

## Recent Developments

### A Failure to Comply: An Initial Assessment of Gaps in IOM's Medical Device Study Committee

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“With great power comes great responsibility”<sup>1</sup>

#### I. INTRODUCTION

In addition to addressing traditional scientific and clinical inquiries, the Institute of Medicine (IOM) is engaged in policy analysis and recommendations.<sup>2</sup> Because of IOM's strong reputation,<sup>3</sup> IOM committees play a powerful role in public policy. Yet, despite this power, IOM committees operate in a largely closed fashion. IOM alone determines committee membership.<sup>4</sup> Committee deliberations are private.<sup>5</sup> Policy

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1. *Tammany is Satisfied: Mr. Gilroy Interviewed at New Orleans*, N.Y. TIMES, Nov. 15, 1892.

2. *About the IOM*, INST. MED., <http://www.iom.edu/About-IOM.aspx> (last updated May 1, 2011).

3. *Cf. Membership*, INST. MED., <http://www.iom.edu/About-IOM/Membership.aspx> (last updated April 2, 2011).

4. NAT'L ACADS., INSTITUTE OF MEDICINE: CHARTER AND BYLAWS 3 (2006), *available at*

recommendations need not be publicly vetted before being issued in final form.<sup>6</sup> IOM decides how to operate, what testimony to elicit, and what studies to conduct.<sup>7</sup> Conversely, government committees and policy development operate in a much more public and transparent fashion.<sup>8</sup>

Because of its great power, IOM has a great responsibility to ensure that its processes and committee membership include all key stakeholders, are fair and unbiased, and are viewed as such. The strength of IOM committee recommendations depends on the quality and completeness of its research and analysis and, equally importantly, on stakeholder acceptance of the fairness and robustness of its processes. A committee that lacks essential expertise and key stakeholder involvement risks not only producing a report and recommendations that are incomplete or incorrect, but also producing a report that lacks the trust of stakeholders.

Unfortunately, IOM's Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process has been subject to substantial criticism for not being inclusive or open.<sup>9</sup> More importantly, the Committee has been roundly criticized for major gaps or omissions in committee membership.<sup>10</sup> The shortcomings with this Committee's composition and processes

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<http://www.iom.edu/~media/Files/About%20the%20IOM/charter-and-bylaws.pdf> ("The membership of committees conducting studies and preparing reports for dissemination outside the Institute and the National Research Council shall be appointed by the President, subject to approval by the Chairman of the National Research Council.")

5. *Federal Advisory Committee Act*, INST. MED., <http://www.iom.edu/About-IOM/Study-Process/FACA.aspx> (last updated Feb. 8, 2011).

6. *Id.*

7. *Policies and Procedures*, NAT'L RES. COUNCIL, <http://sites.nationalacademies.org/NRC/PoliciesandProcedures/index.htm> (last visited May 9, 2011).

8. WENDY GINSBERG, CONG. RESEARCH SERV., R40520, FEDERAL ADVISORY COMMITTEES: AN OVERVIEW (2009), available at <http://www.fas.org/sgp/crs/misc/R40520.pdf>.

9. See, e.g., *Impact of Medical Device Regulation on Jobs and Patients: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 112th Cong. 62 (2011), available at [http://democrats.energycommerce.house.gov/sites/default/files/image\\_uploads/Transcript\\_MedDevice.pdf](http://democrats.energycommerce.house.gov/sites/default/files/image_uploads/Transcript_MedDevice.pdf) (preliminary transcript) (questioning the composition of the IOM panel).

10. *Id.*; see also Letter from Sen. John Kerry to Margaret Ann Hamburg, Commissioner, Food & Drug Admin. (Apr. 13, 2011).

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threaten the strength of the analysis and stakeholders' acceptance of its recommendations. These issues are so serious that the U.S. Food and Drug Administration (FDA) may be legally prohibited from using any of the 510(k) Committee's recommendations.

This article questions whether IOM's 510(k) Committee complies with statutory requirements and good process. We do not yet know the Committee's recommendations, and so our concerns are not influenced by any disagreement with the Committee's conclusions. We also are not questioning the talents of current Committee members—individually they have impressive credentials and specific subject matter expertise. Rather, we question the omissions from the Committee of essential expertise and stakeholders. These critical issues should be addressed immediately to preserve IOM's reputation, ensure fairness, and permit FDA to use the Committee's report.

This article contends that, while the IOM can be an invaluable policy resource, IOM's 510(k) Committee, unfortunately, does not comply with federal law. Therefore, FDA is legally prohibited from using any report from this IOM Committee when deciding what changes to make to the 510(k) process. In order to prevent problems, it may be best for IOM not to issue any report from this Committee until these issues get resolved.

## II. BACKGROUND AND PURPOSE OF THE IOM 510(K) COMMITTEE

FDA is responsible for advancing the public health by providing reasonable assurance that medical devices are safe and effective and also by promoting innovation.<sup>11</sup> Assuring safety and efficacy for patients entails expensive and time-consuming approval processes, while promoting innovation requires making beneficial medical devices available to physicians and patients faster and less expensively. FDA balances these two goals—patient protection and innovation—through its approval processes. The device is first assigned to one of three risk-based classifications. This classification

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11. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 393(b) (2006); *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/default.htm> (last updated Nov. 18, 2010).

determines the applicable FDA approval process.<sup>12</sup>

High-risk medical devices<sup>13</sup> are subject to Premarket Approval (PMA),<sup>14</sup> a rigorous, time-consuming, and expensive process.<sup>15</sup> In comparison, moderate-risk devices<sup>16</sup> can be cleared for market through the faster and less resource-intensive Premarket Notification (PMN) or “510(k)” clearance process.<sup>17</sup> The 510(k) process allows a new device to enter the market if the new device is “substantially equivalent” to a 510(k) product already legally on the market (a “predicate” device).<sup>18</sup> Many more products go through the 510(k) process than the PMA process.<sup>19</sup> Furthermore, because the 510(k)

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12. 21 U.S.C. § 360c (2006).

13. High-risk, or “Class III,” medical devices are those for which “insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness” and typically include devices that are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or “[which present] a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(c) (2006). Examples of high-risk devices approved through the PMA process include heart valves and implantable pacemakers. *General and Special Controls*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm> (last updated Apr. 23, 2009).

14. 21 U.S.C. § 360e (2006).

15. *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (Sept. 3, 2010), <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket/submissions/premarketapprovalpma/default.htm>.

16. Low-risk, or “Class I,” medical devices are those for which general controls, such as manufacturing practices, are adequate to ensure safety and effectiveness. 21 C.F.R. § 850.2(c)(1). Moderate-risk, or “Class II,” medical devices are those for which both general and specific controls, including postmarket surveillance and additional FDA guidelines, are required to ensure safety and effectiveness. *Id.* § 860.3(c)(2).

17. 21 U.S.C. § 360(k) (2006). Products cleared through the 510(k) process include angioplasty catheters and blood glucose monitors. *510(k) Premarket Notification*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmm/pmnm.cfm> (last updated May 9, 2011).

18. 21 U.S.C. § 360c(i) (2006).

19. In 2009, FDA received more than 3500 510(k) applications as compared to 20 original PMA applications and 1394 PMA supplements. U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF DEVICE EVALUATION, ANNUAL PERFORMANCE REPORT: FISCAL YEAR 2009 4 (2009), *available at* <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM223893.pdf>.

system requires a less detailed submission to the FDA than is required for PMA, 510(k) clearances are generally faster than PMA approvals.<sup>20</sup>

Each system assesses the safety and efficacy of the product as part of the FDA's statutory mandate to provide a "reasonable assurance" that a product is safe and effective before marketing.<sup>21</sup> The 510(k) process makes this safety and effectiveness determination by assessing whether the product in question is "substantially equivalent" to a 510(k) device already legally marketed.<sup>22</sup> In some cases clinical data is needed for the 510(k) submission. In other cases, bench testing or compliance with existing government-approved standards is used to establish safety and effectiveness.<sup>23</sup>

The 510(k) process has been criticized by a number of stakeholders. Some argue that the pathway is too easy, allowing unsafe, ineffective, or inadequately tested devices on the market.<sup>24</sup> These stakeholders may argue that all 510(k) products should be subject to placebo controlled, blinded clinical trials.<sup>25</sup> Conversely, others argue that it is unpredictable and burdensome, unnecessarily inhibiting innovation and patient/physician access to new products.<sup>26</sup> For these reasons, in September 2009, FDA launched a review of the 510(k) process. As part of this review, FDA commissioned

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20. *See id.* at 4–9.

21. 21 U.S.C. § 393 (2006).

22. *Id.* § 360c(i).

23. For examples, see presentations made at the third public meeting of the 510(k) Committee on July 28, 2010, available at *Meeting 3: Public Health Effectiveness of the FDA 510(k) Clearance Process*, INST. MED., <http://www.iom.edu/Activities/PublicHealth/510KProcess/2010-JUL-28.aspx> (last updated July 28, 2010).

24. *See, e.g.*, Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 87 AM. J. HUM. GENETICS 451 (2010); *Comments on FDA 510(k) Medical Devices Working Group Preliminary Report and Recommendations*, PUB. CITIZEN, <http://www.citizen.org/Page.aspx?pid=4535> (Oct. 4, 2010).

25. *See* Rita Redberg, Presentation to the Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (July 28, 2010), available at <http://www.iom.edu/~media/Files/Activity%20Files/PublicHealth/510kProcess/2010-JUL-28/02%20Redberg.pdf>.

26. *See, e.g.*, JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES (2010), available at [http://www.nvca.org/index.php?option=com\\_docman&task=doc\\_download&gid=668&Itemid=93](http://www.nvca.org/index.php?option=com_docman&task=doc_download&gid=668&Itemid=93).

the IOM to conduct a detailed analysis of the 510(k) system.<sup>27</sup> As a body of the U.S. National Academies, the IOM is intended to provide the federal government and others with expert, independent analysis and recommendations about issues of health and health care.<sup>28</sup>

In the spring of 2010, IOM created a committee to conduct this review—with IOM itself deciding the committee's membership.<sup>29</sup> The committee held three workshops with invited speakers and allowed other interested parties five minutes apiece to address the committee.<sup>30</sup> Other than asking clarifying questions, the committee did not engage in any dialogue about specific policy recommendations. The committee met a number of times in closed session where, presumably, it debated policy issues and recommendations.<sup>31</sup> The committee also reviewed submitted material, the content of which is not public. Finally, according to IOM procedures, there will be no public input into or discussion of IOM recommendations prior to the final report.<sup>32</sup>

In January 2011, FDA reported twenty-five actions it is

27. Press Release, U.S. Food & Drug Admin., FDA: Institute of Medicine to Study Premarket Clearance Process for Medical Devices (Sept. 23, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183497.htm>.

28. 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](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 . . . .”); see also *About the IOM*, *supra* note 4.

29. *Our Study Process*, NAT'L ACAS., <http://www.nationalacademies.org/studyprocess/index.html#st2> (last visited May 9, 2011).

30. See *Public Health Effectiveness of the FDA 510(k) Clearance Process*, INST. MED., <http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx> (last visited April 25, 2011) [hereinafter *Public Health Effectiveness*].

31. *Project: Public Health Effectiveness of the FDA 510(k) Clearance Process*, NAT'L ACADS., <http://www8.nationalacademies.org/cp/projectview.aspx?key=IOM-BPH-09-03> (last visited May 9, 2011) [hereinafter *Project*].

32. See *Our Study Process*, *supra* note 31; see also *Federal Advisory Committee Act*, *supra* note 7 (“All analyses and drafts of the report remain confidential.”).

considering to improve the 510(k) program.<sup>33</sup> Importantly, FDA reconfirmed the importance of the IOM committee report when it specifically referred seven controversial questions to IOM for analysis and recommendations.<sup>34</sup> IOM is expected to issue its final report in the late spring or summer of 2011.<sup>35</sup>

### III. LEGAL REQUIREMENTS FOR IOM COMMITTEE MEMBERSHIP

IOM studies of this type are not conducted in a legal vacuum. Section 15 of the Federal Advisory Committee Act (FACA) sets forth rules governing FDA's use of IOM studies.<sup>36</sup> Enacted in 1972, FACA requires federal advisory committees to operate openly, efficiently, and objectively to ensure accuracy, fairness, and public trust.<sup>37</sup> When federal agencies like the FDA solicit advice from the National Academy of Sciences (NAS), which includes IOM, the requirements of FACA section 15 apply. Section 15 imposes fewer requirements on IOM committees than other federal advisory committees,<sup>38</sup> but still requires minimal inclusivity and public accountability. Section 15 requires fair balance on committees, public notice of meetings, openness of data-gathering meetings, and public availability of records.<sup>39</sup> Because there are fewer rules IOM committees must follow, those rules that do exist take on heightened importance to ensure transparency, fairness, and public input. IOM's own policies and procedures echo (albeit with more detail) these same basic tenets.<sup>40</sup> If the 510(k) committee fails to meet these rules, then, by statute, FDA "may not use any advice or recommendation" provided by this committee.<sup>41</sup>

Section 15 requires that IOM "make its best efforts to

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33. U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, PLAN OF ACTION FOR IMPLEMENTATION OF 510(K) AND SCIENCE RECOMMENDATIONS (2011), *available at* <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>.

34. *Id.* at 6.

35. *See Project, supra* note 33.

36. Federal Advisory Committee Act, 5 U.S.C. app. 2, § 15 (2006).

37. *See id.* §§ 5–14.

38. *Compare id.* § 15 (setting forth requirements for NAS committees), *with id.* §§ 5–14 (setting forth requirements for federal advisory committees).

39. *See id.* § 15(b).

40. *See Our Study Process, supra* note 31.

41. 5 U.S.C. app. 2, § 15(a).

ensure that . . . the committee membership is fairly balanced . . . for the functions to be performed.”<sup>42</sup> The committee should not contain any individual with a conflict of interest, unless the conflict is “unavoidable” and is “promptly and publicly disclosed.”<sup>43</sup> Any IOM committee that lacks fair balance or that mishandles conflicts of interest fails to comply with section 15. It is important to note that section 15 vests a great deal of discretion in the NAS, stating that “[t]he Academy shall make its best efforts” to ensure the adequacy of the committee’s composition and that the Academy determines whether a conflict is unavoidable.<sup>44</sup> Additionally, the Academy is responsible for determining whether “the committee membership is fairly balanced . . . to be appropriate for the functions to be performed.”<sup>45</sup> Furthermore, the Chair of the National Research Council (NRC) has “[f]inal authority over committee appointments,”<sup>46</sup> and the NRC Executive Office and the General Counsel’s Office jointly determine whether there is a conflict of interest and whether that conflict is unavoidable.<sup>47</sup> This discretion, however, is not unfettered.

First, FACA clearly states that, while conflicts of interest are permissible at the Academy’s discretion, fair balance is necessary. Furthermore, courts, while generally deferential,<sup>48</sup> have on occasion intervened when committees are unbalanced.<sup>49</sup> While no cases involving an NAS committee’s fair balance have yet been brought to court, there have been cases that challenge traditional federal advisory committees subject to section 5 of FACA, which, similarly to section 15,

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42. *Id.* § 15(b)(1).

43. *Id.*

44. *Id.* § 15(b)(1)(A).

45. *Id.* § 15(b)(1)(B).

46. NAT’L ACADS., POLICY ON COMMITTEE COMPOSITION AND BALANCE AND CONFLICTS OF INTEREST FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS 7 (2003), available at [http://www.nationalacademies.org/coi/bi-coi\\_form-0.pdf](http://www.nationalacademies.org/coi/bi-coi_form-0.pdf).

47. *Id.* at 8.

48. *See, e.g.,* *Cargill, Inc. v. United States*, 173 F.3d 323, 334 (5th Cir. 1999) (explaining that the fair balance requirement is “subject to a deferential standard of review”).

49. *See, e.g.,* *Alabama-Tombigbee Rivers Coalition 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).



requires fair balance in committee membership.<sup>50</sup> In cases implicating section 5, courts look at the specific functions of the committees to decide whether there is fair balance. When a committee is charged with a narrow, scientific, or highly technical mandate, fewer viewpoints and areas of expertise may be required on the committee.<sup>51</sup> Where the functions to be performed are not “narrow and explicit,”<sup>52</sup> but instead involve “diverse and far-reaching issues that affect others,” broader representation on the committee is required.<sup>53</sup> This is especially true of committees whose purpose is “to study the effects of a particular type of regulation . . . on the public.”<sup>54</sup>

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

The National Academies’ own internal policies regarding

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50. 5 U.S.C. app. 2 § 5(b)(2). Generally, it is fair to presume that Congress intends a consistent meaning of a phrase when it uses that phrase in several parts of the same statute. *See Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) (“A term appearing in several places in a statutory text is generally read the same way each time it appears.”).

51. *See, e.g., Cargill, Inc. v. United States*, 173 F.3d 323 (5th Cir. 1999); *Pub. Citizen v. Nat’l Advisory Comm. on Microbiological Criteria for Foods*, 708 F. Supp. 359 (D.D.C. 1988).

52. *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).

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

54. *Pub. Citizen*, 708 F. Supp. at 364.

committee member selection, fair balance, conflicts of interest, and bias reflect the legal requirements of FACA section 15. They require that committees contain an “appropriate range of expertise for the task” and a “balance of perspectives,” while striving to avoid conflicts of interest where possible.<sup>55</sup> These policies permit committees to include members who are biased or have expressed a strong opinion on a particular issue of interest. According to the NAS process for committee appointment, “[a] point of view or bias is not necessarily a conflict of interest.”<sup>56</sup> IOM recognizes that member bias is not only permissible, it is sometimes necessary. According to the NAS Policy on Committee Composition and Balance, “[f]or some studies . . . it may be important to have an ‘industrial’ perspective” if such a perspective is “vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee.”<sup>57</sup> However, IOM must balance these perspectives to produce an overall objective committee and avoid bias or the perception of bias. If these individuals have conflicts of interest, they may nevertheless be included on the committee to provide needed expertise, knowledge, balance, or perspective. In such cases, the conflict of interest is “unavoidable” and simply must be disclosed.<sup>58</sup>

A brief examination of recent IOM activities reveals a number of committees in which industry members and/or members with conflicts of interest were included. Out of ten current or recent FDA-sponsored IOM activities, at least half contain members with industry background and at least three committees contain members with disclosed conflicts of interest.<sup>59</sup> For example, the IOM committee on Qualification of

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55. NAT'L ACADS., OUR STUDY PROCESS: ENSURING INDEPENDENT, OBJECTIVE ADVICE 2 (n.d.), available at <http://www.nationalacademies.org/studycommitteprocess.pdf>.

56. *Committee Appointment Process*, NAT'L ACADS., [http://www8.nationalacademies.org/cp/information.aspx?key=Committee\\_Appointment](http://www8.nationalacademies.org/cp/information.aspx?key=Committee_Appointment) (last visited April 25, 2011).

57. NAT'L ACADS., *supra* note 48 at 3 (2003).

58. *Id.*

59. *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 not recently completed projects, so there may have in fact been more than three

Biomarkers and Surrogate Endpoints in Chronic Disease includes a Vice President at Merck & Co.<sup>60</sup> The committee on Accelerating Rare Diseases Research and Orphan Product Development includes a former Vice President of Medtronic, Inc., and a former Senior Vice President of Pfizer.<sup>61</sup> The committee on Review of the Food and Drug Administration's Role in Ensuring Safe Food includes the Senior Vice President and Chief Scientific and Regulatory Affairs Officer of the Grocery Manufacturers Association.<sup>62</sup> Clearly, individuals with industry background or connections are frequently deemed valuable and necessary for IOM committees to fulfill their functions, despite obvious conflicts of interest. Thus, it is not so rare that individuals with "unavoidable" conflicts of interest are included on IOM committees.

In summary, IOM committees must be fairly balanced to perform their functions. They must include all essential areas of expertise, balance the biases and perspectives of their members, and disclose any unavoidable conflicts of interest.

#### IV. ANALYSIS OF IOM'S 510(K) COMMITTEE

The key question we pose is whether the existing IOM Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process has the appropriate representation to fulfill its mission and to satisfy the minimal requirements of FACA Section 15. The twelve-member committee is currently comprised of five physicians, three lawyers, and several academics with selected technical backgrounds.<sup>63</sup> The

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recent committees involving disclosed conflicts of interest.

60. See *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease*, INST. MED., <http://iom.edu/Reports/2010/Evaluation-of-Biomarkers-and-Surrogate-Endpoints-in-Chronic-Disease.aspx> (last updated Feb. 4, 2011), for list of committee members.

61. See *Accelerating Rare Diseases Research and Orphan Product Development*, INST. MED., <http://iom.edu/Activities/Research/OrphanProductResearch.aspx> (last updated Jan. 25, 2011), for list of committee members.

62. See *Review of the Food and Drug Administration's Role in Ensuring Safe Food*, INST. MED., <http://iom.edu/Activities/Nutrition/FDARoleReview.aspx> (last updated Sept. 14, 2010), for list of committee members.

63. *Committee: Public Health Effectiveness of the FDA 510(k) Clearance Process*, NAT'L ACADS. (Feb. 22, 2010) <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49181>. Areas of technical expertise include orthopedic focused tissue engineering and software engineering.

Committee does not include:

Innovators and inventors who have created new device products under current FDA systems;<sup>64</sup>

- 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 innovations;
- Individuals who routinely prepare 510(k) applications;
- Management or other professionals from the medical device industry; or
- Patients or patient advocates.

To assess the adequacy of the Committee's current composition, we look at the Committee's function. FDA asked the Committee to address two critical questions: (1) does the current 510(k) process optimally protect patients and (2) does the current 510(k) process promote innovation in support of public health?<sup>65</sup>

The Committee was explicitly asked to provide recommendations as to how FDA can best optimize patient protection (i.e. minimize risks to patients) while also promoting innovation (i.e. improve the speed and affordability of access to innovative new products). To do this, the Committee must necessarily confront complex policy considerations, balance

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64. One committee member, Dr. Lazar Greenfield, is credited with inventing the life-saving Greenfield vena cava filter. See *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). 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 & TECHNOLOGY MAGAZINE (Summer 2006), available at [http://beta2.americanheritage.com/articles/magazine/it/2006/1/2006\\_1\\_34.shtml](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 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).

65. See *Public Health Effectiveness*, *supra* note 26.

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competing objectives and address politically significant questions of patient autonomy, beneficence, and medical ethics. These include questions about when the patient should have the right to access some particular device despite known risks and under what circumstances the FDA should intervene to make that decision for the patient by barring access to the device. IOM's charge also includes understanding how regulation impacts the complex innovation ecosystem. Innovation is more than just invention—it includes the entire cycle starting from invention, research and development, financing, manufacturing, marketing, and societal improvement.<sup>66</sup> This requires an understanding of innovation, finance, entrepreneurship, product development and regulatory process. Consequently, the function of the IOM Committee is considerably more “diverse and far-reaching” than it is “narrow and specific” or highly technical, and thus requires broader expertise.

Committee membership must have the expertise to answer both these questions. Unfortunately, it does not. First, it is evident that the Committee lacks some of the expertise needed to render advice on patient safety, an undoubtedly broad public issue that requires diverse representation, including representation from patients and industry. Those who invent, finance, develop, test, and manufacture medical devices have much needed expertise as to how to ensure the safety of those devices. They offer valuable perspectives on the types of research systems, manufacturing controls, testing strategies, and design processes that may enhance patient safety. These stakeholders, who are responsible for the invention, design, development, testing and regulatory approval or clearance of essentially all new devices in the United States, are omitted from the Committee. As discussed below, the committee also lacks any representation from patients—the ultimate stakeholder in the balance between safety and access to new products.

Second, as discussed above, innovation is the transformation of an idea into a commercial product for the

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66. 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 MAGAZINE, Fall 2005, at 52, 52 (“Innovation is far more about prospecting, mining, refining and adding value than it is about pure invention.”).

advancement of society. IOM cannot adequately address medical device innovation without insights from entrepreneurs and others who have been involved in the medical device industry—including people who have conceptualized products, designed and developed those products, obtained financing for new product lines, manufactured those products, and brought those products to market. Even the FDA has highlighted the importance of the medical device industry in innovation. In a presentation made to the annual meeting of the Food and Drug Law Institute, the Director of the FDA's Center for Devices and Radiological Health (CDRH) explicitly recognized the vital role of industry in medical device innovation, stating, "U.S. medical device development and innovation 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."<sup>67</sup> But the IOM committee lacks any member with this industry expertise. Without this experience, the committee cannot adequately assess the effects of FDA regulations on innovation. Indeed, this committee is precisely one for 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."<sup>68</sup>

Furthermore, while the Committee includes individuals with expertise in clinical patient care, actual patients or patient advocates are conspicuously not represented on the Committee. The patient is the ultimate stakeholder, the one most affected by policy decisions implicating safety and access to devices. Optimally balancing safety and risk with innovation raises important ethical questions of patient autonomy. Presumably, the patient should have some input as to when and how the FDA may regulate access to life-saving or life-improving medical devices. But the committee includes no patient or patient advocate. This omission is confusing and difficult to justify. 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.<sup>69</sup>

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67. Jeffrey Shuren, 2011: The State of CDRH, Presentation at the Food and Drug Law Institute Annual Meeting (April 5–6, 2011) (presentation slides available from the Food and Drug Law Institute).

68. NAT'L ACADS., *supra* note 48 at 3.

69. See Amir Halevy, *Medical Futility, Patient Autonomy, and*

Others have also noted these critical gaps in the Committee's composition. The CDRH director recently testified before Congress that the Committee lacks inventors, innovators, financing experts, industry representatives, and actual patients.<sup>70</sup> Various members of Congress have also expressed concern regarding these omissions, urging for more transparent processes and opportunities for substantive and meaningful input from all affected stakeholders.<sup>71</sup> Thus, while each current committee member is individually impressive and has expertise worthy of inclusion on the committee, without this broader membership, the committee is inadequate to fulfill its mission.

Additionally, this IOM committee lacks fair balance of perspectives. As previously noted, IOM committees can include individuals with preexisting biases, provided that there are also countervailing viewpoints on the committee. Unfortunately, the 510(k) Committee does not include this balance. 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."<sup>72</sup> Public Citizen is highly critical of the 510(k) process, asserting that medical devices are approved too quickly, allowing dangerous devices enter the market.<sup>73</sup> While this member's participation and viewpoint is certainly appropriate, the lack of an opposing viewpoint on the Committee renders the committee unbalanced and risks both perceived and actual bias.

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*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."); see also Holly Fernandez Lynch et al., *Compliance with Advance Directives*, 29 J. LEGAL MED. 133, 133 & n.2 (2008) (explaining that "physician paternalism has been widely rejected").

70. *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. (2011) (statement of Jeffrey Shuren), available at <http://www.fda.gov/NewsEvents/Testimony/ucm243716.htm>.

71. See Letter from Sen. John Kerry to Margaret Ann Hamburg, *supra* note 12.

72. PUB. CITIZEN, <http://www.citizen.org> (last visited May 9, 2011).

73. Hines et al., *supra* note 26; *Device and Diagnostic Policy*, PUB. CITIZEN, <http://www.citizen.org/Page.aspx?pid=2505> (last visited May 9, 2011); Press Release, Public Citizen, FDA Dodges Responsibility Regarding Medical Device Approval, Defers to IOM: Statement of Dr. Sidney Wolfe, Director, Public Citizen's Health Research Group (Jan. 19, 2011), <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3261>.

Furthermore, IOM could have avoided the gaps in expertise and lack of balance by including any one of a number of highly qualified people, including current NAS members and past IOM committee members.<sup>74</sup> IOM also 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. IOM seemingly concluded in this instance that this critical expertise could not be obtained or was not needed, even though it has been necessary for many other IOM committees. Even if the necessary experts all had conflicts of interest, IOM could have simply disclosed these conflicts as it has done so many times before. IOM's failure to do so has resulted in an incomplete and unbalanced committee, lacking the necessary expertise to fulfill its function and risking actual or perceived bias through a lack of balanced perspectives.

These flaws threaten the integrity of the study and undermine all of the hard work this committee has performed. Ultimately, this committee fails to comply with FACA's requirements and FDA is therefore statutorily forbidden from using any advice or reports this committee offers.

#### V. POLICY CONSIDERATIONS DICTATE A BALANCED COMMITTEE

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

First, government agencies are expected to obtain complete and accurate information from a variety of perspectives before issuing regulations. 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.<sup>75</sup> Thus, the FDA has an enormous impact on the nation

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74. See, e.g., *supra* notes 62–64 and accompanying text.

75. *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).



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and the public relies heavily upon its regulations. However, if the FDA uses information from incomplete or one-sided sources, not only might its ultimate decisions be uninformed, but the public will lose trust in the agency. If FDA wants to use IOM to analyze the 510(k) system, especially when contemplating controversial changes to the system, the IOM committee must include all necessary expertise and must be unbiased and objective. Otherwise, it is both irresponsible and illegal for FDA to use the IOM report, and FDA will risk losing its authority and credibility.

Second, the value and quality of IOM's work will suffer if its committees are unbalanced or lacking in crucial expertise. IOM is renowned for its thorough, robust, and objective research and prides itself on being independent and transparent. Its members are highly competent, respected, and experienced professionals in their fields. But IOM's well-deserved reputation and high caliber of its work product will deteriorate if there is perceived or actual bias or if it failed to include all critical perspectives. It is in IOM's best interest to address this issue now, before it damages its own reputation.

Third, if FDA can elect not to use official advisory committees (which are subject to stricter FACA requirements for public involvement and openness) and, instead, can rely on IOM committees with no such requirements, then FDA can completely circumvent FACA. FACA was enacted to increase transparency in government decision making. Allowing FDA to use IOM committees that are unaccountable to the public, the government, or even its own institutional policies, clearly contravenes FACA's purpose. IOM committees must, at the very least, comply with the minimal legal requirements that apply to it.

Finally, much of what the 510(k) committee does is secret already—deliberative meetings are closed, committee members' resumes are not disclosed, and some material submitted to the committee is confidential. Additionally, IOM does not make its proposed recommendations available to the public for comment. Therefore, it is especially important for IOM to comply with the few openness and balance requirements under section 15. It is insufficient to only allow stakeholder participation in other steps of the process, such as data-gathering and reviewing. The committee needs members on the inside who can provide much-needed perspectives and experience where it is currently lacking. Otherwise, critical expertise and viewpoints cannot be

considered in any meaningful way and any final report will have little credibility.

## VI. CONCLUSION

The IOM 510(k) committee's purpose is to evaluate the 510(k) pathway's ability to advance medical device safety and innovation. This requires broad committee membership, including patients, inventors/innovators, entrepreneurs, financiers and industry. Furthermore, the committee must be fairly balanced to ensure its conclusions are objective and accurate and to maintain public trust and accountability. Unfortunately, the current committee does not contain all of the required areas of expertise and is not fairly balanced. IOM could have avoided these problems by simply including qualified experts in these fields as it routinely does for other committees, but it did not do so.

We have no idea of what the IOM 510(k) committee report may say. We might agree with it or disagree it. Our concerns and conclusions are based on serious gaps in the committee composition, not any disagreement with the report content. Regardless of the committee's final conclusions, the committees' omission of necessary expertise and perspectives is cause for concern. Any committee reports and any of FDA's subsequent actions will be plagued by real or perceived bias, lack of expertise and inaccuracy.

To avoid these problems, FACA prohibits FDA's use of this IOM committee. But we can't unring a bell—once the committee issues its report, we will never know whether FDA saw it, read it, or used it. Anything FDA does thereafter can then be challenged by a stakeholder asserting a violation of FACA section 15. Thus, we should address this situation immediately. Until this matter is resolved, IOM should not issue any report from this committee. Otherwise, it will be placing FDA in an impossible position, while simultaneously damaging its own reputation for fairness, honesty, impartiality, and accuracy.

Finally, the concerns raised here are not limited to only IOM's 510(k) committee—expertise, fairness and balance are essential for all IOM committees. The public deserves nothing less.