been willing to find that the committees are not fairly balanced, and have enjoined the use of such committees.[122] The examination has two prongs: first, what is the committee's function?[123] Second, is additional balance needed to fulfill those functions?

Where the functions to be performed are "narrow and explicit,"[124] less representation on the committee may be required. For example, in *Cargill, Inc. v. United States*,[125] the committee's function was to peer-review a scientific study protocol examining the health effects of diesel exhaust exposure on underground miners. Because the committee only needed "expertise in the scientific method" in order to fulfill its functions, it was sufficient that the committee contained only scientists and statisticians, and not individuals with an "in-depth knowledge of diesel

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[116] Cargill v. United States, 173 F.3d 323, 336 (5th Cir. 1999).

[117] A well-established canon of statutory construction provides that "[a] term appearing in several places in a statutory text is generally read the same way each time it appears." Ratzlaf v. United States, 510 U.S. 135, 143 (1994).

[118] 5 U.S.C. app. 2 § 5(b)(2).

[119] Indeed, Congress explicitly contemplated this balance of "multiple perspectives" when enacting the 1997 FACA amendments. *See supra* note 92 and accompanying text.

[120] Some courts have found this to be a nonjusticiable, political question. *See, e.g.*, Ctr. for Policy Analysis on Trade & Health (CPATH) v. Office of the U.S. Trade Representative, 540 F.3d 940, 945–47 (9th Cir. 2008); Sanchez v. Pena, 17 F. Supp. 2d 1235, 1238 (D.N.M. 1998). However, most courts have held it to be justiciable. *See, e.g.*, Cargill, Inc. v. United States, 173 F.3d 323, 334–36 (5th Cir. 1999); Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods, 886 F.2d 419, 433 (D.C. Cir. 1989) (Edwards, J., concurring in part and dissenting in part); Nw. Ecosystem Alliance v. Office of the U.S. Trade Representative, No. C99-1165R, 1999 WL 33526001, at *3–4 (W.D. Wash. Nov. 9, 1999). Additionally, litigants often encounter problems with fulfilling the standing requirements. *See, e.g.*, *Nw. Ecosystem Alliance*, 1999 WL 33526001, at *2–3 (finding that litigants had standing); *Nat'l Anti-Hunger Coal.*, 711 F.2d at 1073–74 (stating that "[t]he standing question is a close one," but ultimately agreeing that the litigants had standing); Metcalf v. Nat'l Petroleum Council, 553 F.2d 176 (D.C. Cir. 1977) (denying standing).

[121] *See, e.g.*, *Cargill*, 173 F.3d at 334 (explaining that the functional balance requirement is "subject to a deferential standard of review").

[122] *See, e.g.*, Alabama-Tombigbee Rivers Coal. v. Dep't of Interior, 26 F.3d 1103 (11th Cir.) (upholding an injunction where a committee tasked with deciding whether to list a particular species of fish as endangered did not include any representatives who had an economic interest in that fish market).

[123] *Cargill*, 173 F.3d at336 ("In considering whether a committee is fairly balanced in terms of function, courts naturally have looked first at the functions to be performed).

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

[125] 173 F.3d 323 (5th Cir. 1999).

processes."[126] Furthermore, because the committee's task of "providing *scientific* peer review" was "politically neutral and technocratic," the court found that there was no need for mine managers to be represented on the committee.[127] The committee was not called upon to make policy decisions or provide regulatory advice, so broader representation was unnecessary.[128]

Similarly, in *Public Citizen v. National Advisory Committee on Microbiological Criteria for Foods*,[129] the committee at issue was tasked with providing "advice and recommendations on the development of microbiological criteria for foods."[130] Public Citizen, moving for a preliminary injunction, argued that there was no fair balance because there were many food industry-related committee members but no consumer representatives or advocates on the committee.[131] The court, however, found that because the committee was "charged with a highly technical mandate which requires extensive scientific background as well as expertise in processing and distribution practices,"[132] no consumer advocates were necessary to provide fair balance for the committee's particular function. Not "*every* interested party or group affected" is entitled to representation, only those required for the committee to fulfill its function.[133] However, the court noted that had the committee's purpose been "to study the effects of a particular type of regulation of microbiological criteria on the public, then the results might be different."[134]

When the committee is responsible for making broad substantive policy recommendations, however, much greater representation is required. For example, in *National Anti-Hunger Coalition*, the committee at issue originally had the narrow function of "apply[ing] private sector expertise to attain cost-effective management in the federal government."[135] Even though the committee only included corporate executives and no public interest representatives, the court initially found that it was fairly balanced given its specific function of addressing "fiscal management of large . . . organizations."[136] However, later evidence revealed that the committee in fact made recommendations not concerning cost-control, but instead concerning broad policy issues and possible repeal of existing legislation.[137] Specifically, the court was concerned because the committee's recommendations altered the established rights of those who might be affected, and those people were not represented on the committee.[138] Because the committee addressed "areas of general national import," the court found the committee unbalanced and illegal.[139]

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[126] *Id.* at 336–37 (emphasis omitted).
[127] *Id.* at 337.
[128] *Id.*
[129] 708 F. Supp. 359 (D.D.C. 1988).
[130] *Id.* at 360.
[131] *Id.* at 361.
[132] *Id.* at 363.
[133] *Id.* at 363 (quoting Nat'l Treasury Emps. Union v. Reagan, Civ. A. No. 88-186, 1988 WL 21700 (D.D.C. Feb. 26, 1988)).
[134] *Id.* at 364.
[135] Nat'l Anti-Hunger Coal. v. Exec. Comm. of the President's Private Sector Survey on Cost Control, 711 F.2d 1071, 1074 (D.C. Cir. 1983).
[136] *Id.*
[137] Nat'l Anti-Hunger Coal. v. Exec. Comm. of the President's Private Sector Survey on Cost Control, 566 F. Supp. 1515, 1516–17 (D.D.C. 1983).
[138] *Id.* at 1517.
[139] *Id.*

In *Northwest Ecosystem Alliance v. Office of the U.S. Trade Representative*,[140] the court in determining whether two committees were fairly balanced under FACA stated that "[t]he proper question, simply put, is whether the [committee]s perform functions that are so 'narrow and explicit' that fair balance among competing viewpoints is irrelevant."[141] The committees at issue provided trade and industrial recommendations regarding forest products. These committees' advice "affect[ed] the environment nationally and internationally."[142] The plaintiffs, environmental organizations, sought representation on the committees because they had a "direct interest in the advice given by the [committees]."[143]The court found that the committees' functions could not "be characterized as 'politically neutral and technocratic,'" but that the committees "offer[ed] advice on diverse and far-reaching issues that affect others."[144] Therefore, broad representation was required on the committee, especially representation by environmentalists, whose interests were likely to be affected, and so the committees were unbalanced.[145]

In conclusion, upon examining the case law under FACA section 5, a committee whose functions are narrow, scientific, or technical does not require as broad representation as a committee whose functions extend to broader policy matters. A committee tasked with addressing broad policy, regulatory, and legislative matters that affect others and are of "general national import," requires broad representation. Specifically, those key stakeholders most likely to be affected by the committee's recommendations are entitled to representation on the committee.

III. The National Academies' Selection and Requirements for Committees

IOM committees are not only governed by statute—they are also governed by the National Academies' own internal policies regarding member selection, balance, conflicts of interest and bias.

A. Selection and Operation of Committees

National Academies' staff initiates the search for committee candidates, permitting consultations and suggestions from outside groups and authorities.[146] After review, the chair of the National Research Council, who also serves as the president of NAS, appoints members to the committee.[147] Once appointed, members are required to "list all professional, consulting, and financial connections, as well as to describe pertinent intellectual positions and public statements."[148] However, most of this information remains confidential.[149] Only members'

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[140] No. C99-1165R, 1999 WL 33526001 (W.D. Wash. 1999).
[141] *Id.* at *5.
[142] *Id.*
[143] *Id.* at *3.
[144] *Id.* at *7.
[145] *Id.*
[146] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 6.
[147] *Id.*
[148] *Id.*
[149] *Id.*

names, affiliations, and short biographies are posted online for public comment.[150] During the first committee meeting, members discuss the confidential information in a closed session.[151] At this meeting, changes to the committee's composition are proposed and finalized.[152] Final decisionmaking authority regarding committee balance and conflicts of interest rests with the chair of the National Research Council Executive Office and the General Counsel's Office.[153]

Once committee membership is established, the committee holds open data-gathering meetings, which the Academies' defines as "any meeting of a committee at which anyone other than committee members or officials, agents, or employees of the institution is present."[154] Written materials provided by these outside individuals are made publicly accessible.[155] Committees deliberate in closed meetings when developing findings and drafting recommendations.[156] The public is only provided with a brief summary of these meetings,[157] and "all analyses and drafts of the report remain confidential."[158] The report itself remains confidential until it passes through independent review by other experts appointed by the National Academies.[159] Once the review process is complete and appropriate Academies' officials have signed off on the final report, only then is it released to the public.[160] The public has no opportunity to suggest changes or address concerns—the report is final.[161]

B. Committee Balance, Bias and Conflicts of Interest

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[150] *Id.* This is a requirement under FACA. 5 U.S.C. app. 2 §15(b)(1) (2006). It is questionable whether these brief biographies really provide enough information upon which the public can meaningfully comment, since they may omit information indicating possible conflicts of interest. It may be more appropriate, given the statute's spirit of disclosure, to publicly provide committee members' full curriculum vitaes or other detailed background or personal information. This issue, however, is beyond the scope of this Article.

[151] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 7.

[152] *Committee Appointment Process*, NAT'L ACADS., http://www8.nationalacademies.org/cp/information.aspx?key=Committee_Appointment (last visited April 26, 2011).

[153] NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION, *supra* note 100, at 8.

[154] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 12.

[155] NAT'L ACADS., OUR STUDY PROCESS, *supra* note 67. While NAS officially makes the data publicly accessible, the ease of this accessibility is debatable. In February 2011, both authors of this Article independently inquired about the material available from the IOM 510(k) Committee, and have received no response or information as of the date of publication.

[156] *Id.* at 4; NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 10.

[157] Use of the word "brief" may be an understatement here. FACA section 15(b)(4) requires that "brief summar[ies]" of closed meetings be made publicly available. 5 U.S.C. app. 2 § 15(b)(4) (2006). The summary must "identify the committee members present, the topics discussed, materials made available to the committee, and other such matters that the Academy determines should be included." *Id.* The IOM 510(k) committee has provided only this bare minimum information for each of its seven closed meetings, at no point including any "other such matters." *See Project Information*, *supra* note 25 (listing each committee meeting and providing links to the summaries). This minimal provision of information is not unique to IOM's 510(k) committee. *See, e.g.*, Nat'l Acads., *Meeting Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=4363&MeetingNo=5 (May 24, 2010) (providing a brief summary of a closed meeting of the IOM's Accelerating Rare Diseases Research and Orphan Product Development Committee, including only the minimum required information).

[158] NAT'L ACADS., OUR STUDY PROCESS, *supra* note 67, at 4.

[159] *Id.*

[160] *Id.*

[161] *Id.*

The National Academies recognizes the importance of achieving fair balance—not only balance in perspectives, but balance in knowledge and expertise. "[I]f a report is to be . . . effective . . . [it] must be, and must be perceived to be, not only highly competent but also the result of a process that is fairly balanced in terms of the knowledge, expertise, and perspectives utilized to produce it . . . ."[162] Even fully competent committees may be ineffective if "undermined by allegations of conflict of interest or lack of balance and objectivity."[163] Furthermore, whether a committee is appropriately balanced depends heavily upon the specific tasks with which that committee is charged—"a committee that is well-balanced for one purpose may not be appropriately constructed for a modified task."[164] Therefore, the National Academies requires that its committees to meet two criteria—they must contain an "appropriate range of expertise for the task" and they must also contain a "balance of perspectives."[165] This echoes, albeit with more detail, the "fair balance" requirements of FACA.

First, the Academies' requires that its committees "include experts with the specific expertise and experience needed to address the study's statement of task."[166] It is not enough that committee members be highly qualified in terms of knowledge, training, and experience—"[i]t is also essential that the knowledge, experience, and perspectives of potential committee members be thoughtfully and carefully assessed and balanced in terms of the subtleties and complexities of the particular scientific, technical, and other issues to be addressed and the functions to be performed by the committee."[167] "[T]he significant omission of any required discipline from the committee might seriously compromise the quality of the committee's analysis and judgments, even though it is clear to all that the committee is composed of highly qualified and distinguished individuals."[168]

Second, committees must have point-of-view balance, or a "balance of perspectives." Relevant points-of-view must be balanced "so that the committee can carry out its charge objectively and credibly."[169] Without this balance, the committee's work may be undermined by allegations of bias, regardless of its quality or competence.[170] When a committee is otherwise composed of highly qualified experts, but is lacking balance, "the usual procedure is to add members to the committee to achieve the appropriate balance."[171]

Importantly, committee members are permitted, even expected, to have a particular point-of-view on a relevant issue.[172] These personal opinions, biases, or perspectives are not considered disqualifying conflicts of interest.[173] Members may serve on the committee even though they are "committed to a fixed position on a particular issue" through public statements,

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[162] NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION, *supra* note 100, at 1.
[163] *Id.*
[164] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 5.
[165] *Committee Appointment Process*, *supra* note 152.
[166] *Id.*
[167] NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION, *supra* note 100, at 3.
[168] *Id.*
[169] *Committee Appointment Process*, *supra* note 152.
[170] "The credibility of a report can be called into question if the committee that produced it is perceived to be biased." NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 6.
[171] *Id.* at 7.
[172] *Committee Appointment Process*, *supra* note 152 ("Committee members are expected to have points of view . . . .")
[173] NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION, *supra* note 100, at 5.

publications, or by closely identifying or affiliating with particular interest groups.[174] These biases, while not necessarily disqualifying, must be balanced.

In fact, the National Academies' recognizes that sometimes member bias is actually necessary "to ensure that a committee is fully competent."[175] Some studies require particular perspectives, despite potential bias, or even conflicts of interest. For example, the Academies' official Policy on Committee Composition and Balance and Conflicts of Interest explains that "it may be important to have an 'industrial' perspective or an 'environmental' perspective" because "such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee."[176] Thus, potentially biasing backgrounds are acceptable, or even desirable, as long as they are balanced by countervailing perspectives on the committee.

Conflicts of interest are different from points-of-view. The Academies' defines a "conflict of interest" as "any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization."[177] Only current interests are considered conflicts, not past or possible future interests.[178] Conflicts of interest are usually, but not always, financial.[179] When individuals are appointed to a committee, they undergo a rigorous conflict-of-interest review. Generally, individuals with conflicts of interest may not serve on committees because it could cause others to "reasonably question, and perhaps discount or dismiss, the work of the committee."[180]

However, in some situations, the Academies may determine that a conflict of interest is unavoidable, in which case it must promptly and publicly disclose the conflict.[181] For example, the conflict may be unavoidable if "the individual's qualifications, knowledge, and experience are particularly valuable to the work of the committee and if the institution is unable to identify another individual with comparable qualifications, knowledge, and experience who does not also have a conflict of interest."[182]

The National Academies states that unavoidable conflicts only arise in "rare situations"[183] or "exceptional circumstances,"[184] but a brief review of past IOM committees illustrates that this situation is not so "rare" or "exceptional." A search on IOM's website for current or recent FDA-sponsored IOM committees revealed ten such committees, at least half of which contained members with industry background and at least three committees involved disclosed conflicts of interest.[185] For example, the IOM committee on Qualification of Biomarkers and Surrogate

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[174] *Id.*
[175] *Id.* at 3.
[176] *Id.*
[177] *Id.* at 4.
[178] *Id.*
[179] *Id.*
[180] *Id.*
[181] This is required both by FACA and the National Academies' own policies. *See* 5 U.S.C. app. 2 § 15(b)(1)(A); *Committee Appointment Process*, *supra* note 152.
[182] NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION, *supra* note 100, at 8.
[183] *Committee Appointment Process*, *supra* note 152
[184] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 7.
[185] *About Activities*, INST. MED., http://www.iom.edu/Activities.aspx?search=%22food%20and%20drug%20administration%22 (search performed April 26, 2011). Disclosures of committee member conflicts of interest are only available for current projects, but

Endpoints in Chronic Disease includes a Vice President at Merck & Co.[186] IOM concluded that this committee required "at least one person who has extensive current knowledge of the pharmaceutical industry's involvement with efforts to define biomarker qualification strategies."[187] Thus, despite this individual's position at Merck, a large pharmaceutical company that engages in drug discovery and development, his membership was desirable because of his expertise and experience.[188] This committee also included another individual who had a conflict of interest because he "owns a consulting company through which he serves as a consultant to companies in the diagnostic, medical instruments and pharmaceutical industries."[189] His membership was necessary because of his "expertise in clinical chemistry."[190]

The IOM committee on Accelerating Rare Diseases Research and Orphan Product Development was asked to evaluate strategies "to promote research discoveries and development of orphan products to improve the health of people with rare diseases."[191] This committee evaluated public policies and legislative and regulatory initiatives relevant to product development for rare diseases.[192] This task is strikingly similar to the 510(k) Committee's charge of evaluating innovation. Here, IOM determined that the committee must include "someone with expertise and experience in the medical devices industry to help the committee examine factors affecting product development decisions by companies and assess options for accelerating research and development in the area of rare conditions."[193] Therefore, IOM included on this committee a former Vice President of Medtronic, Inc.,[194] who also owned stock and was a consultant to Medtronic, despite his conflict of interest.[195] His conflict of interest was thus "unavoidable" precisely because his "extensive experience and expertise in product research and development in the medical device industry" was considered necessary for the committee to accomplish its task.[196] This same committee also included an individual who was a former Senior Vice President of Pfizer, Inc., owned stock and stock options in Pfizer, and who was also a "partner in a private equity firm focused on drug development programs."[197] This individual was required on the committee because of his "expert knowledge of drug discovery and development in the pharmaceutical industry."[198] Finally, this committee of fourteen people included a third member with a conflict of interest, an individual who consults with pharmaceutical, medical device, and biologics companies, because of her "direct experience with the administration of the FDA orphan product development program."[199]

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not recently completed projects, so the total number of recent committees involving disclosed conflicts of interest may have in fact been greater than the three retrieved through this search.

[186] Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49028 (last visited Apr. 28, 2011).

[187] *Id.*

[188] *Id.*

[189] *Id.*

[190] *Id.*

[191] *Activity: Accelerating Rare Diseases Research and Orphan Product Development*, INST. MED., http://www.iom.edu/Activities/Research/OrphanProductResearch.aspx (last updated Jan. 25, 2011).

[192] *Id.*

[193] Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49099 (last visited Apr. 28, 2011).

[194] Medtronic manufactures medical devices, including devices used in treating certain rare conditions. *Id.*

[195] *Id.*

[196] *Id.*

[197] *Id.*

[198] *Id.*

[199] *Id.*

The IOM committee on Review of the Food and Drug Administration's Role in Ensuring Safe Food reviewed gaps in public health protection in the farm-to-table food safety system and made legislative, regulatory, and administrative recommendations.[200] Two members of this committee had disclosed conflicts of interest. First, the Senior Vice President and Chief Scientific and Regulatory Affairs Officer of the Grocery Manufacturers Association[201] was permitted on the committee because of his "current knowledge of the regulatory and scientific activities and *perspectives of the food industry*."[202] He was appointed to this committee precisely because of his "current, in-depth knowledge of industry activities and perspectives."[203] The second member was an expert in the field of risk analysis and chemical risk assessment, who was appointed to the committee despite his role in a consulting firm that performs risk assessments for food industry clients and "whose financial interests could be affected by the outcome of the committee's study."[204]

Clearly, individuals with conflict of interest are frequently deemed valuable and necessary for IOM committees to fulfill their functions. In fact, it is often the source of these conflicts of interest—the individuals' experience and connections with the industries involved—that makes their membership on the committee essential. Thus, these conflicts are considered "unavoidable." At least three out of ten FDA-sponsored IOM committees contain members with such conflicts of interest. One can hardly view that as "exceptional" or "rare."

IV. IOM's 510(k) Committee

IOM's 510(k) Committee must be fairly balanced for the functions it is to perform. It must include all essential areas of expertise, balance the biases and perspectives of its members, and disclose any unavoidable conflicts of interest. A failure to achieve this balance violates both FACA section 15 as well as the internal National Academies' policies and requirements.

The Committee was originally asked to assess two critical questions: 1) whether the current 510(k) process optimally protects patients and 2) whether it promotes innovation in support of public health.[205] If the Committee found that the 510(k) system did not protect patients or promote innovation, it was asked to recommend any legislative, regulatory, or administrative changes that would be necessary to achieve these goals.[206] In January 2011, the Committee was also referred seven specific issues to consider. These issues covered a broad range of controversial issues, including FDA's authority to fully or partially rescind a 510(k) clearance, clarification as to when a device should no longer be available for use as a predicate, establishment of a new Class IIb device category, whether the FDA should consider off-label use when determining a device's "intended use," requiring each 510(k) submitter to keep at least one unit of the device under review available for the CDRH to access upon request, authorities and

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[200] *Activity: Review of the Food and Drug Administration's Role in Ensuring Safe Food*, INST. MED., http://www.iom.edu/Activities/Nutrition/FDARoleReview.aspx (last updated Sept. 14, 2010).
[201] The Grocery Manufacturers Association is "a trade association that represents food, beverage and consumer products companies whose interest might be affected by the committee recommendations." Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49032 (last visited Apr. 28, 2011).
[202] *Id.* (emphasis added).
[203] *Id.*
[204] *Id.*
[205] *Activity: Public Health Effectiveness of the FDA 510(k) Clearance Process*, *supra* note 19.
[206] *Id.*

requirements for postmarket surveillance studies, and clarification and consolidation of the terms "indication for use" and "intended use."[207] Therefore, the committee's composition must be balanced for not only the initial broad system-wide and policy issues, but also for the specific additional issues it was later asked to address.[208]

The 510(k) Committee has twelve members, consisting of five physicians, three lawyers, and a number of talented academics with a variety of technical backgrounds.[209] Overall, the committee includes a wide range of educational and professional experiences. Each of the individuals on the committee is highly qualified and impressive, and this Article does not question their expertise or competence. However, there are some critical absences on this committee. Notably, the committee does not include:

- inventors and innovators who have created new device products under current FDA systems;[210]
- product developers who have brought products from concept to market through the FDA approval processes;
- entrepreneurs;
- venture capitalists, investment bankers, or angel investors with experience financing new medical device innovation;
- individuals who routinely prepare 510(k) applications;
- management or other professionals from the medical device industry; or
- patients or patient advocates.

The FDA acknowledged some of these omissions in a recent hearing before Congress. Dr. Jeffrey Shuren, the Director of the FDA's Center for Devices and Radiological Health,

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[207] *See* FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS, *supra* note 5, at 11–13, 16–19; FDA, PLAN OF ACTION, *supra* note 7, at 6.

[208] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 5 ("[A] committee that is well-balanced for one purpose may not be appropriately constructed for a modified task.").

[209] Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49181 (last visited Apr. 28, 2011).

[210] One committee member, Dr. Lazar Greenfield, is credited with inventing the Greenfield vena cava filter. *See Activity: Public Health Effectiveness of the FDA 510(k) Clearance Process*, *supra* note 19. However, this invention was introduced in 1973, before there was separate regulation of medical devices by the FDA. *See* Ken Garber, *The Clot Stopper*, 22 INVENTION & TECH. MAG. (Summer 2006), *available at* http://beta2.americanheritage.com/articles/magazine/it/2006/1/2006_1_34.shtml (describing the invention of the Kimray-Greenfield filter in the early 1970s and stating that "at the time, the Food and Drug Administration did not have to approve medical devices . . . "). The Medical Device Amendments creating the initial device regulatory system did not become law until 1976. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539. The modern 510(k) system did not start to take shape until the Safe Medical Device Amendments of 1990. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511. There have been major subsequent changes to the statutory system for medical device regulation, most notably in 1997 and 2007. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296; Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823. Of course, there has been a constant parade of new regulations, guidance documents, and policies in the last 20 years. *See Device Advice: Device Regulation and Guidance*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ (last updated Sept. 27, 2010) (providing information about many of the statutes, regulations and guidance concerning medical devices). The subsequent major changes to the Greenfield filter occurred after Boston Scientific acquired the device—and although Dr. Greenfield made suggestions to improve the filter's design, it was Boston Scientific that navigated the FDA's regulatory process. *Cf.* Ken Garber, *supra* (describing the company's subsequent changes to the filter).

admitted that the IOM committee does not include any innovators or inventors, entrepreneurs or investment and venture capital experts, or patients or patient group representatives.[211] FDA later amended these answers, identifying two committee members as "inventors" or "innovators."[212] However, since these individuals did not contribute to the creation of new devices under current FDA systems,[213] their contributions to this committee as "inventors" and "innovators" are severely limited and not particularly relevant.[214] Without current and relevant experiences and perspectives on the committee, it is hardly "fairly balanced" to answer broad policy questions involving patient safety and innovation, and is also not fairly balanced to adequately address the seven additional questions posed to this committee.

A. The Committee Lacks Balance of Expertise to Address Safety

The Committee must include expertise to address both safety and innovation issues. Patient safety is undoubtedly a broad, public issue, involving policy and regulatory recommendations and affecting the public at large. It is a complex, multifactorial issue, requiring consideration of not only manufacturing controls, device design, and other industry-related factors, but also patient access, autonomy, and acceptable risk. It is not a "narrow and explicit" function,[215] nor is it "politically neutral and technocratic."[216] Rather, the safety of all patients in this country is an issue that most certainly affects "areas of general national import,"[217]and involves "diverse and far-reaching issues."[218] As previously discussed, where committees are called upon to make policy decision or provide regulatory advice, broad representation is

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[211] *Impact of Medical Device Regulation on Jobs and Patients: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 112th Cong. 62 (2011) (statement of Dr. Jeffrey Shuren, Director, FDA Center for Devices and Radiological Health), *available at* http://democrats.energycommerce.house.gov/sites/default/files/image_uploads/Transcript_MedDevice.pdf. FDA later justified these absences by saying that such individuals would have a conflict of interest and would thus be ineligible to serve on the committee—however, IOM's past practices undermine this justification. *See* Letter from Jeanne Ireland, Assistant Comm'r for Legislation, FDA, to Hon. Joseph R. Pitts, Chairman, Subcomm. on Health, H. Comm. on Energy & Commerce (Apr. 12, 2011) (on file with author) [hereinafter Letter from Jeanne Ireland] (justifying the lack of these various individuals on the committee).

[212] *See* Letter from Jeanne Ireland, *supra* note 211, at 15 (identifying Dr. Lazar Greenfield and Dr. Gary Dorfman as the committee's only inventors and innovators).

[213] As explained above, Dr. Greenfield's experience as an inventor or innovator predates any current FDA regulatory schemes. *See supra* note 210. Dr. Dorfman, who "holds several patents related to medical devices," Letter from Jeanne Ireland, *supra* note 211, at 15, may qualify as an "inventor,"—however, his most recent patent was filed in 2002. *See* U.S. Patent No. 6,736,842 (filed July 24, 2002). He does not qualify as an "innovator" because innovation requires more than mere abstract conceptualization and patent-filing. *See infra* notes 223–227 and accompanying text (describing innovation as the transformation of an invention into a helpful commercial product).

[214] This Article only argues that these individuals' experience is insufficient to meet the specific requirements of this particular committee—it in no way intends to diminish their professional qualifications, knowledge, experience, and contributions.

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

[216] Cargill, Inc. v. United States, 173 F.3d 323, 337 (5th Cir. 1999).

[217] Nat'l Anti-Hunger Coal. v. Exec. Comm. of the President's Private Sector Survey on Cost Control, 566 F. Supp. 1515, 1517 (D.D.C. 1983).

[218] Nw. Ecosystem Alliance v. Office of the U.S. Trade Representative, No. C99-1165R, 1999 WL 33526001 (W.D. Wash. Nov. 9, 1999).

necessary.[219] More diverse representation may also be necessary when the committee's purpose is "to study the effects of a particular type of regulation . . . on the public."[220] Therefore, following the reasoning the courts have applied under FACA section 5, the 510(k) system's protection of public safety is an issue requiring diverse committee representation.

Those who invent, design, develop, manufacture, finance and test medical devices have much-needed expertise in how to ensure the safety of those devices. In fact, they are legally required to design, research, test, manufacture, and support the product in a safe manner.[221] They offer valuable perspectives on the types of research systems, manufacturing controls, testing strategies, and design processes that are needed to enhance patient safety.[222] Through their experience, they are familiar with how the FDA's regulatory process affects these factors. These stakeholders are responsible for all new devices marketed in the United States, and it is their experience and work that greatly affects the safety of patients throughout the nation. Yet the committee lacks this expertise. Without at least some of these individuals on the committee, it cannot adequately evaluate the 510(k) system's effect on patient safety and make practical, helpful recommendations as to how to improve it.

B. The Committee Lacks Balance of Expertise to Address Innovation

Innovation is more than just invention. Invention is simply the embodiment of a new idea. It "generates new ideas, patents, prototypes, designs, breakthrough experiments, and working models."[223] Innovation, however, is the transformation of an idea or invention into a commercial product for the betterment of society.[224] It is the identification of a need and the development of a service or product to meet that need.[225] Innovation is responsible for an invention's acceptance in society, profitability, and value. Thus, innovation encompasses more than just invention—it includes the entire cycle, from invention, research and development, manufacturing, marketing, and ultimate value realization in society.[226] Invention is possible without innovation, and innovation does not necessarily require invention.[227]

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[219] *See Cargill*, 173 F.3d at 337 (finding broad representation unnecessary because the committee was not called upon to make policy or regulatory decisions).

[220] Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods, 708 F. Supp. 359, 364 (D.D.C. 1988).

[221] *See, e.g.*, 21 U.S.C. § 360e(d) (conditioning premarket approval on a "showing of reasonable assurance" that the device is safe, as well an examination of the manufacturing, processing, packing, and installation methods, facilities and controls, as well as device performance); *id.* § 351(a)–(d) (defining when a device is "adulterated" and making it illegal to ship such a device); 21 C.F.R. pt. 814.2 (requiring approved devices to be safe and effective); *id.* pt. 820.1 (establishing quality system regulations to ensure that finished devices are safe).

[222] *See* Josh Makower, The Structure of the MedTech Innovation Ecosystem (June 14, 2010), *available at* http://www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/510kProcess/2010-JUN-14/Presentations/14%20Makower.pdf (explaining that good quality systems, beginning with design development and control and continuing through manufacturing and post market surveillance, are primarily responsible for patient safety).

[223] Thomas D. Kuczmarski, *Innovation Always Trumps Invention*, BLOOMBERG BUSINESSWEEK, Jan. 19, 2011, http://www.businessweek.com/innovate/content/jan2011/id20110114_286049.htm.

[224] *Id.* (explaining that innovation "transforms these inventions into commercial products, services, and businesses").

[225] *Id.*

[226] *See* Larry Dignan, *The Difference Between Innovation and Invention*, ZDNET (Mar. 7, 2007, 9:09 AM), http://www.zdnet.com/blog/btl/the-difference-between-innovation-and-invention/4610; *see also* William Buxton, *Innovation vs. Invention*, ROTMAN MAG., Fall 2005, at 52, 52 ("Innovation is far more about prospecting, mining, refining and adding value than it is about pure invention."); Makower, *supra* note 222 (identifying the parts of the

To assess the 510(k) system's promotion of innovation, the committee must include more than lawyers, doctors and academics. It must include more than inventors or patent-holders. IOM's charge requires an appreciation of how regulation impacts the complex innovation ecosystem. It requires an understanding of innovation, finance, entrepreneurship, product development, manufacturing, and regulatory process. At least some committee members must have this knowledge. They must have experience in transforming inventions into commercial products and bringing value to society through these new products. Ideally, the Committee should include people who have worked within the current 510(k) framework when they have conceptualized devices, designed and developed those devices, obtained financing for new product lines, manufactured those devices and successfully brought them to market. Essentially, entrepreneurs and those who have been recently involved in the medical device industry are needed for their experience and insights into the current 510(k) system's effect on innovation. Unfortunately, the committee lacks this expertise.

The FDA has even acknowledged the crucial role industry plays in innovation. In a recent presentation made to the annual meeting of the Food and Drug Law Institute, the Director of CDRH stated: "U.S. medical device development is an ecosystem with shared responsibilities—to remain healthy it needs a strong device industry, a strong U.S. research system, and a strong FDA."[228] Thus, CDRH reconfirmed and explicitly recognized the vital role of industry in medical device innovation. This is precisely one of those situations in which it is crucial to have an "industrial" perspective to achieve an "informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee."[229] After all, it is industry that designs, tests, develops and makes the regulatory submissions for essentially all medical devices marketed in the United States.

While the current 510(k) Committee includes highly qualified, intelligent, and experienced members, individuals with the critical expertise in innovation, manufacturing, entrepreneurship, device development, financing, and marketing are conspicuously absent. Each current committee member is individually impressive and has expertise worthy of inclusion on the committee, but without this broader membership, the committee is inadequate to fulfill its mission. Thus, this committee is not fairly balanced to perform its functions, and fails to satisfy FACA § 15 as well as the National Academies' own policies on committee composition.

C. The Committee Lacks Balance to Address Additional Questions

In addition to the general issues of patient safety and innovation, the IOM 510(k) Committee was also asked to address seven specific issues, as explained above.[230] Without an industry member on the committee, it is not fairly balanced to tackle these additional questions. For example, the committee was asked to "consider defining the scope and grounds for the

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medical technology innovation system, including "fuelers" such as venture capitalists, investors, and public markets, "innovation catalysts" such as small start-ups, large companies, incubators, and other inventors and entrepreneurs, "consumers" such as patients, physicians, and hospitals, and "regulators" such as FDA, CMS, third party payers, and professional societies).

[227] *See* Vernon W. Ruttan, *Usher and Schumpeter on Invention, Innovation, and Technological Change*, Q.J. ECON., 596, 597 (1959) (describing the distinction between innovation and invention).

[228] Jeffrey Shuren, Dir., Ctr. for Devices & Radiological Health, 2011: The State of CDRH (Apr. 6, 2011) (on file with author).

[229] NAT'L ACADS., POLICY ON COMMITTEE COMPOSITION, *supra* note 100, at 3.

[230] *See supra* note 207 and accompanying text.

exercise of the Center's authority to fully or partially rescind a 510(k) clearance."[231] Recommendations as to rescinding 510(k) clearances may "alter the established rights of those who might be affected"[232] (i.e. medical device companies who are currently marketing products cleared through the 510(k) process), and thus those people must be represented on the committee.

As another example, the Committee was also asked to "consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for CDRH to access upon request."[233] This has enormous practical implications for medical device companies—storage and warehousing of functional devices such as large magnetic resonance imaging machines and other imaging devices, as well as complicated and sensitive electronics such as surgical robots, is not only expensive, but requires large amounts of real estate and the creation of specially-designed warehouses that can accommodate the specific weight, chemical, and temperature requirements of these devices. Device installation and calibration also presents significant burdens to industry.[234] Medical device companies have essential insight as to the practicability, or even possibility, of this new requirement. They also offer valuable perspectives on the benefits (or lack thereof) that such a new requirement may have in complaint investigation and corrective action for problematic devices.[235] Theoretically it might be a great idea to keep one of each device ready for inspection at all times, but there are practical limitations that only those involved in the industry may be likely to consider.

Although this Article only discusses two of the seven additional issues, each of the seven questions posed to the IOM Committee could benefit, or even requires, an industry perspective on the committee. Therefore, even if the committee were fairly balanced for its original functions, it is not fairly balanced for these additional tasks.

D. The Committee Lacks Balance of Perspectives

IOM committees must also be balanced with respect to the perspectives and biases of the committee members. While not explicitly required by FACA,[236] this is an explicit requirement according to the National Academies' own policies.[237] As previously noted, IOM committees can include individuals with preexisting biases, since most biases are not conflicts of interest, providing that there are countervailing viewpoints on the committee.[238] Unfortunately, the 510(k) committee does not include a balance of viewpoints.

For instance, one committee member spent almost twenty years at the national public interest law firm Public Citizen Litigation Group, whose motto is "Defending Democracy. Resisting Corporate Power."[239] Public Citizen's goal is to "defend[] democracy from corporate

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[231] FDA, PLAN OF ACTION, *supra* note 7, at 6.
[232] Nat'l Anti-Hunger Coal. v. Exec. Comm. of the President's Private Sector Survey on Cost Control, 566 F. Supp. 1515, 1517 (D.D.C. 1983).
[233] FDA, PLAN OF ACTION, *supra* note 7, at 6.
[234] *See* FDA, 510(K) AND SCIENCE REPORT RECOMMENDATIONS, *supra* note 5, at 17.
[235] *See* 21 C.F.R. pt. 820.100 (2010) (discussing corrective and preventative action regarding medical devices).
[236] But as noted earlier, this is an implicit requirement when a lack of objectivity compromises the ability of the committee to fulfill its function.
[237] *See supra* notes 165, 169–171 and accompanying text.
[238] *See supra* notes 172–176 and accompanying text.
[239] PUB. CITIZEN, http://www.citizen.org (last visited Apr. 29, 2011).

greed."[240] The organization is highly critical of the 510(k) process, asserting that medical devices are approved too quickly so that dangerous or deadly devices enter the market.[241] In fact, the Director of Public Citizen's Health Research Group criticized FDA's deferral to IOM, stating that "the FDA is not being forceful enough about improving the safety and effectiveness of new devices" and is "yield[ing]" to innovation .[242] While this individual's participation and viewpoint is certainly appropriate on this committee, there is no apparent counterweight. The committee actually requires an explicit pro-industry viewpoint to achieve balance.

Thus, the 510(k) Committee is unbalanced with respect to points-of-view, as well as expertise. This imbalance in perspectives subjects the committee to the risk actual bias, or at least the perception of bias, which may undermine the committee's hard work, regardless of the accuracy of its final report.

E. The Committee Needs Patients or Patient Advocates

It is also critical that the patient—the ultimate stakeholder—is not represented on the committee. The charge to the committee requires balancing risk (i.e. the protection of patients) with innovation (i.e. getting patients faster and more economical access to innovative new products). This balancing process raises politically significant questions of patient autonomy, beneficence, and medical ethics.[243] When should the patient have the right to some particular device despite known risks? Under what circumstances should the FDA intervene and make that decision for the patient by barring access to the device? FDA charged this committee with determining the "optimal" balance between these factors.[244]

Any adequate evaluation of patient safety requires a patient or patient advocate's viewpoint and expertise. What constitutes an unacceptable risk or adequate safety is a value-driven determination, varying greatly with each individual and each disease. The stakeholder most affected by that balance and best positioned to opine upon this is the patient. In fact, the patient may be the only person even qualified to make this determination. Innovation concerns also require a patient's perspective. The focus of device innovation is centered around and driven by patient needs.[245] Devices are conceptualized only after identification of a particular patient

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[240] *Id.*

[241] *See, e.g.*, Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, PLOS MED., July 2010, at 1, 3–4, *available at* http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000280 (harshly critiquing the 510(k) process, and acknowledging Brian Wolfman, a current IOM committee member, for his assistance on the article); *see also Device and Diagnostic Policy*, PUB. CITIZEN, http://www.citizen.org/Page.aspx?pid=2505 (last visited Apr. 29, 2011) (explaining that medical devices are "often approved quickly and inappropriately," causing "dangerous and even deadly devices [to] enter the market").

[242] Press Release, Sidney Wolfe, Dir., Public Citizen's Health Research Grp., FDA Dodges Responsibility Regarding Medical Device Approval, Defers to IOM (Jan. 19, 2011), *available at* http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3261.

[243] *See generally* Ben A. Rich, *Medical Paternalism v. Respect for Patient Autonomy: The More Things Change the More They Remain the Same*, 10 MICH. ST. U. J. MED. & L. 87 (2006) (discussing these concepts); Nili Karako-Eyal, *Physicians' Duty of Disclosure: A Deontological and Consequential Analysis*, 14 QUINNIPIAC HEALTH L.J. 1, 6–12 (2010) (same).

[244] *Activity: Public Health Effectiveness of the FDA 510(k) Clearance Process*, *supra* note 19.

[245] *See* Makower, *supra* note 222 (explaining that the focus of MedTech innovation is "completely patient need driven, not technology driven").

need, and only devices that meet these needs can succeed in the market.[246] Thus, the patient perspective is critical to a complete understanding of innovation.

But the committee includes no patient or patient advocate. It is hard to justify this omission—it is easy to find a patient representative without any financial conflict, and many other IOM committees have included such an individual.[247] While the committee does include a number of physicians, they cannot speak for the patient—the patient, not the doctor, is the ultimate decision-maker.[248] The argument that the physician can make these decisions for the patient is long discredited.[249] For example, studies have shown that physicians make different decisions when they themselves are the patient—often recommending to their patients the treatment with the greatest chance of survival, while choosing for themselves the treatment with the lowest complication risk.[250] "[M]edical decision-making can be a function of *who the patient is* as much as *what the patient has*."[251] Arguing that a patient representative is not capable of adding to the debate over this balance is simply paternalism run amok. The patient (or patient advocate) provides a critical area of expertise and an essential perspective, needed to assess both questions of safety and innovation. Without such an individual, the committee is not fairly balanced for either function.

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[246] *Id.*

[247] Many other IOM committees have included patient or consumer advocates. For example, the Committee on Comparative Effectiveness Research Prioritization included a woman from the National Breast Cancer Coalition, who herself had survived breast cancer and radiation-induced sarcoma. *See* Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/committeeview.aspx?key=49051 (last visited Apr. 29, 2011). The Committee on Review of Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials included a member from the Research Advocacy Network, a group "dedicated to advancing patient-focused research," who was also an editor of a newsletter for patient advocates as well as a patient advocate herself. *See* Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/committeeview.aspx?key=49273 (last visited Apr. 29, 2011). The committee on Accelerating Rare Diseases Research and Orphan Product Development included the founder of Parent Project Muscular Dystrophy, a woman who had lost two sons to the debilitating disease. *See* Nat'l Acads, *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49099 (last visited May 1, 2011). The committee on Identifying and Preventing Medication Errors included the president of the nonprofit People's Medical Society, one of "the most influential consumer health advocacy organizations in the United States." *See* Nat'l Acads., *Committee Membership Information*, CURRENT PROJECTS SYS., http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=113 (last visited May 1, 2011). *But see Activity: Assessment of the U.S. Drug Safety System*, INST. MED., http://www.iom.edu/Activities/Quality/USDrugSafetySystem.aspx (last visited May 1, 2011) (lacking a patient or patient advocate on the committee).

[248] *See* Amir Halevy, *Medical Futility, Patient Autonomy, and Professional Integrity: Finding the Appropriate Balance*, 18 HEALTH MATRIX: J. L.-MED., 261 266 (2008) ("In both medical ethics and health law, patient autonomy has replaced medical paternalism as the dominant decision-making model.").

[249] Judge Cardozo may have said it best when he wrote: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . ." Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914). *See also* Holly Fernandez Lynch et al., *Compliance with Advance Directives*, 29 J. LEGAL MED. 133, 133 & n.2 (2008) ("[P]hysician paternalism has been widely rejected . . . ."); Rich, *supra* note 243, at 92 (explaining that "notions of beneficence and nonmaleficence" are paternalistic and without justification).

[250] *See, e.g.*, Peter A. Ubel et al., *Physicians Recommend Different Treatments for Patients than they Would Choose for Themselves*, 171 ARCHIVES INTERNAL MED. 630 (2011).

[251] John B. McKinlay et al., *Non-Medical Influences on Medical Decision-Making*, 42 SOC. SCI. & MED. 769, 769 (1996); *see also* Halevy, *supra* note 248, at 266–67 (explaining that unlike medical paternalism, the patient autonomy model recognizes that each patient is an individual who best "knows his values and goals and thus is in the best position to make decisions regarding his life and health").

V. FDA Cannot Legally Use the IOM 510(k) Committee's Report

As explained above, the IOM 510(k) Committee does not include any innovators, entrepreneurs, financiers, industry employees, patients, or patient advocates. These perspectives are critical for the committee to adequately evaluate the 510(k) system's effect on patient safety and device innovation, as well as to answer the seven additional issues it was asked to address. Without these perspectives, the committee is not "fairly balanced" with respect to either expertise or viewpoints, and therefore is not in compliance with FACA.[252] Since the committee fails to comply with this statutory requirement, the FDA "may not use any advice or recommendation" this committee provides.[253]

These omissions in committee membership are surprising, given IOM's usual diligence in appointing members to committees to ensure the requisite expertise and achieve fair balance.[254] IOM could easily have avoided the gaps in expertise and lack of balance on this committee by including any one of a number of qualified individuals. In fact, many such individuals already belong to the NAS or IOM, or have at least served on other committees in the past.[255] It simply defies credibility that IOM would fail to include essential experts and viewpoints on this particular committee when it already has highly vetted, extremely qualified individuals among its membership. Alternatively, IOM could have looked beyond its membership to any one of a number of distinguished experts and leaders in the medical device field to obtain the required committee membership—but it did not do so.

If IOM was concerned about conflicts of interest, it could have simply disclosed these conflicts as it has done so many times before with other committees.[256] When committees have evaluated drug innovation, pharmaceutical industry members were included on the committee.[257] When committees have evaluated food safety, food industry members were on the committee.[258] When committees assessed issues involving patient safety, patients or patient advocates were on the committee.[259] In those cases, the individuals with conflicts of interest were deemed necessary to achieve balance and provide critical expertise, and so IOM classified those conflicts as "unavoidable." Here, however, IOM seemingly concluded that a committee evaluating medical devices did not require anyone involved in the device industry. This committee evaluating patient safety did not require any patients or patient advocates. This inconsistency is both surprising and alarming, especially coming from an institution renowned for its thoroughness, objectivity, and balance.

Furthermore, for purposes of FACA's fair balance requirement, it is irrelevant that the Committee solicits advice from industry, holds open data-gathering meetings, or even encourages open dialogue with outsiders who are not on the committee. It is also irrelevant that

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[252] *See* 5 U.S.C app. 2 § 15(b)(1)(B) (2006).
[253] *Id.* § 15(a).
[254] *See Our Study Process*, INST. MED., http://www.iom.edu/About-IOM/Study-Process.aspx (last updated Mar. 9, 2011) ("Our consensus studies are conducted by committees carefully composed to ensure the requisite expertise . . . .").
[255] *See, e.g.*, *supra* note 194 and accompanying text (describing the inclusion of a Medtronic executive on an IOM committee).
[256] *See supra* notes 185–204 and accompanying text.
[257] *See, e.g.*, *supra* notes 197–198 and accompanying text.
[258] *See, e.g.*, *supra* notes 201–203 and accompanying text.
[259] *See supra* note 247 and accompanying text.

individuals with the expertise currently lacking from the committee may be independent reviewers of the committee's report before the report is issued. While this type of public input and fairness in the reviewing process are certainly desirable, and even legally required,[260] it does not compensate for the committee's failure to achieve fair balance on the committee itself. Section 15's "fair balance" requirement is a specific requirement that the committee must meet.[261] Therefore, while stakeholder participation through these other methods is necessary and valuable, it is not alone sufficient to satisfy FACA § 15.

As even FDA has acknowledged, IOM's 510(k) committee lacks sufficient expertise and fair balance to perform its functions of assessing patient safety and promoting innovation. As it has done many times before, IOM should have appointed qualified experts with these diverse backgrounds to provide critical expertise and balance. IOM's failure to do so has resulted in an incomplete and unbalanced committee, which threatens the integrity of the study and fails to comply with FACA's requirements. FDA is therefore statutorily forbidden from using any advice or reports this committee offers.

VI. Policy Considerations Dictate a Balanced Committee

It is essential that the 510(k) Committee, as well as any other government-commissioned IOM committee, is balanced, includes all necessary expertise, and complies with FACA requirements. A failure to include appropriate membership on IOM committees has significant implications for the FDA, IOM, and the general public.

The FDA is responsible for regulating the production and marketing of all foods, drugs, medical devices, cosmetics, and many other health products in the United States.[262] Its "regulations have considerable impact on the nation's health, industries, and economy."[263] Government agencies, especially those that play as critical a role in society as does the FDA, are expected to utilize fair, accurate, and transparent processes when crafting rules and regulations. President Barack Obama reconfirmed this expectation through his "Open Government Initiative,"[264] designed to "establish a system of transparency, public participation, and collaboration" in government.[265] Part of this initiative was aimed at providing government decisionmakers with a wider array of information through public input of ideas and expertise.[266] In response, FDA launched its own Transparency Initiative in June 2009.[267] "Transparency in

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[260] 5 U.S.C. app. 2 § 15(b)(1)–(6) (2006).
[261] *See supra* notes 104–108 and accompanying text.
[262] *The Importance of Public Comment to the FDA*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143569.htm (last updated May 1, 2009).
[263] *Id.*
[264] *Open Government Initiative*, WHITE HOUSE, http://www.whitehouse.gov/open (last visited May 1, 2011).
[265] Memorandum from President Barack Obama to the Heads of Exec. Dep'ts & Agencies (Jan. 21, 2009), *available at* http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment/.
[266] *See* Memorandum from Peter R. Orszag, Office of Mgmt. & Budget (Dec. 8, 2009), *available at* http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf ("Participation allows members of the public to contribute ideas and expertise so that their government can make policies with the benefit of information that is widely dispersed in society.").
[267] *FDA Transparency Initiative*, U.S. FOOD & DRUG. ADMIN., http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ (last updated Apr. 26, 2011).

FDA's activities and decision-making allows the public to better understand the Agency's decisions, increasing credibility and promoting accountability."[268]

If the FDA begins to use or rely heavily on information provided from incomplete or unbalanced sources, especially when those sources purport to be fair and balanced, its ultimate decisions may be uninformed and have undesirable effects. Members of Congress have expressed this same concern. For instance, Senator John Kerry recently wrote to the FDA Commissioner, urging her "to establish a deliberative and transparent process for reviewing the IOM recommendations that ensures adequate opportunity to solicit substantive and meaningful input from all stakeholder groups before any recommendations are finalized."[269] He was concerned that the recommendations may be "disruptive to the medical device industry and could have a chilling effect on growth, jobs, and patient access to medical innovation."[270] A number of other members of Congress also wrote a letter to the IOM, expressing concern regarding the lack of expertise on the committee, and requesting opportunities for "substantive and meaningful participation by these stakeholders."[271]

Additionally, the public will also lose trust in the agency. An agency such as the FDA that has such a substantial impact on public health and on which the public heavily relies must use committees that are fairly balanced in order to maintain its own credibility and authority. If FDA intends to make major, controversial changes to the 510(k) clearance system, and plans on using an IOM committee's recommendations when making those changes, that committee must include all necessary expertise and foreclose any appearance of bias. Otherwise, it will be both irresponsible and illegal for FDA to use the IOM report and FDA will lose the public's faith.

Furthermore, if FDA is permitted to defer issues to IOM committees that fail to comply with section 15's requirements, rather than use its own advisory committees or notice-and-comment rulemaking or guidance development, FDA will be able to completely circumvent FACA and other mechanisms for public involvement. FACA was designed to increase the public accountability of committees that advice federal agencies.[272] "What we are dealing with . . . goes to the bedrock of Government decision making. Information is an important commodity in this capital."[273] Section 15 was added to impose some of these requirements, albeit a watered-down version, on NAS committees, like the 510(k) Committee.[274] Since official advisory committees are subject to far more rigorous notification, access, monitoring, and other requirements than are IOM committees,[275] it might be tempting for FDA to simply use an IOM committee rather than an official federal advisory committee. If these IOM committees are not expected to comply with even the minimal section 15 requirements, then FDA will be able to avoid using its own advisory committees in lieu of IOM committees that remain unaccountable—unaccountable to the public, the government, or even its own institutional policies. The result would be a governmental body receiving heavily relied-upon reports from committees that are unelected, unanswerable,

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[268] *Executive Summary*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/ExecutiveSummary/ (last updated June 3, 2010).
[269] Letter from Sen. John Kerry to Margaret Ann Hamburg, Comm'r, FDA (Apr. 13, 2011).
[270] *Id.*
[271] Letter from Congress to David R. Challoner, Inst. of Med. (Mar. 1, 2010) (on file with author).
[272] *See supra* notes 70–73 and accompanying text.
[273] S. REP. NO. 92-1098, at 4 (1972) (quoting Sen. Lee Metcalf).
[274] *See supra* notes 95–99 and accompanying text.
[275] *See supra* notes 72–73 and accompanying text.

incomplete, and disconnected from the public.[276] This is exactly what FACA was intended to prevent.

IOM and the National Academies also have something to lose if this unbalanced committee proceeds. Although FACA only prohibits federal agency use of noncompliant NAS committees, and does not prohibit NAS's own formulation or use of such committees, NAS's reputation and work quality will deteriorate if it excludes necessary perspectives and fails to avoid actual or perceived bias. The National Academies produces 200–300 authoritative reports each year, many of which influence policy decisions.[277] Its recommendations carry so much weight because of "the reputation of the institution for objectivity, integrity, independence, and competence," which it considers to be "one of its most valuable assets."[278] The institution is renowned for its thorough, robust, and objective research.[279] Its members are some of the most respected and experienced professionals in their fields.[280] But the value of the institution's work will suffer if its committees are unbalanced or lack crucial expertise—it will no longer be regarded as objective, and possibly not even as competent.

Additionally, IOM's failure to comply with its own internal policies regarding conflicts of interest, balance and bias will irreparably damage its reputation. IOM depends on its policies and procedures to ensure quality, objectivity and independence. The public trusts that IOM follows its own policies. This particular committee's glaring failure to do so may cast a shadow over other IOM activities as well. There is little point in even having policies if the institution can selectively choose to follow them or not. Once this committee issues its report, the proverbial cat will be out of the bag, and the IOM will forever have a mar upon its historically pristine reputation for completeness, balance, and objectivity.

Finally, much of what the 510(k) committee does is secret already—it deliberates in closed meetings, does not disclose members' CV's or conflict-of-interest forms, and does not makes its proposed recommendations available to the public for comment.[281] "All analyses and drafts of the report remain confidential."[282] The committee held ten meetings, only three of which were open to the public.[283] The "brief summaries" of the seven closed meetings provide little, if any, useful information.[284] Even the material that is supposedly accessible to the public is

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[276] As a side note, it is also irresponsible for the federal government, through the FDA, to spend taxpayer dollars on an IOM committee that contravenes federal law and that the FDA is legally prohibited from using.
[277] NAT'L ACADS., OUR STUDY PROCESS, *supra* note 67, at 2.
[278] NAT'L ACADS., GETTING TO KNOW THE COMMITTEE PROCESS, *supra* note 76, at 4; *see also* NAT'L ACADS., OUR STUDY PROCESS, *supra* note 67, at 1 ("Ensuring Independent, Objective Advice."); NAT'L ACADS., http://www.nationalacademies.org/ (last visited May 1, 2011) ("The National Academies—Where the Nation Turns for Independent, Expert Advice.").
[279] *See Our Study Process*, *supra* note 254 ("The IOM applies the National Academies' rigorous research process, aimed at providing objective and straightforward answers to difficult questions of national importance."); *Our Reputation*, *supra* note 83 ("Over many decades, the [National Academies have] earned a solid reputation as the nation's premier source of independent, expert advice on scientific, engineering, and medical issues.").
[280] The National Academies boasts that more than three hundred of its members are Nobel laureates ad are among the world's most distinguished experts in their fields. *See Who We Are*, NAT'L ACADS., http://www.nationalacademies.org/about/whoweare.html (last visited May 1, 2011).
[281] *See supra* notes 146–161 and accompanying text; *see also Federal Advisory Committee Act*, INST. MED., http://www.iom.edu/About-IOM/Study-Process/FACA.aspx (last visited May 1, 2011) (explaining when committee processes are open to the public and when they are not).
[282] *Federal Advisory Committee Act*, *supra* note 281.
[283] *See Project Information*, *supra* note 25 (listing committee meetings).
[284] *See supra* note 157 (describing the brief summaries).

not easy to obtain.[285] Therefore, it is especially important for IOM to comply with the few openness and balance requirements under section 15. It is not enough to allow stakeholder participation in other steps of the process, such as data-gathering. Nor is it sufficient to have individuals with the required, yet missing, expertise review the report after it is complete. The committee needs members on the inside who can provide much-needed perspectives and experience where it is currently lacking—and this is exactly what FACA prescribes. FACA dictates that the committee itself includes a fair balance of expertise and perspectives.[286] Otherwise, critical expertise and viewpoints cannot be considered in any meaningful way.

CONCLUSION

The IOM 510(k) Committee's purpose is to assess how well the current 510(k) process advances medical device innovation while simultaneously assuring patient safety. It is expected to recommend legislative, regulatory, and/or administrative changes that may help optimally balance these two goals. Safety and innovation are unquestionably broad issues of national import, and the IOM's recommendations will greatly affect the public health. Given the significance and breadth of this evaluation, the IOM committee must contain broad membership, including inventors/innovators, entrepreneurs, product developers, financiers, industry professionals, and patients or patient advocates. These stakeholders can offer valuable, yet currently missing, insights into the current 510(k) system's effect on safety and innovation. These are also the stakeholders that will be most greatly affected by the IOM's recommendations and FDA's subsequent actions.

Unfortunately, the committee does not contain all of the required areas of expertise and perspectives, rendering it not "fairly balanced." IOM could easily have avoided these critical gaps in committee membership by appointing additional qualified experts and individuals in these areas, as it routinely has done for other committees—but it did not do so. The actual content of the IOM report is irrelevant if the process used to arrive at that report is flawed. Thus, the current committee fails to comply with federal law, and also fails to comply with its own internal policies regarding committee composition.

As a result, FDA is legally prohibited from using this IOM committee. However, we cannot unring a bell—once this committee issues its final report, it will be impossible to know whether FDA saw it, read it, or used it. Any of FDA's subsequent actions may thereafter be legally challenged as a violation of FACA section 15. FDA may lose its credibility, and IOM may irreparably damage its reputation for accuracy and objectivity. IOM should refrain from issuing any report from this committee until this matter can be resolved.

The 510(k) system is responsible for clearing most of the life-saving medical devices currently on the market. When contemplating a major overhaul of a system as significant as the 510(k) system, with the public health and entire U.S. medical device market at stake, the FDA must rely on accurate, informed, and objective advice. It cannot be permitted to rely on an IOM committee that is unfairly balanced and in contravention of federal law and National Academies' policies. These concerns are not limited to only this particular committee—expertise, fairness and balance are essential for all IOM committees that influence government decision-making.

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[285] *See supra* note 155 (explaining that both authors of this Article have inquired about available materials, receiving no response whatsoever).

[286] 5 U.S.C. app. 2 § 15(b)(1)(B) (2006).

The IOM, and the government agencies that utilize the IOM, must be held accountable. The public deserves nothing less.