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# Multi-Institutional Healthcare Ethics Committees: The Procedurally Fair Internal Dispute Resolution Mechanism

THADDEUS MASON POPE\*

## INTRODUCTION

Four patients have arrived at City Hospital in a comatose state. The first patient has an advance directive,<sup>1</sup> but its instructions do not clearly address her current circumstances. The family of the second patient wants everything possible done to keep the patient alive, despite the physician's recommendation that this is medically inappropriate and not in the patient's best interest. The hospital has been unable to identify or locate any friends or family of the third patient. The family of the fourth patient is divided: one son favors stopping further aggressive treatment, while a daughter demands that everything be done. In each case, should the *patient's* preferences be honored? If so, what is the most reliable evidence of the patient's preferences?

Complex ethical situations like these occur on a regular basis in healthcare settings. End-of-life decisions are marked with significant conflict.<sup>2</sup> Healthcare ethics committees (HECs) have been the dispute

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1. Advance healthcare directives (advance directives) are "instructions given by individuals specifying what actions should be taken for their health in the event that they are no longer able to make decisions due to illness or incapacity." Wikipedia, Advance Health Care Directive, [http://en.wikipedia.org/wiki/Advance\\_Directive](http://en.wikipedia.org/wiki/Advance_Directive) (last visited Feb. 8, 2009). An advance directive might take the form of a document such as a living will or health care power of attorney. See *id.*

2. See, e.g., Dipanjan Banerjee & Ware G. Kuschner, *Principles and Procedures of Medical Ethics Case Consultation*, 68 BRIT. J. HOSP. MED. 140, 140 (2007); William A. Nelson, *The Organizational Costs of Ethical Conflicts*, 53 J. HEALTHCARE MGMT. 41, 41

resolution forum for many of these conflicts.<sup>3</sup> HECs are typically multidisciplinary groups comprised of representatives from different departments of the healthcare facility—medicine, nursing, law, pastoral care, and social work, for example. HECs were established to support and advise patients, families, and caregivers as they work together to find solutions for delicate circumstances.

HECs generally have been considered to play a mere advisory, facilitative role. But, in fact, HECs often serve a decision making role. Both in law and practice HECs increasingly have been given significant authority and responsibility to make treatment decisions. Sometimes, HECs make decisions on behalf of incapacitated patients with no friends or family. Other times, HECs adjudicate disputes between providers and the patient or patient's family.

Unfortunately, HECs are not up to the task. Many lack the necessary independence, diversity, composition, training, and resources. HECs are overwhelmingly intramural bodies; that is, they are comprised of professionals employed directly or indirectly by the very same institution whose decision the HEC adjudicates. Consequently, many HECs make decisions that suffer from risks of corruption, bias, carelessness, and arbitrariness.

To address the problems of intramural HECs, I propose that their adjudicatory authority be relocated to a multi-institutional HEC. Thereby, no single institution's HEC would have a controlling voice in the adjudication of its own dispute. A multi-institutional HEC preserves the expertise and extrajudicial nature of HECs. But in contrast to an intramural HEC, a multi-institutional HEC possesses better resources, a greater diversity of perspectives, and the neutrality and independence required by due process.

In Part I, I review the history of HECs, and describe their three primary functions. Notable among these functions is the adjudication of treatment disputes. In Part II, I describe four significant problems with intramural HECs: (i) their lack of independence and impartiality, (ii) their lack of sufficient size and diversity, (iii) their lack of adequate resources and training, and (iv) their lack of adequate methods and procedures. I contend that a multi-institutional healthcare ethics committee (MI-HEC) can substantially mitigate these problems.

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(2008), available at [http://www.campfieldpr.com/uploads/Journal\\_of\\_Healthcare\\_Management\\_Jan-Feb\\_2008.pdf](http://www.campfieldpr.com/uploads/Journal_of_Healthcare_Management_Jan-Feb_2008.pdf) ("Ethical conflicts are a common phenomenon in today's health care settings.").

3. HECs are also known as "medical ethics committees," "institutional ethics committees," "bioethics committees," "optimum care committees," "patient care advisory committees," and other names.

In Part III, I describe four types of multi-institutional ethics committees: (i) the network model, (ii) the extramural model, (iii) the quasi-appellate model, and (iv) the joint model. I illustrate each model with examples of actual implementation both in the clinical context and in the analogous research context (with the IRB).<sup>4</sup>

In Part IV, I explain how, with greater resources and detachment from any single institution, the MI-HEC can solve the independence, composition, resources, and procedural problems of intramural ethics committees. Significant and growing experience with multi-institutional committees both in the clinical and research contexts indicates that, by replacing or supplementing intramural HECs, MI-HECs can successfully ameliorate these problems.

Finally, in Part V, I assess why, if they are really so promising, MI-HECs have not been adopted more widely. A number of obstacles have been discussed, including: (i) transaction costs, (ii) locality, (iii) liability, and (iv) confidentiality. But the most significant obstacle is the lack of motivation to fix HECs. The current system both serves the interests of healthcare facilities and satisfies accreditation and regulatory requirements to the limited extent that such requirements exist. But as the limits of HECs are increasingly recognized, a MI-HEC solution will become more attractive to the healthcare community.

## I. BACKGROUND: HEALTHCARE ETHICS COMMITTEES

Should healthcare providers withdraw life support from a brain dead child over his parents' objections? Should these providers restrain a patient who pulls out her nasogastric feeding tube? What is the appropriate end-of-life treatment for a patient without family or close friends? For a patient whose family members disagree with each other? For a patient whose family members disagree with providers? To get guidance in answering such questions, medical professionals typically turn to the HEC.<sup>5</sup>

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4. "IRB" is the eponymous acronym for "Institutional Review Board," an entity that reviews proposed biomedical research on human subjects. See generally DENNIS JOHN MAZUR, *EVALUATING THE SCIENCE AND ETHICS OF RESEARCH ON HUMANS: A GUIDE FOR IRB MEMBERS* (2007); Jesse A. Goldner, *A Review of Current Issues in the Regulation of Human Subject Research in the United States*, in *LEGAL PERSPECTIVES IN BIOETHICS* 10 (Ana S. Iltis et al., eds. 2008).

5. See Alice Herb & Eliot J. Lazar, *Ethics Committees and End-of-Life Decision Making*, in *MEDICAL FUTILITY AND THE EVALUATION OF LIFE-SUSTAINING INTERVENTIONS* 110, 110 (Marjorie B. Zucker & Howard D. Zucker eds., 1997) ("In recent years, institutional ethics committees have increasingly become the forum for the resolution of these dilemmas.").

The HEC is a group established by a healthcare facility and charged with discussing, deciding, and advising on ethical questions and policies that arise in clinical care.<sup>6</sup> Its purpose is to [s]erve as a reasonable and valid institutional endeavor to increase understanding among all concerned—health care providers, families, patients, and society—as well as to resolve many of the ethical, legal, and medical dilemmas facing those who care for critically and terminally ill patients.<sup>7</sup>

The very birth of bioethics was based in the idea that some healthcare decisions are too complicated and momentous to be left in the hands of physicians alone.<sup>8</sup> As medicine began to open the door to new, unexplored areas, bioethics grew to serve as a check on the use of medical technology. For example, as a result of bioethics at work in the research context, investigators must now obtain the approval of an institutional review board (IRB) before engaging in research on human subjects.<sup>9</sup> In the clinical context, the healthcare ethics committee serves an analogous function.<sup>10</sup> The HEC offers a systematic and prin-

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6. See Carol Levine, *Questions and (Some Very Tentative) Answers About Hospital Ethics Committees*, HASTINGS CENTER REP., June 1984, at 9, 9.

7. RONALD E. CRANFORD & A. EDWARD DOUDERA, INSTITUTIONAL ETHICS COMMITTEES AND HEALTH CARE DECISION MAKING 6 (1984) [hereinafter CRANFORD & DOUDERA].

8. See Warren T. Reich, *Revisiting the Launch of the Kennedy Institute: Re-Visioning the Origins of Bioethics*, 6 KENNEDY INST. ETHICS J. 323 (1996). Bioethics is a shift away from science, away from insiders to outsiders; “[h]uman life is too precious and the decisions regarding it too important to leave to any one group of specialists.” *Id.* at 324.

9. See 21 C.F.R. § 56.103(a) (2008) (stating certain “clinical investigation[s]” cannot be initiated unless they “remain[] subject to continuing review by, an IRB meeting”); 45 C.F.R. § 46.101(a) (2008) (“[T]his policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.”).

10. Throughout this Article, I look to the IRB as a close cousin of the HEC. See BOWEN HOSFORD, *BIOETHICS COMMITTEES: THE HEALTH CARE PROVIDER’S GUIDE* 37 (1986); Robert M. Veatch, *The Ethics of Institutional Ethics Committees*, in CRANFORD & DOUDERA, *supra* note 7, at 35, 37 (“The closest cousin to the institutional ethics committee, [is] the [IRB] . . . .”); *id.* at 45 (“An IRB . . . is similar in many ways to ethics committees . . . .”); see also Alexander Morgan Capron, *Decision Review: A Problematic Task*, in CRANFORD & DOUDERA, *supra* note 7, at 174, 181; Joanne Lynne, *Roles and Functions of Institutional Ethics Committees: The President’s Commission’s View*, in CRANFORD & DOUDERA, *supra* note 7, at 22, 27 (“The experience of [the IRBs] is very instructive.”).

ciplined approach to the contemporary dilemma of healthcare decision making.<sup>11</sup>

In this Part, I first review the origin and history of healthcare ethics committees. I then describe their three primary functions: education, policy development, and case consultation. Finally, I explain that HECs are usually intramural decision makers. They are intramural in that they typically are formed by and within a single healthcare facility to serve that same facility. HECs are decision makers in that, while serving their case consultation function, they often have *de jure* or *de facto* adjudicatory authority.

### A. Origin and History of HECs

One of the earliest issues prompting the creation of modern ethics committees involved the allocation of dialysis machines. Renal dialysis became technologically available in the early 1960s, but was not covered by Medicare until 1972.<sup>12</sup> During this time, demand for dialysis far exceeded supply.<sup>13</sup> Committees were therefore established to determine which patients with renal failure would be eligible to receive the treatment.<sup>14</sup>

At about the same time, biomedical research was transitioning to “shared decision making—between scientists, their interdisciplinary peers, and the public.”<sup>15</sup> It had become “clear that the research team,

11. See Gergory A. Jaffe, *Institutional Ethics Committees: Legitimate and Impartial Review of Ethical Health Care Decisions*, 10 J. LEG. MED. 393, 394 (1989) (“IECs have been endorsed because they check the physician’s influence over patients.”).

12. End Stage Renal Disease Act, Pub. L. No. 95-292, 92 Stat. 307 (codified as amended at 42 U.S.C. § 1395c (2006)).

13. See Shana Alexander, *They Decide Who Lives, Who Dies*, LIFE, Nov. 9, 1962, at 102, 104 (“[A]gonizing practical decisions must be made . . . someone must choose which patient out of 50 shall be permitted to hook up to Seattle’s life-giving machines and which shall be denied.”).

14. See *id.* at 124 (describing “the novel double-screening device of a medical board back-stopped by a lay committee . . . [so] all segments of society, not just the medical fraternity [c]ould share the burden of choice as to which patients to treat and which to let die.”); see also PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL & BEHAVIORAL RESEARCH, DECIDING TO FORGO LIFE-SUSTAINING TREATMENT: ETHICAL, MEDICAL, AND LEGAL ISSUES IN TREATMENT DECISIONS 155-56 (1983) [hereinafter PRESIDENT’S COMM’N], available at [http://www.bioethics.gov/reports/past\\_commissions/deciding\\_to\\_forego\\_tx.pdf](http://www.bioethics.gov/reports/past_commissions/deciding_to_forego_tx.pdf). Indeed, even after Medicare funding until 1978, candidates were screened by local medical review boards for appropriateness. See End Stage Renal Disease Act, Pub. L. No. 95-292, 92 Stat. 307 (codified as amended at 42 U.S.C. § 1395c (2006)).

15. John C. Fletcher & Edward M. Spencer, *Ethics Services in Healthcare Organizations*, in INTRODUCTION TO CLINICAL ETHICS 257, 259 (John C. Fletcher et al. eds., 2d ed. 1997).

acting alone, was not able to protect human subjects."<sup>16</sup> Accordingly, in 1966, the Public Health Service promulgated a policy announcing that grants for research involving human subjects would be approved only if a local review board had first approved the project and its plans for informed consent.<sup>17</sup> By 1974, Congress had enacted the National Research Act, requiring that all institutions supported by federal funds have their research reviewed by an IRB.<sup>18</sup>

Looking both to the dialysis committees of the 1960s and to the research committees of the early 1970s,<sup>19</sup> in 1975, Texas pediatrician Karen Teel proposed the use of multidisciplinary committees for "exploring all of the options for a particular patient."<sup>20</sup> Dr. Teel's proposal was famously endorsed the very next year by the New Jersey Supreme Court in *In re Quinlan*.<sup>21</sup>

In *Quinlan*, the Court held that Karen Ann Quinlan had a privacy right to terminate the medical treatments sustaining her non-cognitive, vegetative existence and that such a right could be asserted on her behalf by her father. The court did require that the HEC first confirm that there was no reasonable possibility of Karen emerging from her comatose state. The court further suggested that HECs, rather than courts, should review decisions to withhold or withdraw treatment as "a general practice and procedure."<sup>22</sup>

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16. *Id.* at 259.

17. See John C. Fletcher, *The Bioethics Movement and Hospital Ethics Committees*, 50 MD. L. REV. 859, 867 (1991); John C. Fletcher & Diane E. Hoffmann, *Ethics Committees: Time to Experiment with Standards*, 120 ANNALS INTERNAL MED. 335, 335 (1994).

18. National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974) (codified as amended at 20 U.S.C. § 3401 (2006)).

19. Teel may have also been looking to analogous precedent involving sterilization committees, abortion committees, and Catholic medical-moral committees, the last of which examined the appropriateness of treatments in light of Catholic teachings. See generally CARL L. MIDDLETON, A MODEL MEDICAL-MORAL COMMITTEE FOR CATHOLIC HEALTH CARE FACILITIES (1977); CATHOLIC HOSP. ASS'N OF CAN., MEDICO-MORAL GUIDE (1971); see also Levine, *supra* note 6, at 10. Abortion and sterilization committees, meanwhile, determined the appropriateness of those procedures for particular patients. See *Doe v. Bolton*, 410 U.S. 179 (1973); *Buck v. Bell*, 274 U.S. 200 (1927); see also HOSFORD, *supra* note 10, at 65; JONATHAN D. MORENO, DECIDING TOGETHER: BIOETHICS AND MORAL CONSENSUS 94-96 (1995); T.W. McElin, *Tubal Sterilization. Study at Evanston Hospital*, 97 AM. J. OBSTETRICS & GYNECOLOGY 479 (1967).

20. Karen Teel, *The Physician's Dilemma—A Doctor's View: What the Law Should Be*, 27 BAYLOR L. REV. 6, 9 (1975).

21. 355 A.2d 647 (N.J. 1976).

22. *Id.* at 669 ("[T]he value of additional views and diverse knowledge is apparent."). *Quinlan* is emblematic, as most of the work of ethics committees has concerned end-of-life issues. See *infra* notes 42, 53, 56, and 66.

While some hospitals had ethics committees in the early 1970s, ethics committees in the clinical context (as compared to the research context) were still quite rare.<sup>23</sup> Quinlan changed that state of affairs by “giving credence to the importance of such committees for end-of-life cases.”<sup>24</sup> Over the next decade, appellate courts in many states similarly endorsed the notion that most end-of-life health decision making could be, and should be, handled by ethics committees.<sup>25</sup>

In 1983, the President’s Commission cautiously endorsed hospitals’ use of ethics committees.<sup>26</sup> The Commission even published a model statute on the role and function of ethics committees as an appendix to its widely influential report, *Deciding to Forgo Life-Sustaining Treatment*.<sup>27</sup> In 1986, the New York State Task Force on Life and the Law also encouraged resolving patient care dilemmas at the institutional level.<sup>28</sup> By the mid-1990s, many major medical associations had also endorsed the idea.<sup>29</sup>

Soon, ethics committees were not only encouraged but even effectively legally required at the federal level.<sup>30</sup> In its 1984 “Baby Doe”

23. By the early 1970s, there had been public calls for clinical ethics committees. See Elizabeth Heitman, *Institutional Ethics Committees: Local Perspectives on Ethical Issues in Medicine*, in SOCIETY’S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE 409, 409 (Ruth Ellen Bulger et al. eds., 1995). Some hospitals even had functioning committees. See, e.g., *Optimum Care for Hopelessly Ill Patients: A Report of the Clinical Care Committee of the Massachusetts General Hospital*, 295 NEW ENG. J. MED. 362 (1976); Thomasine Kushner & Joan M. Gibson, *Descriptive Summaries of Extant Institutional Ethics Communities*, in CRANFORD & DOUDERA, *supra* note 7, at 247, 275 (providing self-descriptive report prepared by members of the Hennepin County Medical Center Biomedical Ethics Committee in Minneapolis, Minnesota).

24. Glen McGee et al., *Successes and Failure of Hospital Ethics Committees: A National Survey of Ethics Committee Chairs*, 11 CAMBRIDGE Q. HEALTHCARE ETHICS 87, 87 (2002).

25. See *infra* notes 73-85.

26. PRESIDENT’S COMMISSION, *supra* note 14, at 169-70.

27. *Id.* at 349.

28. See N.Y. STATE TASK FORCE ON LIFE & THE LAW, *DO NOT RESUSCITATE ORDERS: THE PROPOSED LEGISLATION AND REPORT OF THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW* 33-44 (1986).

29. See, e.g., Comm. on Bioethics, Am. Acad. of Pediatrics, *Institutional Ethics Committees*, 107 PEDIATRICS 205 (2001), available at <http://pediatrics.aappublications.org/cgi/reprint/107/1/205.pdf>; Am. Hosp. Ass’n, *Guidelines: Hospital Committees on Biomedical Ethics*, in HANDBOOK FOR HOSPITAL ETHICS COMMITTEES 57, 110-11 (Judith Wilson Ross et al. eds., 1986); Am. Med. Ass’n Judicial Council, *Guidelines for Ethics Committees in Health Care Institutions*, 253 JAMA 2698 (1985).

30. See Heidi Gorovitz Robertson, *Seeking a Seat at the Table: Has Law Left Environmental Ethics Behind as it Embraces Bioethics?*, 32 WM. & MARY ENVTL. L. & POL’Y REV. 273, 312-18 (2009). An early bill for the Patient Self Determination Act would have also mandated HECs. See Heitman, *supra* note 23, at 410-11; Diane E.



rule, the Department of Health and Human Services (DHHS) suggested the usefulness of “Infant Care Review Committees.”<sup>31</sup> Like earlier “Baby Doe” rules,<sup>32</sup> the 1984 regulations were struck down for administrative law reasons.<sup>33</sup> But Congress authorized new regulations under the Child Abuse Prevention and Treatment Act.<sup>34</sup> In response, DHHS promulgated new regulations in 1985.<sup>35</sup> Those regulations, which remain in effect today, “encourage[ ] each recipient health care provider that provides healthcare services to infants . . . to establish an Infant Care Review Committee.”<sup>36</sup>

Ethics committees were also legally mandated at the state level. In 1986, Maryland became the first state to enact legislation requiring the creation of “patient care advisory committees” at hospitals and nursing homes.<sup>37</sup> New Jersey followed in 1990.<sup>38</sup> And Colorado and Texas enacted similar laws in 1992.<sup>39</sup> While other states do not categorically mandate the formation and maintenance of ethics committees, many

Hoffmann, *Regulating Ethics Committees in Health Care Institutions—Is it Time?*, 50 MD. L. REV. 746, 753 (1991). But this requirement was deleted from the final version of the bill “because of concerns among smaller hospitals about the costs.” Fletcher, *supra* note 17, at 871.

31. Nondiscrimination on the Basis of Handicap; Procedures and Guidelines Relating to Health Care for Handicapped Infants, 49 Fed. Reg. 1622 (Jan. 12, 1984) (codified as amended at 45 C.F.R. §§ 84.1-61 (2008)).

32. See Jaffe, *supra* note 11, at 398-400.

33. See *Bowen v. Am. Hosp. Ass’n*, 476 U.S. 610 (1986).

34. See 42 U.S.C. § 5103 (repealed 1996).

35. Services and Treatment for Disabled Infants; Model Guidelines for Health Care Providers to Establish Infant Care Review Committees, 50 Fed. Reg. 14,893 (Apr. 15, 1985).

36. 45 C.F.R. § 84.55 (2008). See *id.* § 1340.15; JAMES L. BERNAT, ETHICAL ISSUES IN NEUROLOGY 117-18 (2008).

37. See Act of May 27, 1986, ch. 749, 1986 Md. Laws 2841 (codified as amended at MD. CODE ANN., HEALTH-GEN §§ 19-370 to -374 (LexisNexis 2005)); Paula C. Hollinger, *Hospital Ethics Committees and the Law: Introduction*, 50 MD. L. REV. 742, 742 (1991). Nursing homes were not included until 1990. See Act of May 29, 1990, ch. 545, 1990 Md. Laws 2376 (codified as amended at MD. CODE ANN., HEALTH-GEN § 19-370(e) (LexisNexis 2005)).

38. N.J. ADMIN. CODE § 8:43G-5.1(h) (2009) (including as hospital licensing standards: “The hospital shall have a multidisciplinary bioethics committee . . .”). See N.J. STAT. ANN. § 26:2H-65(a)(5) (West 2007) (requiring all healthcare facilities to establish an institutional dispute resolution mechanism to deal with issues surrounding advance directives); N.J. ADMIN. CODE § 8:39-9.6(i)-(j) (requiring long-term care facilities, residential care facilities, and home health agencies to maintain a mechanism for dealing with ethical dilemmas).

39. COLO. REV. STAT. § 15-18.5-103(6.5) (2008) (“The assistance of a health care facility medical ethics committee shall be provided . . .”); 25 TEX. ADMIN. CODE § 405.60(a) (2009) (“An ethics committee must be established by each facility.”).

of those states do mandate their use for certain types of treatment decisions.<sup>40</sup>

But perhaps the most significant event in the history of ethics committees occurred in 1992, when having a HEC effectively became a necessary condition for hospital accreditation. The Joint Commission, an independent, not-for-profit organization, is the nation's predominant standards-setting and accrediting body in healthcare.<sup>41</sup> Joint Commission accreditation is critically important to a healthcare facility's certification for Medicare and Medicaid and to licensing in many states.<sup>42</sup> Consequently, most facilities took notice—and took action—when, in 1992, the Joint Commission amended its accreditation standards to require a “mechanism” for considering ethical issues.<sup>43</sup> “[H]ospital ethics committees have been the most common response to [this] mandate.”<sup>44</sup>

### B. Missions and Functions of HECs

More healthcare facilities have an ethics committee than do not.<sup>45</sup> But what exactly does an ethics committee do? HECs have three pri-

40. See, e.g., FLA. STAT. ANN. § 765.404 (West 2005) (requiring a judicially appointed guardian to consult with the HEC before withdrawing life-sustaining medical treatment from a patient in a persistent vegetative state).

41. Joint Comm'n, About Us, <http://jointcommission.org/aboutus> (last visited Mar. 6, 2009) (“The Joint Commission accredits and certifies more than 15,000 health care organizations and programs in the United States.”).

42. ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE 43-45 (2006); ROBERT D. MILLER, PROBLEMS IN HEALTH CARE LAW § 2-4.5, at 73-74 (9th ed. 2006).

43. See JOINT COMM'N ON THE ACCREDITATION OF HEALTHCARE ORGS., ACCREDITATION MANUAL FOR HOSPITALS § RI.1.1.6.1, at 104 (1992); *id.* § RI.1.2.3, at 156; see also JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK § RI.1.10 (2007).

44. See Ellen L. Csikai, *The Status of Hospital Ethics Committees in Pennsylvania*, 7 CAMBRIDGE Q. HEALTHCARE ETHICS 104, 104 (1998); see also Brief of Alliance of Catholic Health Care et al. as Amici Curiae Supporting Petitioners at 30, *Wendland v. Wendland*, 28 P.3d 151 (Cal. 2001) (No. S087265); McGee et al., *supra* note 24, at 87; Robert S. Olick & Paul W. Armstrong, *Health Care Directives*, in NEW JERSEY PRACTICE § 37.36 (3d ed. 2008) (“This provision is widely interpreted to refer to an ethics committee . . . .”); Elizabeth Pharr, *The Hospital Ethics Committee: Bridging the Gulf of Miscommunication and Values*, TRUSTEE, Mar. 2003, at 24, 25.

45. While this is statistically true, it is important not to overstate the prevalence of HECs. Many rural healthcare facilities lack a functioning HEC. See Ann Cook & Helena Hoas, *Are Healthcare Ethics Committees Necessary in Rural Hospitals?*, 11 HEC FORUM 134 (1999); Karen M. Having et al., *Ethics Committees in the Rural Midwest: Exploring the Impact of HIPAA*, 24 J. RURAL HEALTH 316, 319 (2009) (“The current study brings to light the lack [only 36.7%] of formal EC in rural health facilities.”).

mary functions: education, policy development, and case consultation.<sup>46</sup> All these functions primarily concern end-of-life situations, such as determinations of patient capacity and the withholding and withdrawal of life-sustaining medical treatment.<sup>47</sup>

Most HECs, like most IRBs in the research context, are institutionally based.<sup>48</sup> Each healthcare facility establishes its own IRB to review its own scientists' research proposals.<sup>49</sup> Similarly, each healthcare facility establishes its own HEC to educate and develop policies for its

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46. See PRESIDENT'S COMMISSION, *supra* note 14, at 441; U.S. OFFICE OF TECH. ASSESSMENT, *LIFE-SUSTAINING TECHNOLOGY AND THE ELDERLY* 127 (1987); Ronald E. Cranford & A. Edward Doudera, *The Emergence of Institutional Ethics Committees*, in CRANFORD & DOUDERA, *supra* note 7, at 5, 11-14; Fletcher & Spencer, *supra* note 15, at 264-79; Heitman, *supra* note 23, at 413; Diane E. Hoffmann & Anita J. Tarzian, *The Role and Legal Status of Health Care Ethics Committees in the United States*, in LEGAL PERSPECTIVES IN BIOETHICS 46, 50 (Ana S. Iltis et al. eds., 2008); Jaffe, *supra* note 11, at 401-09; see also MD. CODE ANN., HEALTH-GEN § 19-373 (LexisNexis 2008) (describing duties and responsibilities of "patient care advisory committees"); N.J. ADMIN. CODE § 10:48B-2.1 (2009) (defining the term "Ethics Committee" to mean "a multi-disciplinary standing committee, which shall . . . have a consultative role . . . in reviewing a recommendation for a 'Do Not Resuscitate Order' . . . or for withholding or withdrawing an individual's life-sustaining medical treatment"); Harold F. Olsen, *Hospital Ethics Committees and the Role of the Board*, TRUSTEE, Dec. 1989, at 28. Additional functions include regulatory compliance, biomedical research, palliative care, and organizational ethics. See Thomas P. Gonsoulin, *A Survey of Louisiana Hospital Ethics Committees*, 119 LARANGOSCOPE 330, 333 (2009).

47. See Myra Christopher, *Role of Ethics Committee Networks and Ethics Centers in Improving End-of-Life Care*, 2 PAIN MED. 162, 162 (2001); Janet Fleetwood & Stephanie S. Unger, *Institutional Ethics Committees and the Shield of Immunity*, 120 ANNALS INTERNAL MED. 320, 321 (1994); Mary Beth Foglia et al., *Ethical Challenges Within Veterans Administration Healthcare Facilities*, AM. J. BIOETHICS, Apr. 2009, at 28; Diane E. Hoffmann, *Does Legislating Hospital Ethics Committees Make a Difference? A Study of Hospital Ethics Committees in Maryland, the District of Columbia, and Virginia*, 19 L. MED. & HEALTH CARE 105, 110, 113 (1991) [hereinafter Hoffmann Study]; Hoffmann & Tarzian, *supra* note 46, at 51; Ruth Macklin, *Consultative Roles and Responsibilities*, in CRANFORD & DOUDERA, *supra* note 7, at 157, 160, 166; Susan M. Wolf, *Ethics Committees and Due Process: Nesting Rights in a Community of Caring*, 50 MD. L. REV. 798, 819, 826 (1991) [hereinafter Wolf 1991]; Susan M. Wolf, *Ethics Committees in the Courts*, HASTINGS CENTER REP., June 1986, at 12, 12 [hereinafter Wolf 1986].

48. See Robert G. Wilson & Thomas G. Gallegos, *The Community Bioethics Committee: A Unique Pathway Out of Bioethical Dilemmas*, 4 HEC FORUM 372, 372 (1992); see also Raymond DeVries & Carl P. Forsberg, *Who Decides? A Look at Ethics Committee Membership*, 14 HEC FORUM 252, 253-54 (2002) (finding ninety percent of IRBs have a majority of affiliated members and half have eighty percent affiliated).

49. IRBs review research proposals in order to safeguard the rights, safety, and well-being of human subjects. See MIRIAM SHERGOLD, *GUIDING GOOD RESEARCH: BIOMEDICAL RESEARCH ETHICS AND ETHICS REVIEW* 23 (2008), available at [http://www.rand.org/pubs/documented\\_briefings/2008/RAND\\_DB536.pdf](http://www.rand.org/pubs/documented_briefings/2008/RAND_DB536.pdf) ("The granting or

staff and to review treatment issues regarding its own patients. It is generally believed that the best review is local review.<sup>50</sup> Intramural committees have substantial advantages over extramural bodies. They know both the institution and the treatment team. And intramural committees can readily meet with the patient, the patient's family, and the treatment team.<sup>51</sup>

### 1. Education

HECs provide information and education to three separate groups.<sup>52</sup> First, the HEC engages in self-education, often through literature review and invited presentations. After all, the HEC must be familiar with the relevant legal framework for healthcare decisions, with the principles of bioethics and ethical reasoning, and with relevant institutional policies.<sup>53</sup> Second, HECs educate institutions' staff and residents through in-service programs. Third, HECs educate the community, often making presentations about advance care planning.<sup>54</sup>

### 2. Policy Development

In addition to education, ethics committees are also typically responsible for the development of policies pertaining to end-of-life and other bioethical issues involving patient consent and refusal of treatment.<sup>55</sup>

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withholding of ethical approval decides whether a given research project can be realized . . .").

50. See *infra* Part V.A.2.

51. See Ronald B. Miller, *Extramural Ethics Consultation: Relections [sic] on the Mediation/Medical Advisory Panel Model and a Further Proposal*, 13 J. CLINICAL ETHICS 203, 203-04 (2002).

52. Cf. MD. CODE ANN., HEALTH-GEN § 19-373(b) (LexisNexis 2005) ("[T]he advisory committee may . . . [e]ducate represented hospital and related institution personnel, patients, and patients' families concerning medical decision-making.").

53. See Mark P. Aulisio & Robert M. Arnold, *Role of the Ethics Committee: Helping to Address Value Conflicts and Uncertainties*, 134 CHEST 417, 419 (2008).

54. See Kathy Kinlaw, *The Hospital Ethics Committee as Educator*, in ETHICS BY COMMITTEE: A TEXTBOOK ON CONSULTATION, ORGANIZATION, AND EDUCATION FOR HOSPITAL ETHICS COMMITTEES 203 (D. Micah Hester ed., 2008) [hereinafter ETHICS BY COMMITTEE].

55. See, e.g., MD. CODE ANN., HEALTH-GEN § 19-373(b)(2) (LexisNexis 2005) (providing that the advisory committee may also "[r]eview and recommend institutional policies and guidelines concerning the withholding of medical treatment"); N.J. ADMIN. CODE § 8:43G-5.1(h) (2009) ("The committee . . . shall have at least the following functions: . . . formulation of hospital policy related to bioethical issues . . . [and] formulation of policy related to advance directives.").

Specifically, HECs often review and recommend institutional policies and guidelines pertaining to: (i) decision-making capacity, (ii) confidentiality, (iii) informed consent, (iv) Do-Not-Resuscitate (DNR) Orders,<sup>56</sup> (v) withholding and withdrawing life-sustaining treatment, (vi) organ donation, (vii) advance directives, (viii) medical futility, and (ix) brain death.<sup>57</sup> To a lesser extent, HECs also deal with (x) genetic testing, (xi) abortion, (xii) fertility treatments, and (xiii) compromised infants.<sup>58</sup>

### 3. Case Consultation

While education and policy development are important tasks, the paradigm function of an ethics committee is prospective case consultation.<sup>59</sup> In this role, the HEC reviews specific ongoing patient care situ-

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56. These are now often referred to as Do Not Attempt Resuscitation (DNAR) or Allow Natural Death (AND) orders. In many states, they are also subsumed under Physician Orders for Scope of Treatment (POST), Physician Orders for Life-Sustaining Treatment (POLST), or Medical Orders for Scope of Treatment (MOST).

57. See, e.g., UNIV. OF KAN. MED. CTR., HOSPITAL ETHICS HANDBOOK (5th ed. 2002), available at <http://www.kumc.edu/hospital/ethics/ethics.pdf>.

58. See Aulisio & Arnold, *supra* note 53, at 420; McGee et al., *supra* note 24, at 92; P. A. Schneider, *A Study of Twelve Hospital Ethics Committees in Eastern South Carolina*, 96 J. S.C. MED. ASS'N 409 (2000). HECs also deal with other issues like disaster preparedness. See, e.g., Catholic Health Ass'n, *Ethics Survey Results of CHA Ethicists 25* (2008), [http://www.chausa.org/NR/rdonlyres/E7F8EF0F-DF81-4FBC-BDF5-A6535BC82C7F/0/2008EthicsSurveyResults\\_Ethicist.pdf](http://www.chausa.org/NR/rdonlyres/E7F8EF0F-DF81-4FBC-BDF5-A6535BC82C7F/0/2008EthicsSurveyResults_Ethicist.pdf).

59. See Capron, *supra* note 8, at 178; John F. Monagle & Michael P. West, *Hospital Ethics Committees: Roles, Memberships, Structures, and Difficulties*, in *HEALTH CARE ETHICS: CRITICAL ISSUES FOR THE 21ST CENTURY* 251, 257 (Eileen E. Morrison ed., 2009); Veatch, *supra* note 10, at 42 (“[T]he first task people think of for an institutional ethics committee is participation in individual patient care decisions.”); Jack Freer, *Ethics Committee Function and Composition*, <http://wings.buffalo.edu/faculty/research/bioethics/man-comp.html> (last visited May 2, 2009) (“The most common function of ethics committees is to provide clinical case consultation.”). In this Article, I do not distinguish between HECs and ethics consultation services. Cf. Banerjee & Kushner, *supra* note 2, at 140. Some argue that ethics committees are less needed due to the availability of bioethics consultants. See, e.g., Terrence F. Ackerman, *Conceptualizing the Role of the Ethics Consultant: Some Theoretical Issues*, in *ETHICS CONSULTING IN HEALTH CARE* 37, 37 (John C. Fletcher et al. eds., 1989); Kenneth A. Berkowitz & Nancy Neveloff Dubler, *Approaches to Ethics Consultation*, in *HANDBOOK FOR INSTITUTIONAL ETHICS COMMITTEES* 139, 140-42 (2006). Indeed, most clinical ethics issues are resolved by individual consultants or small teams rather than full committees. See Ellen Fox et al., *Ethics Consultation in United States Hospitals: A National Survey*, *AM. J. BIOETHICS*, Feb. 2007, at 16.

But the HEC still plays a central role. First, where a dispute cannot be resolved, the case is typically referred to the full committee. See, e.g., SIBLEY MEM'L HOSP., *ETHICS CONSULTATION SERVICES* (2008), available at [http://www.sibley.org/downloads/Ethics\\_](http://www.sibley.org/downloads/Ethics_)

ations and offers advice and recommendations.<sup>60</sup> While HECs typically review end-of-life cases,<sup>61</sup> they also review cases concerning capacity determinations, informed consent, and other issues.<sup>62</sup> Prospective case consultation is generally considered to be the HEC's most important role.<sup>63</sup>

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Consultation.pdf ("The on-call group . . . may be able to help those involved come to agreement . . . . If not, the full Ethics Advisory Committee . . . will be called together to consider a case."). Second, the committee must still exercise oversight over the individual consultants. See, e.g., AM. MED. ASS'N, CODE OF MEDICAL ETHICS § E-9.115 (2008); N.J. ADMIN. CODE § 8:43G-5.1(h)(3) (2009) ("The committee may partially delegate responsibility . . . to any individual or individuals who are qualified . . ."); Fletcher, *supra* note 17, at 878-80; Fletcher & Hoffmann, *supra* note 17, at 336 ("Dependence by a committee on a single ethics consultant risks unchecked ethical bias . . . ."); HOSFORD, *supra* note 10, at 97; Ralph Pinnock & Jan Crosthwaite, *The Auckland Hospital Ethics Committee: The First 7 Years*, N.Z. MED. J., Nov. 2004, at 7, available at <http://www.nzma.org.nz/journal/117-1205/1152/content.pdf> ("As professionally trained ethicists become available they were seen as complementary to but not substitutes for the committees.").

60. See, e.g., MD. CODE ANN., HEALTH-GEN § 19-373(a) (LexisNexis 2005); N.J. ADMIN. CODE § 8:43G-5.1(h)(3) (2009) ("The committee . . . shall have the following functions: . . . resolution of patient-specific bioethical issues . . . responsibility for conflict resolution concerning the patient's decision-making capacity and in the interpretation and application of advance directives").

61. See Aulisio & Arnold, *supra* note 53, at 421; Ritabelle Fernandes et al., *Enhancing Residents' Training in Medical Ethics: An Exploratory Study Assessing Attitudes of Internal Medicine Residents*, 67 HAW. MED. J. 317 (2008); Ron Hamel, *A Critical Juncture*, HEALTH PROGRESS, Mar.-Apr. 2009, at 12, 17 ("The most frequently mentioned issues . . . were end-of-life care and futile treatment."); Eric Racine, *Enriching Our Views on Clinical Ethics: Results of a Qualitative Study of the Moral Psychology of Healthcare Ethics Committee Members*, 5 J. BIOETHICAL INQUIRY 57, 63 (2008).

62. See, e.g., Pinnock & Crosthwaite, *supra* note 59, at 3 (listing, in addition, the genetic testing of children, pre-implantation genetic diagnosis, sterilization, nonresident access to healthcare, HIV infection, and confidentiality).

63. See Sharon E. Caulfield, *Health Care Facility Ethics Committees: New Issues in the Age of Transparency*, HUM. RTS., Fall 2007, at 12, available at <http://www.abanet.org/irr/hr/fall07/caulfall07.html>. "Case consultation is perhaps the most useful role . . . a committee can play." *Id.* (internal quotation marks omitted); see also Bernard Lo, *Behind Closed Doors: Promises and Pitfalls of Ethics Committees*, 317 NEW ENG. J. MED. 46 (1987); David C. Thomasma, *Hospital Ethics Committees and Hospital Policy*, QUALITY REV. BULL., July 1985, at 204, 206 ("Perhaps the most important . . . role of the hospital ethics committees is consultation."). But see Aulisio & Arnold, *supra* note 53, at 420 ("[E]ducation is ultimately the most important function of an ethics committee because the majority of ethical issues in clinical medicine will always be handled by clinicians . . .").

How do HECs fulfill this case consultation function? HECs are generally described as mere advisory bodies.<sup>64</sup> Many clarify that “the bioethics committee will not make decisions for you or dictate treatment.”<sup>65</sup> HECs facilitate problem resolution by encouraging dialogue, identifying issues, and offering viable options.<sup>66</sup>

But HECs certainly also can and do make decisions.<sup>67</sup> “[HECs] in most states serve a role as a mechanism for ‘alternative’ dispute resolution.”<sup>68</sup> For example, they are formally authorized to decide treatment for surrogateless patients.<sup>69</sup> HECs adjudicate when there is a dispute

64. See, e.g., JONATHAN D. MORENO, IS THERE AN ETHICIST IN THE HOUSE? 84-85 (2005); Andrew L. Merritt, *The Tort Liability of Hospital Ethics Committees*, 60 S. CAL. L. REV. 1239, 1273 (1987) (“Most ethics committees . . . do not have formal authority to issue binding opinions . . . . More typically, ethics committees are advisory bodies that offer recommendations rather than mandatory directives.”).

65. San Antonio Cmty. Hospital (Upland, CA), Homepage, <http://www.sach.org> (last visited Mar. 30, 2009).

66. See Thaddeus M. Pope & Ellen A. Waldman, *Mediation at the End of Life: Getting Beyond the Limits of the Talking Cure*, 23 OHIO ST. J. ON DISP. RESOL. 143 (2007).

67. See, e.g., HAW. REV. STAT. ANN. § 663-1.7(a) (LexisNexis 2008) (defining HEC as a committee “whose function is to . . . make decisions regarding ethical questions, including decisions on life-sustaining therapy”); see also Fox, *supra* note 59, at 18; Carmel Shachar, *Strengthening Clinical Ethics Committees: An Examination of the Jurisprudence and a Call for Reform*, 3 HARV. L. & POL’Y REV. 1, 1 (2009); Robin Fretwell Wilson, *Rethinking the Shield of Immunity: Should Ethics Committees Be Accountable for Their Mistakes?*, 14 HEC FORUM 172, 172 (2002) (explaining that states “repose considerable authority for ethical decisions in individual institutions”). Cf. N.C. GEN. STAT. § 90-270.15(a)(22) (2008) (requiring psychologists to cooperate promptly and completely with a HEC).

68. Hoffmann & Tarzian, *supra* note 46, at 46.

69. See, e.g., ALA. CODE § 22-8A-11(d)(7) (LexisNexis 1975); ARIZ. REV. STAT. § 36-3231 (2008); FLA. STAT. ANN. § 765.404 (West 2005); GA. CODE ANN. § 31-39-4(e) (2006); IOWA CODE § 135.29 (2008) (“[T]he local substitute medical decision-making board may act as a substitute decision maker for patients incapable of making their own medical care decisions if no other substitute decision maker is available to act.”); MISS. CODE § 41-41-215(a) (2008), N.Y. MENTAL HYGIENE CODE § 80.05 (2008); OR. CODE § 127.635 (2008); TENN. COMP. R. & REGS. § 1200-8-11.12(16)(h)(1) (2008) (“If . . . none of the individuals eligible to act as a surrogate . . . is reasonably available, the designated physician may make health care decisions for the resident after the designated physician either: . . . Consults with and obtains the recommendations of a facility’s ethics mechanism or standing committee in the facility that evaluates health care issues; or . . . Obtains concurrence from a second physician who is not directly involved in the resident’s health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician’s decision-making, influence, or responsibility.”); TEX. HEALTH & SAFETY CODE ANN. § 166.046 (Vernon Supp. 2008) (describing interaction of committee with the patient or “the person responsible for the health care decisions”); 25 TEX. ADMIN. CODE § 405.60(c)(1)-(2) (2009) (“Consultation with the ethics

between default surrogates of the same class.<sup>70</sup> They adjudicate medical futility disputes.<sup>71</sup> And even when HECs do not have formal authority, their recommendations often have a practically dispositive effect.<sup>72</sup>

Recognizing that decisions to withdraw life-sustaining treatment would be frequent and routine, courts have wisely determined that such decisions could and should be made without judicial review.<sup>73</sup> Courts have enthusiastically supported HECs.<sup>74</sup> Judges do not want to

committee . . . should be sought as follows: (1) when an individual is unable to give direction regarding the withholding or withdrawal of life-sustaining treatment, has no legal guardian, and has no person legally designated to make such a decision according to [state law]; and (2) when a decision regarding the withholding or withdrawal of life-sustaining treatment is to be made and there is a conflict between or among the decision-makers.”); W. VA. CODE § 16-30-9(a)(7) (2008).

70. See, e.g., DEL. CODE § 16-2507(b)(8) (2008); TEX. HEALTH & SAFETY CODE § 166.039(e) (Vernon 2001); 25 TEX. ADMIN. CODE § 405.60(c)(2) (2009); W. VA. CODE ANN. § 16-30-5(d) (LexisNexis 2008).

71. TEX. HEALTH & SAFETY CODE ANN. § 166.046 (Vernon Supp. 2008).

72. See George J. Agich, *Authority in Ethics Consultation*, 23 J.L. MED. & ETHICS 273, 275 (1995) (observing that recommendations have a “practical effect akin to power”); LISA BELKIN, *FIRST DO NO HARM* 73 (1992) (“Officially, the committee only gives consultation and advice . . . [but t]he advice is almost always followed.”); Ronald E. Cranford & A. Edward Doudera, *The Emergence of Institutional Ethics Committees*, in CRANFORD & DOUDERA, *supra* note 7, at 5, 16 (“[I]t is hard to believe that a committee’s recommendation would not carry weight.”); Gonsoulin, *supra* note 46, at 339 (“While HEC recommendations were considered advisory, they were usually followed by the physicians involved.”); HOSFORD, *supra* note 10, at 94 (“It is inescapable that a bioethics committee will influence physicians’ decisions . . . .”); *id.* at 231 (explaining that HEC “recommendations carry weight”: “De facto we are making decisions . . . .” (quoting Ronald Cranford)); *id.* at 232 (“A gradual evolution will probably take place, with committees assuming more authority.”); *id.* at 277 (quoting Dr. Norman C. Fost describing HECs as engaged in “de facto decision making” because they can place “enormous pressures on physicians”); Shelia A.M. McLean, *Clinical Ethics Committees, Due Process and the Right to a Fair Hearing*, 15 J.L. & MED. 1, 1 (2008) (finding that HECs are “increasingly authoritative”); Shachar, *supra* note 67, at 7 (“[A] patient’s family may feel disempowered . . . lack of resources . . . [or perceive the HEC decision] as authoritative.”); Margaret Somerville, *The Ethics of Allowing Babies to Die*, MONTREAL GAZETTE, Mar. 25, 2009 (referring to a lawsuit recently filed against a Montreal HEC: “Ethics committees . . . are very influential.”); David N. Sontag, Comment, *Are Clinical Ethics Consultants in Danger? An Analysis of the Potential Legal Liability of Individual Clinical Ethicists*, 151 U. PA. L. REV. 667, 700-03 (2002) (discussing causal relationship between HEC decisions and harm caused by medical negligence).

73. See generally ALAN MEISEL & KATHY L. CERMINARA, *THE RIGHT TO DIE: THE LAW OF END-OF-LIFE DECISIONMAKING* §§ 3.19-.20, .23, .26 (3d ed. 2004 & Supp. 2007) (collecting relevant authority).

74. See *supra* Part I.A.



decide these cases.<sup>75</sup> Moreover, the general consensus has been that there is no need for judicial review<sup>76</sup> because HECs are both better positioned and better equipped to resolve treatment disputes.<sup>77</sup>

Judicial review is generally thought to be an inappropriate mechanism for resolving medical treatment disputes.<sup>78</sup> First, it is cumbersome, being both time-consuming and expensive.<sup>79</sup> Thus, it cannot usefully address complex, urgent medical issues. Second, as courts are adversarial and open to the public, they are an unwelcome forum in

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75. See, e.g., *In re A.C.*, 573 A.2d 1235, 1237 n.2 (D.C. 1990) (“[I]t would be far better if judges were not called to patients’ bedsides . . . . Because judgment in such a case involves complex medical and ethical issues as well as the application of legal principles, we would urge the establishment . . . of another tribunal to make these decisions . . . .”); *In re Nemser*, 273 N.Y.S.2d 624, 629 (N.Y. 1966) (“[I]n no way does [this] court intend to imply that an individual must be judicially declared incompetent before it will or may intervene in his or her behalf. . . . It seems incongruous in light of the physicians’ oath that they even seek legal immunity prior to action necessary to sustain life. . . . Emergency requirements . . . should not be delayed nor the responsibility therefor shirked while fearful physicians and hospitals first seek judicial sanction . . . .”).

76. See MEISEL & CERMINARA, *supra* note 73, § 3.19 n.265.

77. *Id.* § 3.25(a); Brief for Alliance of Catholic Health Care et al., *supra* note 44, at 31 (“[E]thics committees are capable of an interdisciplinary review that no trial or appellate court could ever match . . . .”); Jack B. Weinstein, *Some Benefits and Risks of Privatization of Justice through ADR*, 11 OHIO ST. J. ON DISP. RESOL. 241, 289-90 (1996) (arguing that bioethics disputes are “probably better resolved privately”). This general position has been challenged most forcefully by Professor Robin Fretwell Wilson, of Washington and Lee University School of Law. See Robin Fretwell Wilson, *Hospital Ethics Committees as the Forum of Last Resort: An Idea Whose Time Has Not Come*, 76 N.C. L. REV. 353 (1998); Wilson, *supra* note 67, at 187-88 (stating that judges have resolved highly technical cases and stressing the benefits of court proceedings).

78. MEISEL & CERMINARA, *supra* note 73, § 3.26. Bear in mind that ethics committees may be considered, and evaluated, as another form of alternative dispute resolution. They offer most of the same benefits: speed, low cost, ease of access, informality, and confidentiality.

79. See PRESIDENT’S COMM’N, *supra* note 14, at 159 (describing court involvement with treatment disputes as intrusive, slow, costly and framed in adversarial terms). In futility disputes, for example, courts typically issue a temporary injunction ordering continued treatment pending a full evidentiary hearing; but the patient often dies in the meantime, mooted the dispute. See Thaddeus Mason Pope, *Involuntary Passive Euthanasia in U.S. Courts: Reassessing the Judicial Treatment of Medical Futility Cases*, 9 MARQ. ELDER’S ADVISOR 229 (2008). Requiring judicial review for approval of treatment decisions may, because of the required time and expense, effectively deny a right to such treatment. See, e.g., Mike E. Jorgensen, *Today Is the Day We Free Electroconvulsive Therapy?*, 12 QUINN. HEALTH L.J. 1, 1, 56 (2008).

which to resolve sensitive medical treatment disputes.<sup>80</sup> Third, judicial review is an encroachment on the medical profession.<sup>81</sup>

In contrast, the responses of ethics committees are “more rapid and sensitive” and “closer to the treatment setting.”<sup>82</sup> “[T]heir deliberations are informal and typically private,”<sup>83</sup> which is important for medical decisions and for the informal resolution of disputes.<sup>84</sup> And ethics committees better respect the role and judgment of physicians.

Courts themselves recognize these comparative strengths and weaknesses. While they remain open to resolve intractable disputes, courts have shown a willingness to consider the role and capabilities of the HEC, as well as the substance of its recommendations, as significantly impacting the final result.<sup>85</sup> Thus, it appears HECs significantly influence—and sometimes control—the outcome. The HEC is often the forum of last resort.

80. See Herb & Lazar, *supra* note 5, at 111.

81. See Wilson, *supra* note 67.

82. PRESIDENT’S COMM’N, *supra* note 14, at 169.

83. *Id.*

84. See *In re Jobes*, 529 A.2d 434, 451 (N.J. 1987) (stating that “committee review can be more sensitive, prompt, and discreet” than judicial review); PRESIDENT’S COMM’N, *supra* note 14, at 165 (observing that “ethics committees will probably be less formal and burdensome than judicial review in any particular case”).

85. See, e.g., *Quill v. Vacco*, 80 F.3d 716, 731 n.4 (2d Cir. 1996) (suggesting states allowing assisted suicide might “require the establishment of local ethics committees as resources for physicians faced with questions relating to requests for lethal medications”), *rev’d*, 521 U.S. 793 (1997); *Bernstein v. Sup. Ct.*, No. B212067, at 21 (Cal. App. Feb. 2, 2009); *Severns v. Wilmington Med. Ctr., Inc.*, 421 A.2d 1334, 1341-44 (Del. 1980); *In re A.C.*, 573 A.2d 1235 (D.C. 1990); *DeGrella v. Elston*, 858 S.W.2d 698, 710 (Ky. 1993); *In re Spring*, 405 N.E.2d 115, 120 (Mass. 1980) (“[T]he concurrence of qualified consultants may be highly persuasive . . . .”); *Superintendent of Belchertown State Sch. v. Saikewicz*, 370 N.E.2d 417, 429 (Mass. 1977); *In re Torres*, 357 N.W.2d 332, 336 n.2 (Minn. 1984) (“[T]hese committees are uniquely suited to provide guidance . . . .”); *In re Jobes*, 529 A.2d at 463-64; *In re Moorhouse*, 593 A.2d 1256, 1257 (N.J. Super. Ct. App. Div. 1991); *In re Doe*, 45 Pa. D. & C.3d 371 (C.C.P. 1987); *In re L.W.*, 482 N.W.2d 60, 63-64 (Wis. 1992); see also BETHANY SPIELMAN, *BIOETHICS IN LAW* 41-56 (2007); Hoffmann, *supra* note 30, at 780; Alexander M. Capron, *Legal Perspectives on Institutional Ethics Committees*, 11 J.C. & U.L. 416 (1985). In some respects, HECs are analogous to medical review panels in the liability context. While the decisions of neither forum typically are formally dispositive, they have significant practical effect. Cf. N.H. REV. STAT. ANN. § 519-B:1 (2008).

## II. PROBLEMS WITH INTRAMURAL ETHICS COMMITTEES

Since their beginnings, ethics committees have been subjected to nearly constant criticism.<sup>86</sup> Neither prior criticisms nor those appearing in this Article can be properly directed at *all* ethics committees. Many do a fine job. But ethics committees are subject to almost zero oversight. Furthermore, government regulation, self-regulation, certification, and accreditation have done little to strengthen HEC accountability.<sup>87</sup> Consequently, there is enormous variation in quality among HECs at different facilities.<sup>88</sup>

Professor Hunter<sup>89</sup> describes four distinct types of risks applicable to medical decisions: (i) the risk of corruption, (ii) the risk of bias,

86. See McLean, *supra* note 67, at 6 (“Criticism of the make-up and procedures of HECs in the United States is not uncommon.”).

87. See Charles L. Bosk & Joel Frader, *Institutional Ethics Committees: Sociological Oxymoron, Empirical Black Box*, in *WHAT WOULD YOU DO: JUGGLING BIOETHICS AND ETHNOGRAPHY* 39, 41 (Charles L. Bosk ed. 2008) (“IECs . . . grew in a much more free-form way, with no regulations for representation, no clear delineated tasks, no set procedures . . . .”); Hoffmann & Tarzian, *supra* note 46, at 46 (“[HECs] remain unregulated and lack homogeneity in structure and operation.”); *id.* at 54 (“Because there are virtually no regulations governing ethics committees, their operations and procedures vary from committee to committee.”); see also Nancy Neveloff Dubler & Jeffrey Blustein, *Credentialing Ethics Consultants: An Invitation to Collaboration*, *AM. J. BIOETHICS*, Feb. 2007, at 35, 37 (“[C]linical ethics consultation is a field without adequate standards, training, or quality review.”); David A. Fleming, *Responding to Ethical Dilemmas in Nursing Homes: Do We Always Need an “Ethicist”?*, 19 *HEC FORUM* 245, 251 (2007) (“Presently, there are no unified standards of clinical ethics education, training, or practice.”); Fox et al., *supra* note 59, at 13, 20 (“[T]here appear to be . . . few mechanisms for quality control.”); *Hearing Before Texas H.R. Comm. on Public Health*, 80th Legis. (2007) (statement of Colleen Horton, Univ. of Tex. Ctr. for Disabilities Studies) (testifying about the lack of HEC oversight, monitoring, accountability, consistency, and standardization); *Hearing Before Texas H.R. Comm. on Public Health Interim Rep.*, 80th Legis. (2006) (statement of Richard Mullin) (complaining that committees have no system of review, are not held to clear standards, do not impose qualifications for membership, do not report whether their decisions are unanimous or by a slim majority or whether dissent existed); SPIELMAN, *supra* note 85, at 180.

88. See *Hearing Before Texas H.R. Comm. on Public Health*, 80th Legis. (2007) (statement of Gregory Hooser) (“[E]thics committees come in all shapes and sizes.”); Wilson, *supra* note 67, at 177; Wolf 1991, *supra* note 47, at 847.

89. Nan Hunter is a law professor at the Georgetown University Law Center.

(iii) the risk of arbitrariness, and (iv) the risk of carelessness.<sup>90</sup> Many HECs suffer from some or all of these decision-making risks.<sup>91</sup>

A “corrupted decision” is one driven by the self-interest of the decision maker.<sup>92</sup> For example, a treatment decision may be *corrupted* when the decision maker has a financial interest in the outcome. A “biased decision” is one reflecting a pattern of unfairness, which disparages the interests of certain persons or classes of persons.<sup>93</sup> For example, a treatment decision may be *biased* when the decision maker is prejudiced against the race of the patient. A “careless decision” is one based on ill-considered or unsupported beliefs due to insufficiencies in the decision maker’s training.<sup>94</sup> For example, a treatment decision may be *careless* when the decision maker misapplies relevant standards, such as those for determining capacity. Finally, an “arbitrary decision” is one that is the product of an abuse of appropriate process norms.<sup>95</sup> For example, a treatment decision may be *arbitrary* when the decision maker fails to obtain relevant information or engage in adequate deliberation.

#### A. *Intramural HECs Make Corrupt Decisions*

Ideally, HECs are independent and neutral forums.<sup>96</sup> After all, their purpose is to provide a perspective broader than that of the clinical team involved with the patient’s treatment.<sup>97</sup> The American

90. Nan D. Hunter, *Managed Process, Due Care: Structures of Accountability in Health Care*, 6 YALE J. HEALTH POL’Y L. & ETHICS 93, 109 (2006) (citing Mark A. Hall et al., *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?*, 79 MILBANK Q. 613, 620-24 (2001)).

91. See I. Glenn Cohen, *Negotiating Death: ADR and End-of-Life Decision Making*, 9 HARV. NEGOT. L. REV. 253, 309 (2004).

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. See PRESIDENT’S COMM’N, *supra* note 14, at 4 (“Health care institutions . . . have a responsibility . . . to overcome the influence of dominant institutional biases . . . .”); Daniel Wikler, *Institutional Agendas and Ethics Committees*, HASTINGS CENTER REP., Sept.-Oct. 1989, at 21, 22 (“Giving some weight to institutional concerns . . . would deliberately skew the results of moral judgment toward expediency . . . . [T]he ethics committee will generally do its job best if it does not concern itself with the hospital’s interests.”). If the HEC is viewed as an ADR mechanism, then it even more obviously must comply with due process principles like neutrality and independence. See AAA, ABA & AMA COMM’N ON HEALTH CARE DISPUTE RESOLUTION, FINAL REPORT (July 27, 1998).

97. See Susan B. Apel, *Access to Assisted Reproductive Technologies*, 12 MICH. ST. J. MED. & L. 33, 42-43 (2008) (“The advantage of using the ethics committee is that it removes the dispute from those most intimately involved, and places the issue before a

Medical Association advises that “[c]ommittee members should not have other responsibilities that are likely to prove incompatible with their duties as members of the ethics committee.”<sup>98</sup> The Universal Declaration of Bioethics states that to “provide advice on ethical problems in clinical settings,” HECs should be “independent, multidisciplinary, and pluralist.”<sup>99</sup>

But the objectivity of HECs is seriously compromised. Structural factors inhibit their ability to act impartially. Since most members of an intramural HEC work for the institution, they have a conflict of interest when adjudicating disputes in which the institution has a stake. This insider composition corrupts the HEC’s decisions. This corruption is exacerbated by the dynamics of group decision making.

### 1. HEC Conflicts of Interest

Intramural committees suffer from a significant conflict of interest. Most (and often all) members of HECs are employed directly or indirectly by the very institution in which the committee is situated.<sup>100</sup> As a result of this economic dependence, the committee members may tend to act out of a sense of duty to the institution.<sup>101</sup> “As an institu-

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new-and supposedly neutral-audience that is skilled in making ethical determinations.”).

98. See AM. MED. ASS’N, CODE OF MEDICAL ETHICS § 9.11 (2008); Council on Judicial & Ethical Affairs, *Guidelines for Ethics Committees in Health Care Institutions*, 253 JAMA 2698, 2698 (1985), available at [http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja\\_ei84.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_ei84.pdf).

99. UNITED NATIONS, EDUC., SCIENTIFIC & CULTURAL ORG., UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS, at art. 19, U.N. Doc. SHS/EST/BIO/06/1 (2005) [hereinafter UNESCO DECLARATION], available at <http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>.

100. See MEISEL & CERMINARA, *supra* note 73, § 3.26[c] (“[M]ost institutions have no established structure for review of such decisions by disinterested individuals . . . .”); MORENO, *supra* note 64, at 83 (“Certainly, a committee system can easily lead to abuse . . . their nature warrants caution.”); Fleetwood & Unger, *supra* note 47, at 323 (“[M]ost ethics committee members are employees of the facility . . . .”); Miller, *supra* note 51, at 205 (“[T]he preponderance of ethics committee members are health care professionals and work in the hospital (even if not technically hospital employees) . . . .”); Robert D. Truog, *Tackling Medical Futility in Texas*, 357 NEW ENG. J. MED. 1, 2 (2007), available at <http://content.nejm.org/cgi/content/full/357/1/1> (“[HEC members] are unavoidably ‘insiders’ . . . .”).

101. See ROBERT P. CRAIG ET AL., ETHICS COMMITTEES: A PRACTICAL APPROACH 5 (1986) (“IECs might be tempted to look after the interests of their colleagues and the institution they serve.”); JUDITH WILSON ROSS ET AL., HEALTHCARE ETHICS COMMITTEES: THE NEXT GENERATION 40 (1993) (“[W]orking in any institution over time places blinders on the employee.”); George Annas, *Do Ethics Committees Work: No*, TRUSTEE, July 1994, at 17 (“[E]thics committees . . . can’t be objective.”); *id.* at 19 (arguing that

the failure of IRBs “can generally be traced to an over-identification with the perceived needs and interests of the institution,” in reference to the artificial heart experiment at the University of Utah and the Baby Face experiment at Loma Linda); Mildred K. Cho et al., *Strangers at the Benchside: Research Ethics Consultation*, AM. J. BIOETHICS, Nov. 2008, at 4 (“[C]ritics have questioned the independence of most institutionally-based ethics consultation and have raised the worry that a built-in conflict of interest could undermine the value of such a service.”); Mildred K. Cho & Paul Billings, *Conflict of Interest and Institutional Review Boards*, 45 J. INVESTIGATIVE MED. 154, 155 (1997) (“[T]he placement of the IRB within its own institution and its composition being primarily of members of the institution may itself create conflicts of interest.”); California Law Review Commission, *Staff Memorandum 98-63: Health Care Decisions: Comments on Tentative Recommendations 13-14* (Sept. 18, 1998); Kenneth A. De Ville & Gregory L. Hassler, *Healthcare Ethics Committees and the Law: Uneasy But Inevitable Bedfellows*, 13 HEC FORUM 13, 25 (2001); Fleetwood & Unger, *supra* note 47, at 323 (“[M]embers may feel inclined to make decisions in the interest of their employer . . . . [A]dministrators or colleagues might place pressure on members . . . .”); Eleanor Kinney, *Tapping and Resolving Consumer Concerns About Health Care*, 26 AM. J. L. & MED. 335, 392 (2000) (“[T]he decision maker must be knowledgeable and unbiased. This is particularly a problem when the . . . provider ‘owns’ the adjudicative process.”); Frank Leavitt, Letter, *Hospital Ethics Committees May Discourage Staff from Making Own Decisions*, 321 BRIT. MED. J. 1414, 1414 (2000), available at <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1119129&blobtype=pdf> (“[E]thicists . . . who are hired . . . by hospitals . . . may naturally be selected to serve the interests of management.”); Linda T. Powell, *Hospital Ethics Committees and the Future of Health Care Decision Making*, HOSP. MATERIAL MGMT. Q., Aug. 1998, at 82, 83 (1998) (“It is likely that committee members will act from a sense of duty to the institution, their fellow professionals . . . .”); Samuel L. Tilden, *Ethical and Legal Aspects of Using an Identical Twin as a Skin Transplant Donor for a Severely Burned Minor*, 31 AM. J. L. & MED. 87, 112 (2005) (“Examination of the individual makeup of the [HEC] reveals that its decisions were ripe for inherent bias. All committee members were either employed by the hospital or served as members of its medical staff . . . .”); Wilson & Gallegos, *supra* note 48, at 379 (describing committee members’ view of their role as one of service to the physician; a means of preserving their place in the institution); Wilson, *supra* note 67, at 180 (same); Wolf 1991, *supra* note 47, at 838 (describing HECs as “[s]till dominated” by institutional forces); *id.* at 852 (“[I]f the committee exists within a health care institution and is composed of members of that institution’s staff, then the committee will never provide the independent judgment of a body such as a court.”). Cf. See CAROLYNN M. RYAN, INTERNAL DISPUTE RESOLUTION 4 (1998) (“The concept of a neutral in-house decision maker obviously leads to complex problems and to skepticism about IDR . . . .”); *id.* at 13 (“Persons chosen as neutrals may not want to damage their own careers in the firm by antagonizing management.”); Samuel R. Bagenstos, *The Structural Turn and the Limits of Antidiscrimination Law*, 94 CAL. L. REV. 1, 28 (2006) (“While professional cultures can sometimes be enlisted to effect changes within organizations, there are good reasons to doubt the wisdom of a strategy that broadly empowers intermediaries to set workplace equality norms and the means of achieving them.”); *id.* at 31 (“Although professionals occasionally employ their own norms to transform workplaces, a professional’s own interests and milieu necessarily constrain and mold those norms. And when a professional works for management, she must heed managers’ interests as well.”); Richard S. Saver, *What IRBs*

tional player, an HEC may internalize and perpetuate the interests and biases of its parent hospital.”<sup>102</sup> Therefore, HECs may not promote patient interests that conflict with institutional interests.<sup>103</sup>

Admittedly, most HEC members have no personal, direct, substantial pecuniary interest in the committee’s parent institution.<sup>104</sup> Still, those members are not impartial.<sup>105</sup> Giles Scofield asks, “Who hires them? Who are they accountable to? What group do they least wish to offend?”<sup>106</sup> Scholars and policymakers have extensively discussed the influence of even small gifts (especially from the drug industry) on physician behavior.<sup>107</sup> When pharmaceutical companies

*Could Learn from Corporate Boards*, IRB ETHICS & HUM. RES., Sept.-Oct. 2005, at 1, 2 (“Inside directors . . . may be averse to challenging current management . . .”).

102. See Wilson & Gallegos, *supra* note 48, at 382 (“[T]he committee may be concerned about preserving its place in the institution . . . [and] may internalize and perpetuate its parent hospital’s dominant institutional biases.”); see also Wilson, *supra* note 67, at 180.

103. BELKIN, *supra* note 72 (showing an HEC taking into consideration the financial impact of care provided); Bosk & Frader, *supra* note 87, at 57 (“[T]he problem is the propriety of a committee ruling on a procedure in which so much is at stake institutionally.”); De Ville & Hassler, *supra* note 101, at 25; Hoffmann, *supra* note 30, at 785 (“[T]here is a danger that ethics committees may act as ‘puppets’ of the health care institution in which they serve.”); Cynthia B. Cohen, *The Social Transformation of Some American Ethics Committees*, HASTINGS CENTER REP., Sept.-Oct. 1989, at 21, 21 (“Ethics committees are experiencing new pressures to safeguard the institution’s financial interests . . . to help meet institutional marketing goals . . .”); Richard A. McCormick, *Ethics Committees: Promise or Peril?*, L. MED. & HEALTH CARE, Sept. 1984, at 150, 154 (describing “inhouse protectionism” as “a potential problem against which we should guard”); J. Randal, *Are Ethics Committees Alive and Well?*, HASTINGS CENTER REP., Dec. 1983, at 10, 12 (warning that ethics committees might “be pressed into service and handmaidens to money saving strategy”). See *In re Smith*, 133 P.3d 924, 926 (Or. Ct. App. 2006) (observing that the Department of Human Services did not seek appointment as healthcare guardian of severely disabled three-year-old because “such an appointment could create the appearance of a conflict of interest, in that . . . continued care . . . could cost the state a large amount of money”); F. Ross Woolley, *Ethical Issues in the Implantation of the Total Artificial Heart*, 310 NEW ENG. J. MED. 292 (1984) (describing how the IRB responsible for approving the protocol for the artificial heart was under intense pressure to approve it).

104. *Compare* *Tumey v. Ohio*, 273 U.S. 510, 522 (1927) (discussing, in a different context, application of the general rule that “officers acting in a judicial or quasi-judicial capacity are disqualified by their interest in the controversy to be decided”).

105. See *supra* Part II.A.1.

106. Giles R. Scofield, *Ethics Consultation: The Least Dangerous Profession?*, 2 CAMBRIDGE Q. HEALTHCARE ETHICS 417 (1993) (arguing that the HEC has too little critical distance to exercise independent objective judgment).

107. See, e.g., Robert A. Berenson & Christie K. Cassel, *Consumer-Driven Health Care May Not Be What Patient Medicine Caveat Emptor*, 301 JAMA 321, 321 (2009) (“Evidence amassed over two decades suggests that the gravitational pull of market

established their own ethics committees, many seriously questioned whether bioethicists could be “taken seriously if they are on the payroll of the very corporations whose practices they are expected to assess.”<sup>108</sup>

The tendency of insiders to favor their own institution is well-recognized.<sup>109</sup> For example, the New Jersey Medical Society Futility Guidelines caution ethics committee members to watch their “allegiance.”<sup>110</sup> The Alameda-Contra Costa Medical Association criticized giving ethics committees the authority to make decisions for “friendless incompetents”; that is, incapacitated patients without friends or family to speak on their behalf.<sup>111</sup> The Association doubted whether committee members could make decisions “that were free and independent of their hospital’s administrative or financial goals.”<sup>112</sup>

These concerns appear to be well-grounded. HECs do seem to get pressed into serving the institution’s financial goals, mainly in avoiding uncompensated care and liability exposure.<sup>113</sup> For example, the

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pressures frequently thwarts physician commitment or capacity to fulfill professional ideals.”); Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252 (2002). If corporations and other business entities have a significant advantage in third-party ADR, then they certainly have it in internal dispute resolution (IDR), where they more directly and completely control the process. See Peter L. Murray, *The Privatization of Civil Justice*, 91 JUDICATURE 272, 275, 315 (2008); Weinstein, *supra* note 72, at 260-61.

108. Carol Elliott, *Pharma Buys a Conscience*, AM. PROSPECT, Sept. 14, 2001.

109. See *supra* Part II.A.1.

110. Cf. U.S. DEP’T OF COMMERCE & U.S. DEP’T OF LABOR, FINAL REPORT: DUNLOP COMMISSION ON THE FUTURE OF WORKER MANAGEMENT RELATIONS ch. IV (1995) (“[P]otential for abuse . . . concerns are obvious if the process is controlled unilaterally by employers . . .”).

111. Kate Scannell, *What to Do About Patients Without a Friend in the World?*, ALAMEDA TIMES-STAR, Sept. 14, 2003.

112. *Id.*

113. See, e.g., Belkin, *supra* note 72, at 8 (“[D]iscussions of money have been increasingly difficult to avoid . . .”); *id.* at 177; *id.* at 258 (“The problem of finances always manages to enter Room 3485 . . .”). Intramural HECs also suffer from a conflict of interest when they serve as the designated decision makers regarding whether the institution can proceed with high-profit procedures like organ transplants. In Singapore and the Philippines, for example, where most organs come from live donors, intramural HECs have been attacked as insufficiently robust to ensure that donations are bona fide. See, e.g., Alastair McIndoe, *Filipinos Find It Harder to Sell Organs*, STRAITS TIMES, Oct. 8, 2008; Lee Siew Hua, *Transplants: No National Ethical Panel*, STRAITS TIMES, Aug. 27, 2008; see also Barbara Martinez, *Pursuing Charitable Mission Leaves a Hospital Struggling*, WALL ST. J., Dec. 12, 2008 (suggesting that a more profit-oriented Chicago hospital concluded a patient’s cancer was “incurable . . . too far advanced . . . irrespective to treatment,” while a hospital focused on its charitable mission provided uncompensated chemotherapy).



very day after comatose three-year-old Brianna Rideout's insurance was exhausted, the Hershey Medical Center HEC authorized the unilateral withdrawal of her ventilator over her parent's vehement objections.<sup>114</sup>

Financial relationships influence intramural HECs not only in subtle ways but also rather overtly. Many ethics committees<sup>115</sup> deliberately aim to serve a risk management role for the institution.<sup>116</sup> This should not be surprising, considering HECs often include institutional

114. *Rideout v. Hershey Med. Ctr.*, 30 Pa. D. & C.4th 57 (C.C.P. 1995).

115. This is especially true of administration HECs, as compared to medical staff HECs. See Jack Freer, *Ethics Committee Models* (1997), <http://www.wings.buffalo.edu>.

116. See SPIELMAN, *supra* note 85, at 190; George Annas, *Ethics Committees in Neonatal Care: Substantive Protection or Procedural Diversion?*, 74 AM. J. PUB. HEALTH 843, 843 (1984) ("Institutions and their staffs often see the primary function of ethics committees as protecting them against potential legal liability for treating or not treating particular patients."); Capron, *supra* note 85, at 429 ("[S]ome people . . . favor ethics committees in the belief that they will protect physicians or hospitals."); Capron, *supra* note 8, at 177 ("[T]here is a real danger in this area that institutions will regard the purpose of protecting hospitals and physicians as the primary one . . ."); Caulfield, *supra* note 63; Cohen, *supra* note 103, at 21 (Ethics committees "have been encouraged to gloss over especially difficult cases to avoid expensive legal maneuvers that could work to the institution's disadvantage. The structure of some committees has been designed to protect institutional interests . . ."); Fletcher & Hoffmann, *supra* note 17, at 336; Hoffmann Study, *supra* note 47, at 112 (seventy-two percent of surveyed DC-area ethics committees responded that they were significantly influenced by legal consequences); Hoffmann, *supra* note 30, at 767 (noting a conflict among goals: to protect the institution, providers, and the patient); Levine, *supra* note 6, at 11; McGee et al., *supra* note 24, at 91 ("One [survey respondent] wrote that the ethics committee functioned 'mostly for risk management.'"); Melinda Murray & Amy Templeton, *The Role of Legal Counsel on Hospital Ethics Committees*, ETHICSCOPE, Spring 1990 ("[T]he committee often considers whether or not an action is legal or at least defensible, from a risk management perspective."); Kevin B. O'Reilly, *Willing, But Waiting: Hospital Ethics Committees*, AM. MED. NEWS, Jan. 28, 2008 [hereinafter *Willing, But Waiting*] ("[T]oo many ethics committees and consult teams operate under the aegis or with the review of risk management at their institution."); Kevin B. O'Reilly, *AMA Meeting: Delegates Weigh Ethics Committee's Role*, AM. MED. NEWS, Dec. 1, 2008 ("[D]elegates complained that ethics services too often operate in secrecy and avoid cases that could pose challenges for the organization . . . . It's not the committee's job to cover the hospital's butt."); John A. Robertson, *Committees as Decision Makers: Alternative Structures and Responsibilities*, in CRANFORD & DOUDERA, *supra* note 7, at 85, 88-89; J.W. Summers, *Closing Unprofitable Services: Ethical Issues and Management Responses*, 30 HOSP. HEALTH SERVS. ADMIN. 8, 10 (1985); see also Univ. of Chi. MacLean Ctr. for Clinical Med. Ethics, Services and Resources: Consultation, <http://medicine.uchicago.edu/centers/cmce/consult.htm> (last visited Mar. 17, 2009) ("The ethics consultation service works closely with the Office of Medical Legal Affairs . . .").

risk managers and lawyers,<sup>117</sup> and the very creation of such committees was “motivated in part by a need for legal protection.”<sup>118</sup> Even the nation’s Supreme Court observed that “the committee’s function is protective. It enables the hospital appropriately to be advised that its posture and activities are in accord with legal requirements.”<sup>119</sup>

In *In re Edna M.F.*, for example, the sister (who was also the guardian) of a 71-year-old severely demented patient, sought HEC review of her decision to withdraw the patient’s feeding tube.<sup>120</sup> But in conducting this review, “[t]he committee seemed to understand that its function was to reach a determination that would insulate the facility from legal liability.”<sup>121</sup> Fulfillment of the patient’s wishes or best interests, not consensus, is the appropriate healthcare decision-making standard; yet the HEC agreed to withdrawal of the feeding tube *only if* no family member objected.<sup>122</sup> One did object, so the HEC disallowed the withdrawal, even though it was likely in the patient’s best interest.<sup>123</sup> Wisconsin Chief Justice Abrahamson refused to give weight to

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117. See Freer, *supra* note 59 (“Some committees are heavily represented by hospital administration or hospital counsel, and maintain a defensive posture for the institution . . . .”); Gonsoulin, *supra* note 46, at 333 (“Most HECs had at least one hospital administrator as a member.”); Hoffmann Study, *supra* note 47 (stating eighty-six percent of committees have a lawyer as a member). See also Lawrence E. Gottlieb, *Point and Counterpoint: Should an Institution’s Risk Manager/Lawyer Serve as HEC Members?*, 3 HEC FORUM 91 (1991); Robert F. Weir, *Pediatric Ethics Committees: Ethical Advisers or Legal Watchdogs?*, 15 J.L. MED. & ETHICS 99, 106 (“Rather than giving primacy to the institution’s interests, this conflict of interest means that the hospital legal counsel will advise—urge, try to compel—the committee to take the position on a case that is least likely to cause legal problems for the institution.”); Bruce White, *Point and Counterpoint: Should an Institution’s Risk Manager/Lawyer Serve as HEC Members?*, 3 HEC FORUM 87 (1991); Wilson & Gallegos, *supra* note 48.

118. See Fred Rosner, *Hospital Medical Ethics Committees: A Review of their Development*, 253 JAMA 2693, 2694 (1985); see also George J. Annas, *Legal Aspects of Ethics Committees*, in CRANFORD & DOUDERA, *supra* note 7, at 51, 52-53 (“[I]t is really a ‘risk management’ or ‘liability control’ committee.”); *id.* at 55 (describing doctors “fear that they might be criminally and civilly liable” if they terminate life support for an incompetent patient, and suggesting such fear spawns ethics committees); John A. Robertson, *Committees as Decision Makers: Alternative Structures and Responsibilities*, in CRANFORD & DOUDERA, *supra* note 7, at 85, 88-89; H. Hirsch, *Establish Ethics Committees to Minimize Liability*, 3 HOSPITAL RISK MANAGEMENT 45 (1981).

119. *Doe v. Bolton*, 410 U.S. 179, 197 (1973) (emphasis added).

120. See *In re Edna M.F.*, 563 N.W.2d 485, 495-96 (Wis. 1997).

121. *Id.* at 496.

122. *Id.*

123. *Id.*

the HEC recommendation and criticized the HEC for its marked institutional bias.<sup>124</sup>

More recently, Kalilah Roberson-Reese underwent a cesarean section at Memorial Hermann Hospital.<sup>125</sup> But amniotic fluid began to leak into her lungs, forcing providers to put her on a ventilator.<sup>126</sup> Later, her tracheal tube fell out and she went without oxygen for twenty minutes, which caused serious brain damage.<sup>127</sup> Within days, the hospital initiated Texas's statutory process by which, with approval of the HEC, providers could withdraw life-sustaining treatment even over family objections.<sup>128</sup> But again, the HEC was conflicted: the patient had exhausted her Medicaid benefits and it appeared that the hospital was trying to "bury mistakes" and avoid exposure to both liability and uncompensated treatment.<sup>129</sup>

The same corruption and conflict of interest problems plague the close cousin of the intramural HEC, the intramural IRB that approves research with human subjects.<sup>130</sup> IRB members are conflicted for three main reasons. First, the investigator's research grants may affect both the IRB member's compensation and the prestige of their institution.<sup>131</sup> Second, members review the proposals of colleagues and

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124. *Id.*

125. Todd Ackerman, *Texas' Patient Care Law at Hub of Houston Dispute*, HOUS. CHRON., July 9, 2006, at A1. Another case involving Sabrina Martin is now being litigated with very similar allegations. Chris Vogel, *Doctors v. Parents: Who Decides Right to Life?*, HOUS. PRESS, Apr. 29, 2008, <http://www.houstonpress.com/2008-05-01/news/doctors-vs-parents-who-decides-right-to-life/>. See Mimi Swartz, *Not What the Doctor Ordered*, TEX. MONTHLY, Mar. 1995 (describing case in which CIGNA pressured the HEC chair to stop expensive treatment for end-stage AIDS patient James D. Bland); see also *In re Estate of Bland v. CIGNA Health Plan of Tex.*, No. 93-52630A (Harris Cty., Tex.).

126. Ackerman, *supra* note 131, at A1.

127. *Id.*

128. *Id.* (referring to TEX. HEALTH & SAFETY CODE ANN. § 166.046 (Vernon Supp. 2008)).

129. *Id.*

130. See DeVries & Forsberg, *supra* note 48, at 253-55; Christine Vogeli et al., *Policies and Management of Conflicts of Interest Within Medical Research Institutional Review Boards: Results of a National Study*, 84 ACAD. MED. 488 (2009).

131. Leslie Francis, *Institutional Review Boards and Conflicts of Interest*, in CONFLICT OF INTEREST IN CLINICAL PRACTICE AND RESEARCH 418 (Roy G. Spece Jr. et al. eds., 1996); Erica Heath, *The History, Function, and Future of Independent Institutional Review Boards*, ONLINE ETHICS CENTER, June 14, 2006, <http://www.onlineethics.org/cms/8080.aspx> ("IRB board members . . . often have a collegial relationship with the investigators for whom they provide review, . . . may share office space with the institutional arm that obtains grants and contracts, . . . [and may be] concerned about the financial well-being and prestige of the institution that employs them."); Sharona

friends.<sup>132</sup> Third, members know that their own proposals will be reviewed and the rules extracted from their review decisions will be applied to them.<sup>133</sup> Because of this “built-in self-interest,” IRBs “are often friendly regulators.”<sup>134</sup>

Famously, in *Grimes v. Kennedy Krieger Institute*, the Maryland Court of Appeals found that IRBs have a conflict of interest because they are committees of the very research institute that they are charged to oversee.<sup>135</sup> The IRB in *Grimes* had approved research exposing small children to risks of lead poisoning while offering those same children no prospect of direct medical benefit.<sup>136</sup>

HECs may be beholden not only to their respective institutions but also to the individual physicians who refer the cases to the committee.<sup>137</sup> The repeat player phenomenon provides that the party that arbitrates many disputes (hospitals) will have greater experience with and exposure to the process than the party that typically arbitrates just

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Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365, 378 (2005).

132. See Robert Dingwall, “Turn Off the Oxygen. . .,” 41 L. & SOC’Y REV. 787, 788-89 (2007).

133. See Cinead R. Kubiak, Note, *Conflicting Interests & Conflicting Laws: Re-Aligning the Purpose and Practice of Research Ethics Committees*, 30 BROOK. J. INT’L L. 759 (2005).

134. Leonard H. Glantz, *Contrasting Institutional Review Boards with Institutional Ethics Committees*, in CRANFORD & DOUDERA, *supra* note 7, at 129, 131 (emphasis added).

135. 782 A.2d 807 (Md. 2001).

136. At least federal regulations address this conflict of interest in some contexts. See, e.g., 45 C.F.R. § 46.304 (2008) (requiring that, with research on prisoners: the majority of the IRB “have no association with the prison[ ] involved” and at least one member “shall be a prisoner or prisoner representative”).

137. Cf. Bosk & Frader, *supra* note 87, at 55 (“[I]n the closed world of the tertiary care hospital . . . an independent judgment . . . should not be a taken-for-granted outcome.”); Cho & Billings, *supra* note 101, at 156 (“[I]ndividual conflicts stem from the relationship between an individual IRB member and his or her colleagues. Institutional conflicts are linked to the relationship between the IRB as a group and its institution.”). Accountability can be defined by location in the institutional hierarchy. Heitman, *supra* note 23, at 419. If a HEC reported to the medical executive committee, it might not have independence to question physicians. On the other hand, if a HEC reported to the administration, it might be too aligned with risk management.

one dispute (patient, surrogates).<sup>138</sup> Eager to maintain relationships with physicians, committees over-identify with their interests.<sup>139</sup>

In sum, HECs are creatures of the healthcare institutions in which they are situated. Since, in many treatment disputes, the interest of the institution may not align with that of the patient, HECs cannot act as sufficiently impartial, independent decision makers. They serve “two sets of masters.”<sup>140</sup> Susan Wolf<sup>141</sup> states that “to ask institutional committees dominated by caregivers to be the guardians of patients’ rights and interests is like asking the fox to guard the chicken coop.”<sup>142</sup>

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138. See generally Marc Galanter, *When the ‘Haves’ Come Out Ahead: Speculations on the Limits of Legal Change*, 9 L. & SOC’Y REV. 95 (1974); Hunter, *supra* note 90, at 155; Carrie Menkel Meadow, *Do the ‘Haves’ Come Out Ahead in Alternative Judicial Systems? Repeat Players in ADR*, 15 OHIO ST. J. ON DISP. RESOL. 19 (1999); Powell, *supra* note 101 (act out of sense of duty to fellow professionals).

139. See *Washington v. Harper*, 494 U.S. 210, 251-52 (Stevens, J., dissenting) (arguing that psychiatrists had a conflict of interest in reviewing their colleagues who would then review their performance); SPIELMAN, *supra* note 85, at 183-84; *id.* at 190 (reputation COI); Winifred Ann Meeker-O’Connell, *Institutional Review Boards: Current Compliance Trends and Emerging Models*, 9 J. HEALTH CARE COMPLIANCE 5 (2007) (“Members may also face non-financial conflicts in an academic setting, for example, when approving a colleague’s or competitor’s project could impact an IRB member’s career.”); Jonathan D. Moreno, *Institutional Ethics Committees: Proceed with Caution*, 50 MD. L. REV. 895 (1991) (describing intricacies of small group relations); Tilden, *supra* note 101, at 112-13 (describing procedural inadequacies with a HEC that approved skin harvesting from six-year-old girl for her sister: the only surgeon on the committee “worked as the direct supervisor to and colleague of [the burned girl’s] surgeon”; he may have been “conflicted regarding the preservation of his interpersonal relationship . . . demonstration of supportive leadership for his faculty, maintenance of divisional harmony, and avoidance of encroachment on the surgeon-patient relationship”); Wilson, *supra* note 77, at 382; Joann Starr, *The Ethical Implications of the Use of Power by Hospital Ethics Committees* 80 (2002) (unpublished dissertation for Graduate Theological Union) (“[C]ollegial manner ethics committees become sites of resistance to the institutional power-over-dynamic.”). See also Saver, *supra* note 101, at 2 (“[M]embers can become entangled in a web of personal associations.”); Wilson & Gallegos, *supra* note 48, at 379 (suggesting members defer to the health care providers because of the dynamics of group decision making).

140. Wolf 1991, *supra* note 47, at 820.

141. Professor of Law, University of Minnesota.

142. Susan M. Wolf, *Due Process in Ethics Committee Case Review*, 4 HEC FORUM 83, 92-93 (1992). See *id.* at 94 (“Committees . . . lack the necessary independence of a court.”). See Bosk & Frader, *supra* note 87, at 65 n.10 (“[T]hey are and can be nothing more than an attempt to preserve professional power by internalizing a critique and thereby dissolving it. In this line of thought, IECs are simply a away of silencing resistance and challenges to medical authority by taking charge of the dispute process . . . .”); Veatch, *supra* note 10, at 47 (arguing against the notion of “quasi-judicial authority” in HECs because “[t]he committee at best will reflect the moral consensus of the institution and its sponsors”).

Moreover, as if an *actual* lack of neutrality were not bad enough, the perception of bias creates among patients and families “serious suspicions of complicity, rubber-stamping, or cover-up.”<sup>143</sup>

## 2. Exacerbating Conflicts with Groupthink and Bandwagons

Even if only some individual members are motivated or affected by a conflict of interest, the overall HEC decision-making process may still be corrupted. Sometimes a mere few individuals control, or the chairperson dominates the deliberation.<sup>144</sup> Sometimes when an aggressive lawyer speaks, other members of the HEC feel as though the discussion has ended.<sup>145</sup> The remaining members may not independently reflect or assert their position but instead just go along with the crowd.<sup>146</sup>

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143. Miller, *supra* note 51, at 205. Notably, most ADR programs in health care operate “independently of health care providers, operating instead as outsourced contractors.” Susan J. Szmania, *ADR in Medical Malpractice: A Survey of Emerging Trends and Practices*, 26 CONFL. RESOL. Q. 71, 78 (2008).

144. See Hoffmann Study, *supra* note 47, at 111 (stating three percent of surveyed DC-area ethics committees reported being “dominated by a few individuals”); Hoffmann, *supra* note 30, at 764; Thomasine Kushner & Joan M. Gibson, *Institutional Ethics Committees Speak for Themselves*, in CRANFORD & DOUDERA, *supra* note 7, at 96, 105 (“[C]ommittees may simply reflect the views of the dominant members.”); DAVID ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 211-12 (1991); Saver, *supra* note 101, at 2 (“Nonaffiliated members can easily find their own concerns dismissed or marginalized.”); Tilden, *supra* note 101, at 112-13 (describing a committee in which the opinion of the “lone surgeon” “carried great weight with the committee” since he served in “politically powerful capacities within the institution”); Wikler, *supra* note 96, at 23 (“[T]he administrator who might sit on the committee can control perquisites, salaries, and career paths for some of the other committee members.”).

145. See Chris Hackler & D. Micah Hester, *Introduction: What Should a Hospital Ethics Committee Look and Act Like?*, in ETHICS BY COMMITTEE, *supra* note 54, at 1, 15; Hoffmann Study, *supra* note 47, at 111 (finding that roughly one-quarter of surveyed DC-area ethics committees reported that their recommendations were most influenced by lawyers); Jaffe, *supra* note 11, at 414 (suggesting that not only will counsel protect the interests of the institution, but others are likely to accede); R.L. Lowes, *How an Ethics Panel Can—and Can’t Help You*, MED. ECON., May 18, 1992, at 166, 173; Weir, *supra* note 117, at 106 (“[A]ttorneys . . . can easily become a dominant figure in the committee’s review of a case.”). But see Kenneth A. De Ville & Gregory L. Hassler, *Handling the Law in Hospital Ethics Committee Deliberations*, in ETHICS BY COMMITTEE, *supra* note 54, at 267, 272-82 (defending the role of lawyers on HECs).

146. See Bosk & Frader, *supra* note 87, at 45 (“[T]he well-known tendency of legal opinions to quiet if not quash discussion . . . may also undermine ideal moral problem solving.”); Fleetwood & Unger, *supra* note 47, at 323 (“[C]ommittee members may pressure one another . . . may fail to consider alternatives . . . may be pushed into hasty decisions . . . .”); Gregory P. Gramelspacher, *Institutional Ethics Committees and Case*

This bandwagon phenomenon means that not all arguments, perspectives, or alternatives are considered by the HEC because its members do not want to rock the boat, or are content to ride the wave.<sup>147</sup> Either way, the committee is not likely to consider its less powerful, less vocal members' input,<sup>148</sup> for once the more powerful members hint at or broadcast their position, discourse is hindered and participation is demobilized.<sup>149</sup>

Increasingly, this problem is being recognized and addressed in analogous entities. The Food and Drug Administration, for example, now requires that the members of its advisory panels vote simultaneously.<sup>150</sup> Research had showed that when they voted one-by-one, panel members altered their positions based on how colleagues voted.<sup>151</sup>

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*Consultation: Is There a Role*, 7 ISSUES L. & MED. 73 (1992); Hoffmann, *supra* note 30, at 764 (arguing that HECs are too homogenous, too isolated, too cohesive); Lo, *supra* note 63, at 48 (“[C]ommittees may inadvertently pressure members to reach consensus . . . .”); Saver, *supra* note 101, at 2 (describing “pressures to conform to the group” that “discounts critical examination of alternatives and urges consensus among members even if suboptimal and inaccurate decisions result”); C.A. Schuppli & D. Fraser, *Factors Influencing the Effectiveness of Research Ethics Committees*, 3 J. MED. ETHICS 297 (2007); Wilson, *supra* note 67, at 180 (“[T]he dynamics of group decisionmaking may inadvertently cause committees to avoid controversial alternatives that prevent quick agreement.”). Cf. Gardiner Harris, *British Balance Benefit vs. Cost of Latest Drugs*, N.Y. TIMES, Dec. 2, 2008, at A1 (“[G]aps in the idea of openness remain . . . . The committee’s chairman . . . was so intent on keeping the meeting brief that he told a committee member ‘This must be the last question. It must be relevant. Otherwise you will feel my wrath.’”).

147. See McCormick, *supra* note 103, at 154 (“Since ethics committees can easily be oversensitive to the felt need of consensus, many people distrust them. Such a felt need, it is asserted, can flatten the sharp differences . . . in ethics.”); Jordan Silberman et al., *Pride and Prejudice: How Might Ethics Consultation Services Minimize Bias?*, AM. J. BIOETHICS, Feb. 2007, at 32, 33.

148. See Don Milmore, *Hospital Ethics Committees: A Survey in Upstate New York*, 18 HEC FORUM 222, 235, 239 (2006); see also Belkin, *supra* note 72, at 201 (the idea of asking tough questions “intimidated” the new member of the committee); Edmund G. Howe, *How Ethics Committees May Go Wrong*, MID-ATLANTIC ETHICS COMMITTEE NEWSL., Spring 2008, at 1, 3 (“Commonly, members ‘higher’ on the ‘medical hierarchy’ . . . tend to speak most during committee discussions, and others say less, in part, because they may feel intimidated.”).

149. Cf. ENCYCLOPEDIA OF U.S. CAMPAIGNS, ELECTIONS, AND ELECTORAL BEHAVIOR 58 (Kenneth F. Warren ed., 2008).

150. U.S. Food & Drug Admin., Draft Guidance for FDA Advisory Committee Members and FDA Staff: Voting Procedures for Advisory Committee Meetings (Nov. 2007), <http://www.fda.gov/oc/advisory/VotingGuidance.html>.

151. *Id.*

Unfortunately, such a quick-fix procedural rule is unlikely to work in the case of intramural HECs. Bandwagon thinking does not corrupt an otherwise neutral HEC, such that one or a few members with a conflict “infect” the other members. Rather, the bandwagon phenomenon exacerbates already-existing widespread corruption in the HEC. Not only do a majority of committee members have a conflict of interest, but also the minority is unlikely to check the majority’s self-serving decisions.

### B. *Intramural HECs Make Biased Decisions*

HECs make “corrupted” decisions, driven by the self-interest of the HEC. But they also make “biased” decisions, reflecting a pattern of unfairness which disparages certain persons or entire classes of persons—such as those of a particular gender, ethnicity, or age.<sup>152</sup> “Non-white race of the patient and diagnosis of [AIDS] have been cited to be important reasons to withdraw support.”<sup>153</sup> Private dispute resolution generally exaggerates prejudices to minority participants,<sup>154</sup> and the HEC is no different in this regard.

Bias has been well-documented from the earliest ancestor of the modern ethics committee, the dialysis allocation committee.<sup>155</sup> In Seattle, one such committee considered patients’ social or moral worth in deciding whether to allocate scarce dialysis treatment.<sup>156</sup> By mea-

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152. Cf. Hunter, *supra* note 90, at 108-09.

153. Seetharaman Harihan, *Futility of Care Decisions in the Treatment of Moribund Intensive Care Patients in a Developing Country*, 50 CAN. J. ANESTHESIA 847, 850 (2003).

154. See Richard Delgado et al., *Fairness and Formality: Minimizing the Risk of Prejudice in ADR*, 1985 WIS. L. REV. 1359, 1375-91(1985); Kimberlee K. Kovach, *Privatization of Dispute Resolution: In the Spirit of Pound, but Mission Incomplete: Lessons Learned and a Possible Blueprint for the Future*, 48 S. TEX. L. REV. 1003, 1036 (2007); see also Lawrence J. Schneiderman & Alexander Morgan Capron, *How Can Hospital Futility Policies Contribute to Establishing Standards of Practice?*, 9 CAMBRIDGE Q. HEALTHCARE ETHICS 524, 528-29 (2000) (arguing that prejudices about the lives of some patients may affect the committee’s judgments; this is the reason for community representatives).

155. See *supra* notes 12-14 and accompanying text. Even earlier, therapeutic abortion committees were established because physicians disagreed about acceptable indications for abortion. These committees were criticized as a “smokescreen” and as being susceptible to being set up to “make it do anything you want.” HYMAN RODMAN ET AL., *THE ABORTION QUESTION* 182 (1987).

156. See R.C. FOX & J.P. SWAZEY, *THE COURAGE TO FAIL: A SOCIAL VIEW OF ORGAN TRANSPLANTS AND DIALYSIS* 246-79 (1974); Alexander, *supra* note 13, at 106 (describing factors used by “Life or Death Committee”); Robert P. Baker & Victoria Hargreaves, *Organ Donation and Transplantation: A Brief History of Technical and Ethical Developments*, in *THE ETHICS OF ORGAN TRANSPLANTATION* 32-35 (Wayne Shelton & John Balint eds., 2001); Moreno, *supra* note 139, at 898 (observing that even those



suring applicants in accordance with their own middle class value system, committee members chose transplant recipients with similar backgrounds, rejecting a prostitute, a playboy, and others the committee perceived as lacking the requisite decency and responsibility.<sup>157</sup>

No safeguards apply to the modern ethics committee that would prevent or mitigate these continuing biases.<sup>158</sup> Because it is often unconscious, such partiality goes uncorrected.<sup>159</sup> “[A] committee composed completely of health care insiders might, however inadvertently, misrepresent the actual needs and concerns of patients and their family members.”<sup>160</sup> Recommendations and decisions will be applied unevenly because HECs are influenced by the patient’s income, age, gender, and political power, along with the parent institution’s financial status.<sup>161</sup>

This bias can be substantially mitigated by attending to the composition of the HEC. A HEC will be less biased where it has a larger membership with a diversity of disciplinary and life perspectives.<sup>162</sup> Cognizant of this, the DHHS “encourages” federally-funded infant care

“well-meaning people” who initially decided who would receive kidney dialysis “came to see their inclination toward middle-class patients with backgrounds similar to theirs as troubling”).

157. Baker & Hargreaves, *supra* note 156, at 34; FOX & SWAZEY, *supra* note 156, at 232; David Sanders & Jesse Dukeminier, Jr., *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 357, 378 (1968).

158. Cf. Bosk & Frader, *supra* note 87, at 47 (“[A] powerful group of (mostly) professionals, the IEC, simply chose to support one value system . . . over another . . . held by those with much less institutional and social power, families of patients.”); Miller, *supra* note 51, at 205 (“[S]uspicious of complicity, rubber-stamping, or cover-up . . . may be more common than we think . . .”).

159. See Dana & Loewenstein, *supra* note 107, at 252; Bagenstos, *supra* note 101, at 5-6.

160. RICHARD E. THOMPSON, SO YOU’RE ON THE ETHICS COMMITTEE? 59 (2007). See SIGRID FRY-REVERE, THE ACCOUNTABILITY OF BIOETHICS COMMITTEES AND CONSULTANTS 100 (1992) (“I have seen the concerns of some individuals be ignored because they are old, young, women, or health care personnel other than physicians.”).

161. See Terese Hudson & Kevin Lumsdon, *Are Futile Care Policies the Answer? Providers Struggle with Decisions for Patients Near the End of Life*, 68 HOSPS. & HEALTH NETWORKS, Feb. 1994, at 26, 32; Karl Schupp, *Discussion*, 89 AM. J. OBSTETRICS & GYNECOLOGY 353, 353 (1964) (“It is perfectly obvious when you set up one of these committees that you can make it do anything you want depending on how many people you put on it, what their religious convictions are . . .”); see also Ann Cook & Helena Hoas, *Ethics and Rural Healthcare: What Really Happens, What Might Help?*, AM. J. BIOETHICS, Apr. 2008, at 52 [hereinafter *Ethics and Rural Healthcare*].

162. See SUE DILL CALLOWAY, ETHICS, RIGHTS, AND RESPONSIBILITIES: WINNING STRATEGIES FOR JCAHO AND CMS COMPLIANCE 154 (2005); LINDA FARBER POST ET AL., HANDBOOK FOR HEALTH CARE ETHICS COMMITTEES 203 (2007); W.R. SEXSON & J. Thigpen, *Organization and Function of a Hospital Ethics Committee*, 23 CLINICAL

providers “to establish an Infant Care Review Committee.”<sup>163</sup> Its regulations advise that such a committee should be “composed of individuals representing a broad range of perspectives”<sup>164</sup> including a “representative of a disability group, or a developmental disability expert.”<sup>165</sup> Encouragingly, after being swept into a high profile debacle in the Ashley X case, the Seattle Children’s Hospital added a disability rights representative.<sup>166</sup> And some Texas hospitals have responded to bias charges by appointing disability advocates to their HECs.<sup>167</sup>

Outsiders can reduce prejudices, biases, and cover-ups.<sup>168</sup> Accordingly, most commentators agree that HECs should include rep-

PERINATOLOGY 429 (1996); Laszlo T. Vasvar et al., *Hospital Ethics Case Consultations: Practical Guidelines*, 31 COMPREHENSIVE THERAPY 279, 280 (2005).

163. 45 C.F.R. § 84.55(a) (2008) (stating the purpose of this recommended committee is “to assist the health care provider in the development of standards, policies and procedures for providing treatment to handicapped infants and in making decisions concerning medically beneficial treatment in specific cases,” but also clarifying that “such committees are not required”)

164. *Id.*

165. 45 C.F.R. § 84.55(f)(2)(v) (describing the Department’s advisory “Model Infant Care Review Committee,” which proposes mandatory constituency requirements). See N.J. ADMIN CODE § 10:48B-3.1 (2006) (requiring HECs to include “at least one member of the committee interested in and experiences with individuals with developmental disabilities”).

166. See Alicia Oullette, *Growth Attenuation, Parental Choice, and the Rights of Disabled Children: Lessons from the Ashley X Case*, 8 HOUS. J. HEALTH L. & POL’Y 207, 243 (2008). Ashley was born with static encephalopathy in 1997, leaving her permanently at an infant mental level. See Ashley’s Mom & Dad, *Towards a Better Quality of Life for “Pillow Angels”* 1, <http://pillowangel.org/Ashley%20Treatment%20v7.pdf> (last visited Feb. 13, 2009). To better care for Ashley, her parents consented to a variety of growth attenuation procedures. *Id.* at 3. These medical treatments and surgeries were aimed at limiting Ashley’s sexual development and keeping her as “child-like” as possible. See David R. Carlson & Deborah A. Dorfman, Washington Protection & Advocacy System, *Investigative Report Regarding the “Ashley Treatment”* 11 (May 8, 2007), <http://www.disabilityrightswa.org/news-1> (follow “Full Report” hyperlink) (“[T]he parents maintain that this procedure was not intended to ease their work as Ashley’s primary supports,” yet wrote that it “helped make ‘it more possible to include her in the typical family life and activities that provide her with needed comfort, closeness, security and love: meal time, car trips, snuggles, etc.’”). These procedures included “the removal of Ashley’s uterus and breast buds and the administration [of] high doses of hormones.” *Id.* at 7.

167. See *Hearing Before the Comm. on State Affairs*, 2009 Leg., 81st Sess. (Tex. Apr. 14, 2009) (statement of Suzanne Shepherd, Seton Family of Hospitals).

168. See Bosk & Frader, *supra* note 87, at 57 (“Membership indicates who can speak, whose opinions are counted, and whose discounted. Membership may determine which issues are seen . . .”); Daniel Callahan, *Ethics by Committee?*, HEALTH PROGRESS, Oct. 1988, at 76 (arguing that membership “can correct for individual

representatives from the community.<sup>169</sup> Indeed, in the more regulated research context, each IRB must include at least one unaffiliated member.<sup>170</sup> However, this bare minimum is recognized to be insufficient. The National Bioethics Advisory Commission, for example, recommended that at least twenty-five percent of any IRB's membership consist of persons from outside the institution.<sup>171</sup> Other countries require at least fifty percent of an IRB's members to be outsiders.<sup>172</sup>

These outside members can help provide the committee with a solid sense of the surrounding community's moral views.<sup>173</sup> In this

idiosyncrasies and biases"); DeVries & Forsberg, *supra* note 48, at 256 (expressing concern over "the over-representation of certain voices"); Hoffmann, *supra* note 30, at 792; HOSFORD, *supra* note 10, at 98; A. Nyika et al., *Composition, Training Needs, and Independence of Ethics Review Committees across Africa: Are the Gatekeepers Rising to the Emerging Challenges*, 35 J. MED. ETHICS 189, 192 (2009) ("[A] committee made up of members from the institution that hosts it, without external members, faces a high risk of bias in its work."); ROSS, *supra* note 101, at 40 ("The ethicist who comes from beyond the hospital walls may be able to broaden the committee members' views because his or her perspective differs from theirs . . ."); DAVID ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING (1991); Daniel Wikler, *Institutional Agendas and Ethics Committees*, HASTINGS CENTER REP., Sept. 1989, at 21 (arguing that HECs should be "insulate[d] from less noble imperatives in their midst"); Saver, *supra* note 101, at 2 ("Nonaffiliated members drawn from the community are supposed to . . . provide a check against bias . . ."); Silberman et al., *supra* note 147, at 33 ("One method to offset these biases is to purposefully create diversity within the members . . .").

169. See Heitman, *supra* note 23, at 420 (diverse age, gender, ethnicity, socioeconomic); Hoffmann, *supra* note 30, at 792 ("[A] significant percentage of the members [should] be from outside of the hospital [and reflect] the patient population with respect to 'race, age, gender, income, education, and religion'"); *id.* at 793 (stating that in the event of a simple majority vote, outsiders could get outvoted); HOSFORD, *supra* note 10, at 42; Pinnock & Crosthwaite, *supra* note 59 ("[S]ome health professional members should be external to the institution to avoid parochialism."); Jeffrey Spike & Jane Greenlaw, *Ethics Consultation: High Ideas or Unrealistic Expectations*, 133 ANNALS INTERNAL MED. 56 (2000) (arguing that at least one member "should not be employed by the institution's administration or malpractice office").

170. 45 C.F.R. § 46.107(d) (2005); 21 C.F.R. § 56.107(d) (1991) ("Each IRB shall include at least one member who is not otherwise affiliated with the institution."); PROTECTING HUMAN RESEARCH SUBJECTS, IRB GUIDEBOOK (1993) (discussing the desirability of requiring a diverse background including racial and cultural heritage).

171. NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 12 (2001).

172. SHERGOLD, *supra* note 49, at 18. New Zealand IRBs must have fifty percent lay members and a lay chair. See Pinnock & Crosthwaite, *supra* note 59, at 1. The UK requires a one-third "lay member," or community membership. DEP'T OF HEALTH GOVERNANCE, ARRANGEMENTS FOR NHS RESEARCH ETHICS COMMITTEES (2001).

173. See Merritt, *supra* note 64, at 1247; Tex. Dep't of Aging & Disability Servs., Ethics Committees & Ethics Process, <http://qmweb.dads.state.tx.us/Ethics.asp> (last

sense, the HEC serves much the same role as a jury.<sup>174</sup> And just as it is important for a jury to represent a diverse cross-section of the community,<sup>175</sup> so too is it important for the HEC.<sup>176</sup>

But most HECs have few outside members.<sup>177</sup> Many HECs have zero unaffiliated members.<sup>178</sup> Nearly half have only one unaffiliated member.<sup>179</sup> Moreover, even the few HECs with community members on the roster may not benefit from their participation. Given the laxity or absence of quorum or voting requirements, community members may neither attend nor participate in HEC activities.<sup>180</sup> The picture is

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visited Mar. 17, 2009) [hereinafter Texas DADS] (“Using a multidisciplinary ethics group helps to guard against the tendency to create policies that are based solely [on] a single perspective. . . . A multidisciplinary committee is better able to reflect the richness and diversity of the moral life in a pluralistic society.”).

174. Cf. Capron, *supra* note 8, at 182; Hoffmann & Tarzian, *supra* note 46, at 48.

175. RANDOLPH N. JONAKAIT, *THE AMERICAN JURY SYSTEM* 114-27 (2003).

176. Cf. 45 C.F.R. § 46.107(a) (2002) (“The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds . . . .”); see also *id.* § 46.107(d); 42 C.F.R. § 121.3(a)(ii) (requiring the Board of Directors of an Organ Procurement Transplant Network to include “25 percent transplant candidates, transplant recipients, organ donors, and family members . . . [and] to the extent practicable, the minority and gender diversity of this population”).

177. This is not surprising since there is little motivation to serve. HECs almost never provide compensation, and participating creates social tension and bad feelings. Ronald G. Spaeth et al., *Quality Assurance and Hospital Structure: How the Physician-Hospital Relationship Affects Quality Measures*, 12 *ANNALS HEALTH L.* 235, 239-40 (2003).

178. Milmore, *supra* note 148, at 227-28 (reporting that thirteen percent of upstate New York facilities surveyed had zero unaffiliated members).

179. *Id.* at 228 (finding that forty-five percent of upstate New York facilities surveyed had zero or one unaffiliated members). See Hoffmann Study, *supra* note 47, at 108 (finding that one-half of surveyed DC-area ethics committees reported no community representative); *id.* at 767 (finding that they also lack broad representation); Powell, *supra* note 101 (finding two-thirds of committees had no community member); Mary Beth West & Joan McIver Gibson, *Facilitating Medical Ethics Case Review: What Ethics Committees Can Learn from Mediation and Facilitation Techniques*, 1 *CAMBRIDGE Q. HEALTHCARE ETHICS* 63, 66 (1992).

180. See Cho & Billings, *supra* note 101, at 155 (observing that lay members “may not feel competent or empowered to comment critically”); DeVries & Forsberg, *supra* note 48, at 253-55; Glantz, *supra* note 134, at 132; (reporting community members being outnumbered, intimidated, and underappreciated; and reporting the impact on the decision process of variable attendance); Schuppli & Fraser, *supra* note 146, at 294; HOSFORD, *supra* note 10, at 270-71; R. Pedersen et al., *What Is Happening During Case Deliberation in CECs: A Pilot Study*, 35 *J. MED. ETHICS* 147 (2009) (observing “content and results” of deliberation were influenced by attendance and composition); THOMPSON, *supra* note 160, at 52-53 (“Often, the committee member needed for a specific agenda item can’t make it to a meeting.”); *id.* at 59 (“[W]e [doctors] are very

much the same for IRBs,<sup>181</sup> the close cousin of HECs, but IRBs at least are held to minimum diversity standards.<sup>182</sup>

In sum, since most HECs are comprised entirely, or almost entirely, of healthcare professionals, HECs are upper middle-class and homogenous across a range of relevant values.<sup>183</sup> They are aligned with the powerful and are not constituted so as to mitigate bias.<sup>184</sup>

One of the earliest expressions of judicial skepticism toward ethics committees is perhaps the most eloquent. The Massachusetts Supreme Judicial Court explained: "Detached but passionate investigation and decision . . . forms the ideal on which the judicial branch of the government was created."<sup>185</sup> This is "not to be entrusted to any other group . . . no matter how highly motivated or impressively constituted."<sup>186</sup> In fact, HECs are often neither highly motivated nor impressively constituted.

### C. *Intramural HECs Make Careless Decisions*

Not only do intramural HECs make corrupt and biased decisions, but they also lack adequate expertise or training to make those decisions.<sup>187</sup> HECs should feature a diverse membership if they are to have the expertise necessary to resolve the medical, ethical, social,

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likely to ignore, however inadvertently, the concerns of co-workers like nurses, technicians, and therapists.”).

181. See Saver, *supra* note 101, at 2 (“[O]nly a token number of nonaffiliated members serve on most IRBs.”).

182. 45 C.F.R. § 46.107(a) (2002) (“The IRB shall be sufficiently qualified through . . . the diversity of the members, including consideration of race, gender, and cultural backgrounds. . . . If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.”); 21 C.F.R. § 56.107(c) (2002) (“Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.”); *id.* § 56.107(d) (“Each IRB shall include at least one member who is not otherwise affiliated with the institution . . .”).

183. See Hoffmann, *supra* note 30, at 765-66, 782-83; Powell, *supra* note 101, at 83; DeVries & Forsberg, *supra* note 48, at 253-54.

184. See Milmore, *supra* note 148; DeVries & Forsberg, *supra* note 48, at 256 (describing the “over-representation of certain voices”).

185. Superintendent of Belchertown State Sch. v. Saikewicz, 370 N.E.2d 417, 435 (Mass. 1977).

186. *Id.*

187. See Willing, *But Waiting*, *supra* note 116 (“[T]oo many ethics committees are bare-bones efforts . . .”).

religious, and philosophical issues surrounding complex medical decisions.<sup>188</sup>

A diverse committee “can identify a greater range of value[s] and options.”<sup>189</sup> Accordingly, the committee needs representatives from different disciplines.<sup>190</sup> It should ideally include physicians (including specialists in critical care and palliative care), hospital administrators, clergy, attorneys, social workers, nurses, psychiatrists, psychologists, patient advocates, philosophers, and representatives of a disability group.<sup>191</sup>

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188. See, e.g., IOWA ADMIN. CODE r. 641-85.3(1) (2008) (requiring local substitute medical decision-making boards to include a physician, a nurse, or a psychologist in addition to either a social worker or a licensed attorney); MD. CODE ANN., HEALTH-GEN. § 19-372(a)(1) (LexisNexis 2008) (requiring committee to include a physician, a nurse, and a social worker); N.J. ADMIN. CODE §§ 10:48B-2.1, -3.1 (2006); Am. Acad. of Pediatrics: Comm. on Bioethics, *Institutional Ethics Committees*, 107 PEDIATRICS 205, 208 (2001) (“Ideally, the members of an IEC encompass a wide range of clinical experiences, personal backgrounds, and professional perspectives . . . .”); Hoffmann, *supra* note 30, at 764-65 (comparing HECs to to juries as being committees that are “broadly representative of the values within our society”); *id.* at 785 (describing the “advantage of a broadly constituted committee”); Wilson & Gallegos, *supra* note 48, at 373 (“The members . . . should be chosen from a wide variety of perspectives . . . wisdom, life experiences, knowledge of options . . .”).

189. Jaffe, *supra* note 11, at 407. See also Banerjee & Kuschner, *supra* note 2, at 141 (“Professional diversity among members ensures a broader knowledge base . . . .”); Peter Winn & Jacque Cook, *Ethics Committees in Long Term Care*, 8 ANN LONG TERM CARE 35, 40 (2000) (“The number of members of an ethics committee should be sufficient . . . to promote divergent points of view, to allow it to function with absenteeism and to be both multidisciplinary and representative.”).

190. See, e.g., N.J. ADMIN. CODE § 8:43G-5.1(h) (2006) (“The hospital shall assure participation by individuals with medical, nursing, legal, social work, and clergy backgrounds.”); *id.* 10:48B-3.1; Ronald E. Cranford & A. Edward Doudera, *The Emergence of Institutional Ethics Committees*, in CRANFORD & DOUDERA, *supra* note 7, at 5, 15; Norman Fost & Ronald E. Cranford, *Hospital Ethics Committees: Administrative Aspects*, 253 JAMA 2687, 2689 (1985). See UNESCO DECLARATION, *supra* note 99; ASSOC. OF AM. MED. COLLS., PROTECTING SUBJECTS, PRESERVING TRUST, PROMOTING PROGRESS II (2002), available at <http://www.aamc.org/research/coi/2002coireport.pdf> (“[T]he inclusion of public members will increase the transparency of the committee’s deliberations and enhance the credibility of its determinations.”); THOMPSON, *supra* note 160, at 59; Eleanor Updale, *The Challenge of Lay Membership of Clinical Ethics Committees*, CLINICAL ETHICS, Mar. 2006, at 60.

191. Fost & Cranford, *supra* note 190; Having et al., *supra* note 42, at 318; Jaffe, *supra* note 11, at 410-15. Maryland requires four members: a physician not directly involved in the patient’s care, a registered nurse not directly involved, a social worker, and the CEO or a designee. MD. CODE ANN., HEALTH-GEN § 19-372(a)(1) (LexisNexis 2008). Heitman is more specific, suggesting physicians of various specialties (critical care, neurology, psychiatry), nurses of various specialties, discharge planners, and physical and respiratory therapists. Heitman, *supra* note 23, at 420-23. Some

While some HECs consist of members representing a broad array of disciplinary perspectives,<sup>192</sup> many others, especially those in rural areas, lack multidisciplinary professionals.<sup>193</sup> Some suggest that the optimal number of members is around fifteen.<sup>194</sup> A recent survey of upstate New York facilities shows the average ethics committee has thirteen members.<sup>195</sup> But elsewhere, many HECs have three or fewer members.<sup>196</sup>

HEC composition varies dramatically from institution to institution. In 1980, the New York Court of Appeals derogatorily described the ethics committee as an “ill-defined, amorphous body.”<sup>197</sup> During the subsequent three decades, HECs have failed to acquire any additional definition or shape.

Commentators have long observed that the quality of HECs varies tremendously.<sup>198</sup> This is to be expected, as HECs “have no established

committees actually have this much diversity. See, e.g., Dartmouth-Hitchcock Med. Ctr., Ethics Committee, [http://www.dhmc.org/webpage.cfm?site\\_id=2&org\\_id=512](http://www.dhmc.org/webpage.cfm?site_id=2&org_id=512) (last visited Mar. 17, 2009). One commentator suggests that, because end-of-life care for animals is often more humane, a veterinarian should be on HECs. Doctor Gifford Jones, *Euthanasia Debate*, TORONTO SUN, Feb. 7, 2009.

192. Fox et al., *supra* note 59, at 17.

193. William A. Nelson, *Ethics Programs in Small Rural Hospitals*, HEALTHCARE EXECUTIVE, Nov.-Dec. 2007, at 30, 30.

194. See Vasvar et al., *supra* note 162; see also Jeffrey Spike & Jane Greenlaw, *Ethics Consultation: High Ideals or Unrealistic Expectations?*, 133 ARCHIVES INTERNAL MED. 55 (2000). One result of larger size may be that members “never become completely at ease with one another,” though it might be desirable that “everyone be a little bit on edge.” BELKIN, *supra* note 72, at 71.

195. Milmore, *supra* note 148, at 227-28. See N.J. ADMIN. CODE § 10:48B-3.1 (2006) (requiring “a membership of no less than five individuals optimally drawn from different disciplines”).

196. *Id.*; Hoffmann & Tarzian, *supra* note 46, at 48. See Martin L. Smith et al., *Texas Hospitals’ Experience with the Texas Advance Directives Act*, 35 CRITICAL CARE MED. 1271, 1272 (2007) (remarking that fifty-six percent of surveyed hospitals had a “medical appropriateness review committee distinct from their ethics committee” and that “the number of members was most frequently 1-5”). Compare MD. CODE ANN., HEALTH-GEN § 19-372(a)(1) (LexisNexis 2008) (requiring only four members), with 25 TEX. ADMIN. CODE § 405.60(b) (2008) (requiring seven members, two of whom must be unaffiliated). Another survey in the Washington, D.C. area showed pretty much the same thing. Hoffmann Study, *supra* note 47, at 107 (finding that the size of surveyed D.C.-area ethics committees ranged from four to thirty, with an average around thirteen). See Csikai, *supra* note 44, at 105; Starr, *supra* note 139, at 35 (finding seventy-five percent of surveyed hospitals “have between ten and twenty members with half of the committees having exactly fifteen members”).

197. *In re Eichner*, 426 N.Y.S.2d 517, 549 (1980).

198. See, e.g., George J. Annas, *At Law: Ethics Committees: From Ethical Comfort to Ethical Cover*, HASTINGS CENTER REP., May-June 1991, at 18, 19 (stating that

training curriculum . . . [or] fixed job descriptions.”<sup>199</sup> A recent survey shows that fewer than twenty percent of ethics committee members have formal training in bioethics.<sup>200</sup> At least one-third of HECs, especially those in rural institutions,<sup>201</sup> have zero trained members.<sup>202</sup> Professor Nancy Dubler is “horrified at the number of people out there who don’t have appropriate training” and wishes she could just “stamp

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institutional ethics committees “vary widely in terms of purpose, composition, authority, and resources”); Apel, *supra* note 97, at 43 (“[W]hether or not an ethics committee consultation adds anything of value to the deliberations concerning access issues appears to depend on the luck of the draw.”); DeVries & Forsberg, *supra* note 48, at 253-55; Fleetwood & Unger, *supra* note 47, at 321; Fox et al., *supra* note 59, at 20 (“[T]here appear to be wide variations in practice . . . .”); Hoffmann, *supra* note 30, at 762 (“The quality of ethics committees is likely to vary considerably . . . . Not all institutions have the resources and expertise necessary to operate a committee . . . .” (internal quotation marks omitted)); Laura Williamson, *The Quality of Bioethics Debate: Implications for Clinical Ethics Committees*, 34 J. MED. ETHICS 357 (2008); Wilson & Gallegos, *supra* note 48, at 371; Wilson, *supra* note 67, at 177; Wolf, *supra* note 142, at 94 (“[C]ommittees vary enormously in quality . . . .”); Wolf 1991, *supra* note 47, at 808 (“[A]n ethics committee is not an ethics committee is not an ethics committee.”).

199. James M. Dubois, *The Varieties of Clinical Consulting Experience*, 15 HEC FORUM 303, 307 (2003). See *Core Competencies for Ethics Consultations*, MED. ETHICS ADVISOR, Nov. 1, 2008 (“[T]here’s no clearly regulated national standards . . . .”) (quoting Ellen Fox); Fleming, *supra* note 87, at 251 (“Presently, there are no unified standards of clinical ethics education, training, or practice.”); John D. Lantos, *Complex Ethics Consultations: Cases That Haunt Us*, 360 NEW ENG. J. MED. 738, 738 (2009); Giles R. Scofield, *What Is Medical Ethics Consultation?*, 36 J. L. MED. & ETHICS 95 (2008) (severely criticizing the field and concluding that “the field of medical ethics consultation is, if not an ethics disaster, a disaster waiting to happen”). On the other hand, this situation is at least being addresses. See Mark Kuczewski & Kayhan Parsi, *The Making of a Clinical Ethicist: Reviewing the Big Questions*, HEALTH PROGRESS, Mar.-Apr. 2009, at 42.

200. Milmore, *supra* note 148, at 229-30, 236.

201. See Nelson, *supra* note 193, at 30; Denise Niemira et al., *Multi-Institutional Ethics Committees*, 1 HEC FORUM 77, 77 (1989).

202. Milmore, *supra* note 148, at 229-30, 236. See Carol Bayley, *Ethics Committees DV: Failure to Thrive*, 18 HEC FORUM 357, 357 (2006) (“They frequently have no training, no administrative support, and no budget.”); Fox et al., *supra* note 59, at 17; Hamel, *supra* note 61, at 13 (describing the Catholic Healthcare Association’s 2008 survey as finding the overwhelming majority of HEC members have no formal training); Thomas May, *The Breadth of Bioethics: Core Areas of Bioethics Education for Hospital Ethics Committees*, 26 J. MED. & PHIL. 101 (2001). Cf. Edith Valdez Martinez et al., *Institutional Ethics Committees in Mexico: The Ambiguous Boundary between Health Care Ethics and Research Ethics*, 24 PAN-AMERICAN MAG. PUB. HEALTH (2008) (finding fewer than three percent of Mexican HEC members had at least a masters degree and fewer than twenty percent had any training whatsoever).



her foot and make them go away.”<sup>203</sup> Much “half-baked ethics analysis”<sup>204</sup> is conducted without reference to or reliance on settled bioethics principles.<sup>205</sup>

The situation is little better in the research context with respect to IRBs.<sup>206</sup> Indeed, IRBs are both better developed and better regulated than HECs.<sup>207</sup> Just as HECs mediate and adjudicate treatment disputes in the clinical context, IRBs are positioned between investigators and human subjects in the research context. IRBs are more often, more clearly, and more formally empowered to serve this gatekeeping role. Yet, the IRB members often have no more training than HEC members.<sup>208</sup>

Courts have noted the lack of ethics committee training. For example, in *In re Edna M.F.*, the Chief Justice of Wisconsin wrote a concurring opinion specifically to call out that the ethics committee in that case “functioned without either a shared body of rules or training in ethics.”<sup>209</sup>

203. Ruth Shalit, *When We Were Philosopher Kings*, NEW REPUBLIC, Apr. 29, 1997. See Aulisio & Arnold, *supra* note 53, at 419 (“[E]thics committees are staffed primarily by health professionals and others who have had little or no formal training in either clinical ethics or conflict resolution.”); Dubler & Blustein, *supra* note 87, at 35 (“It has been a quietly growing scandal . . . [that] [m]any who now participate or direct bioethics consultation have little if any formal training.”); *id.* (“[C]linical ethics consultation is a field without adequate standards, training, or quality review.”); Laura Landro, *Life and Death: Helping Families on Big Questions*, WALL ST. J., June 25, 2008, at D1.

204. Evan G. DeRenzo, *The Imperative of Training for Ethics Consultations*, MID-ATLANTIC ETHICS COMMITTEE NEWSL., Summer 2000, at 1, 1.

205. While necessary, substantive bioethics knowledge is not sufficient. HEC members should also have expertise in: (i) information gathering, (ii) conceptual clarification and analysis, (iii) normative analysis, and (iv) facilitation or mediation. See Aulisio & Arnold, *supra* note 53, at 421. Other core competencies may be required in Catholic organizations. Hamel, *sputa* note 61, at 19-20.

206. See Hoffman & Berg, *supra* note 131, at 375; Saver, *supra* note 101, at 1 (“Many IRBs lack sufficient resources and expertise . . .”). On the other hand, the problem is now under serious regulatory investigation. Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs, 73 Fed. Reg. 37,460 (July 1, 2008).

207. See, e.g., 21 C.F.R. § 56.107(a) (2008) (“Each IRB shall . . . be sufficiently qualified through the experience and expertise of its members . . .”).

208. See, e.g., Request for Information and Comment on the Implementation of Human Subjects Protection Training and Education Programs, 73 Fed. Reg. 37,460 (July 1, 2008).

209. *In re Edna M.F.*, 563 N.W.2d 485, 495 (Wis. 1997).

In *In re Gianelli*, the parents of a seriously ill fourteen-year-old boy asked to stop his life-sustaining treatment.<sup>210</sup> The boy had Hunter's Syndrome, a serious genetic disorder that would be fatal within two years.<sup>211</sup> He was dependent on a ventilator and a feeding tube, but was alert and could sense his surroundings.<sup>212</sup> "The members of the ethics committee independently came to the conclusion that the mother's decision was an ethical one."<sup>213</sup> Nevertheless, the court refused to credit the HEC's opinion because the only physician on the committee "did not have experience with Hunter's Syndrome and was not well versed in [this patient's] care and condition."<sup>214</sup>

Of course, not every member of an HEC needs bioethics or mediation training.<sup>215</sup> Sometimes an HEC needs leaders—people who are respected and who create a sense of enthusiasm.<sup>216</sup> It needs people "to enhance the credibility" of the committee and its "standing within the institution."<sup>217</sup> And the HEC needs community members.<sup>218</sup> But there is little danger of overstatement here. The overwhelming majority of HEC members continue to have no bioethics or mediation training.<sup>219</sup>

#### D. Intramural HECs Make Arbitrary Decisions

We have seen that HEC decisions are often corrupt, biased, and careless. In addition, HEC decisions are frequently arbitrary. Admittedly, some ethics committees do operate in a formal manner, pursuant to detailed bylaws. Maryland law requires that each HEC have a written procedure by which it is convened.<sup>220</sup> But those requirements

210. *In re Gianelli*, 834 N.Y.S.2d 623, 624 (2007).

211. *Id.*

212. *Id.* at 626.

213. *Id.*

214. *Id.* at 629-30. *See id.* at 625 (noting that the physician was "serving in an administrative position at the hospital" and the "nurse on the team was not a pediatric nurse").

215. FRY-REVERE, *supra* note 160, at 95.

216. Heitman, *supra* note 23, at 420; William A. Nelson, *Evaluating Your Ethics Committees*, HEALTHCARE EXECUTIVE, Jan.-Feb. 2000, at 48, 49 (discussing desirability of committee leadership).

217. Susan Fox Buchanan et al., *A Mediation/Medical Advisory Panel Model for Resolving Disputes About End-of-Life*, 13 J. CLINICAL ETHICS 188, 201 (2002); Jaffe, *supra* note 11, at 411

218. *See supra* Part II.C.

219. Milmore, *supra* note 148 (stating only nineteen percent of ethics committee members in upstate New York facilities surveyed had training and twenty-nine percent of committees had no trained members).

220. MD. CODE ANN., HEALTH-GEN. § 19-371(a)(2) (LexisNexis 2008).

are quite thin.<sup>221</sup> For example, a Maryland ethics director explained that how a vote turns out often may depend on a number of “highly arbitrary” factors such as “who happens to be present at a given meeting.”<sup>222</sup>

Outside Maryland, HECs operate in an even more informal and casual manner.<sup>223</sup> In *In re Edna M.F.*, for example, Chief Justice Shirley Abrahamson criticized a La Crosse, Wisconsin ethics committee for failing to prepare formal minutes, for having no shared body of rules, and for failing to prepare a report.<sup>224</sup> Similarly, in *Rideout v. Hershey Medical Center*, some ethics committee members at the Hershey Medical Center could not even recall a recent discussion of a case in which the committee authorized the treating physician to unilaterally withdraw a ventilator from a three-year-old girl over her parents’ objections.<sup>225</sup>

In *In re Martin*, a wife wanted to withdraw life-sustaining medical treatment from her husband, Michael Martin, who was in a minimally conscious state.<sup>226</sup> The HEC agreed with her that withdrawal was the appropriate action.<sup>227</sup> Aware that HEC opinions have historically been quite persuasive evidence of the propriety of difficult healthcare decisions, Martin’s wife offered the HEC recommendation to the court.<sup>228</sup> But the court placed little weight on the recommendation, as the HEC

221. *Id.* § 19-372(a)(3) (requiring consultation of specific parties); *id.* § 19-372(b) (allowing petitioner to be accompanied).

222. Howe, *supra* note 148, at 1. See Sigrid Fry-Revere, *Some Suggestions for Holding Bioethics Committees and Consultants Accountable*, 2 CAMBRIDGE Q. HEALTHCARE ETHICS 449, 452-53 (1993).

223. FRY-REVERE, *supra* note 160, at 100 (observing that many HECs operate “without knowledge of the key decision makers such as the patient, the attending physician, or the patient’s surrogate”); Hoffmann Study, *supra* note 47, at 111 (reporting that of surveyed D.C.-area ethics committees, ninety percent operate by consensus and seven percent by majority); Wilson, *supra* note 67, at 177. Cf. Hunter, *supra* note 90, at 109 n.62 (observing that HECs suffer from process deficiencies); SHERGOLD, *supra* note 49, at 23 (observing that IRB “internal processes of decision making have been likened to a ‘black box’ and that the soundness of judgments has been questioned.”).

224. *In re Edna M.F.*, 563 N.W.2d 485, 495 (Wis. 1997).

225. See *Rideout v. Hershey Med. Ctr.*, 30 Pa. D. & C.4th 57 (C.C.P. 1995); see also Alison Delsite, *Suit Against Hershey Raises Touchy Questions*, THE PATRIOT, Mar. 8, 1996, at A1.

226. *In re Martin*, 538 N.W.2d 399 (Mich. 1995).

227. Petition for Writ of Certiorari, *Martin v. Major*, No. 95-821, 1995 WL 17035828, at \*3 (Nov. 20, 1995).

228. *Id.*

had never consulted other members of Michael's family in producing it.<sup>229</sup>

Courts are good at observing procedural regularities,<sup>230</sup> and generally provide litigants a principled, thorough review of the issues in dispute.<sup>231</sup> If HECs purport to substitute for courts, they must also follow procedural guidelines.<sup>232</sup> HECs must base their decisions on reasonable rationales that appeal to relevant evidence, reasons, and principles.<sup>233</sup>

Lamenting this procedural laxity, commentators warned that reviewing courts would start looking more closely at HEC minutes to see how carefully their meetings were conducted.<sup>234</sup> This prediction was accurate, as courts today are more carefully scrutinizing the bases for HEC recommendations, being increasingly unwilling to continue their tradition of deference to ethics committees.<sup>235</sup>

229. *In re Martin*, 504 N.W.2d 917, 920 (Mich. Ct. App. 1993).

230. See generally Richard Abel, *Informalism: A Tactical Equivalent to Law?*, 19 CLEARINGHOUSE REV. 375, 383 (1985); Richard Delgado et al., *Fairness and Formality: Minimizing the Risk of Prejudice in Alternative Dispute Resolution*, 1985 WIS. L. REV. 1359, 1398-99 (1985); William H. Simon, *Legal Informality and Redistributive Politics*, 19 CLEARINGHOUSE REV. 384, 385 (1985).

231. PRESIDENT'S COMM'N, *supra* note 14, at 159 ("[J]udicial decisionmaking is (ideally, at least) principled—with like cases decided alike and pains taken to develop reasoned bases for decisions.")

232. Hoffmann, *supra* note 30, at 765 ("[E]thics committees often lack substantive guidelines for decision making . . . ."); Wolf, *supra* note 142, at 94 ("[E]thics committees now wield sufficient influence over the fate of real patients[;] . . . they must do so responsibly, accountably, and with some guiding rules . . . . Committees . . . are bound by no commonly accepted rules of reasoning or system of precedent . . . .").

233. M. Sheehan, *Should Research Ethics Committees Meet in Public?*, 34 J. MED. ETHICS 631, 632 (2008).

234. JAMES F. DRANE, *CLINICAL BIOETHICS: THEORY AND PRACTICE IN MEDICAL ETHICAL DECISION MAKING* 99, 117 (1994) (predicting that courts will scrutinize the qualities of HECs, including their longevity, preparation, and grounding in ethics). See Fleetwood & Unger, *supra* note 44, at 321; Hoffmann & Tarzian, *supra* note 46, at 63 ("Courts may wish to give different weight to committee recommendations as ethics committees vary significantly in composition, experience, expertise, and procedures."); Jaffe, *supra* note 11, at 427 ("The more uniform and formal the committee procedures and the more open its processes, the more likely that a court will give this evidence substantial weight and deference.")

235. See, e.g., *Wendland v. Wendland*, 28 P.3d 151, 155 (Cal. 2001) (ignoring recommendation of 20-member HEC that agreed with patient's wife determining appropriateness of life support withdrawal without consulting patient's mother or sister); *In re Doe*, 418 S.E.2d 3 (Ga. 1992); *Martin v. Martin*, 538 N.W.2d 399, 413 (Mich. 1995) (disagreeing with committee's recommendation); *In re Gianelli*, 834 N.Y.S.2d 623, 630 (N.Y. Sup. Ct. 2007); *In re Edna M.F.*, 563 N.W.2d 485, 573 (Wis.

### E. *The Problems of Intramural HECs Are Worth Fixing*

HEC decisions are often corrupt, biased, careless, and arbitrary. Yet I write not to bury HECs but to praise them. HECs are ubiquitous. They can and do serve an important role in our healthcare system.<sup>236</sup> The modern HEC as an institution is not inherently flawed; rather, it is a victim of neglect. There are at least three significant reasons to repair HECs rather than replace them altogether.

First, HECs are well-entrenched in our healthcare infrastructure. They are recommended by professional medical associations;<sup>237</sup> practically required by accreditation standards;<sup>238</sup> and often literally required by regulation and statutes.<sup>239</sup> Scrapping the HEC would be not only an unpopular idea among medical professionals, but also legally unrealistic.

Second, the trend, both in and out of healthcare, is for businesses to fashion internal systems for conflict management and resolution.<sup>240</sup> Like other engines of "internal dispute resolution," HECs have significant advantages over extra-institutional arbiters.<sup>241</sup> They are cheaper

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1997). On the other hand, where the HEC's process is more careful, courts are more prepared to defer. See, e.g., *In re I.H.V.*, [2008] A.B.Q.B. 250, ¶ 31 (Can. Ct. Q.B.), available at <http://www.albertacourts.ab.ca/jdb/2003-qb/civil/2008/2008abqb0250.pdf> ("I am not satisfied that we as judges should be replacing our opinion with that of the medical community that has obtained extensive unbiased third party analysis, including opinions from medical ethicists . . . not associated with this health region . . .").

236. See Len Doyal, *Clinical Ethics Committees and the Formulation of Health Care Policy*, J. MED. ETHICS, Apr. 2001, at i44, i44 ("In North America, CECs have . . . become an integral part of the organizational infrastructure . . ."); Marshall B. Kapp, *Handbook for Health Care Ethics Committees*, 9 CARE MANAGEMENT J. 38, 38 (2008) ("[T]he IEC device has become a common and valuable fixture throughout the current American healthcare enterprise . . . . [F]ormal resort to the judicial system for a legally definitive adjudication is very rarely desirable from anyone's perspective."); Wilson, *supra* note 67, at 173 ("HECs have become a fixture . . ."); Wilson & Gallegos, *supra* note 48, at 357 ("[H]ospital ethics committees are so ingrained in American medicine . . .").

237. See, e.g., AMA CODE OF MEDICAL ETHICS § E-9.1115 (2001); Am. Med. Dir. Ass'n, Resolution D97: Ethics Committees in Nursing Homes, <http://www.amda.com/governance/resolutions/d97.cfm> (last visited Mar. 17, 2009).

238. See *supra* notes 30-40 and accompanying text.

239. See *supra* notes 41-44 and accompanying text.

240. Carrie Menkel-Meadow, *Why Hasn't the World Gotten to Yes? An Appreciation and Some Reflections*, 22 NEGOTIATION J. 485 (2006).

241. CAROLYNN M. RYAN, INTERNAL DISPUTE RESOLUTION 2 (1998); NORMAN DANIELS, JUST HEALTH CARE: MEETING HEALTH NEEDS FAIRLY 132 (2008) ("With a well-developed internal dispute resolution process, patients or clinicians adversely affected by decisions may be less inclined to seek the help of authorities . . . . Even if litigation

and faster than courts.<sup>242</sup> And committee members are usually concerned about the patient's welfare and familiar with the medical treatment context.<sup>243</sup> Consequently, many are urging an expanded role for HECs.<sup>244</sup>

Third, for ongoing ethical controversies such as "medical futility,"<sup>245</sup> HECs have been the most constructive mechanism yet devised.<sup>246</sup> Though the bioethics community cannot conclusively address the *substantive* issues raised by some treatment disputes, the HEC can at least address the *procedure* through which such conflicts are settled.<sup>247</sup>

So while HECs are riddled with problems relating to independence, composition, and resources, they should not be replaced, but improved upon.<sup>248</sup> Improvement does not mean stripping them of decision-making power, but helping them exercise that power bet-

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and legislation are pursued, however, the presence of a strong internal dispute resolution mechanism can lead to improved external deliberation." *But see* Wilson, *supra* note 67, at 172.

242. *See infra* notes 73 -85 and accompanying text.

243. Lynne, *supra* note 10, at 24.

244. Jorgensen, *supra* note 79, at 27 (arguing that, with respect to electroconvulsive therapy, HECs "could provide meaningful recommendations without the necessity of a judicial hearing" and "assume the role of hearing officers").

245. *See* Barbara Resnick, *Ethics and Medical Futility: The Healthcare Professional's Role*, in HIGHLIGHTS OF THE NATIONAL CONFERENCE OF GERONTOLOGICAL NURSE PRACTITIONERS 25TH ANNUAL MEETING (2006), available at <http://www.medscape.com/viewarticle/550278> ("Medical futility is described as proposed therapy that should not be performed because available data have shown that it will not improve the patient's medical condition.").

246. FRY-REVERE, *supra* note 160, at 11; MORENO, *supra* note 19, at 93-96 ("[HECs] promise a politically attractive way for moral controversies to be procedurally accommodated."); McCormick, *supra* note 103, at 152 ("[C]ommittees have been seen as appropriate vehicles to achieve a livable policy—to permit yet to control [sterilization]."); RODMAN ET AL., *supra* note 155, at 182 ("[A]bortion committees clearly served a purpose for hospitals and physicians in a situation where little consensus could be achieved . . . .").

247. *See* NORMAN DANIELS & JAMES E. SABIN, SETTING LIMITS FAIRLY 4 (2002) ("When we lack consensus on principles . . . we may nevertheless find a process or procedure that most can accept as fair to those who are affected by such decisions."); Thaddeus Mason Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 71 TENN. L. REV. 1, 68-69, 79-80 (2007).

248. Hoffmann, *supra* note 30, at 761 n.93 ("This article . . . assumes that these committees have the potential to work well and provide some benefit to their users."); Wolf, *supra* note 142, at 93 ("Instead of offering the more radical proposal to move case review out of the institution . . . my proposal pursues a middle course . . . . In matters of health care the fox always guards the chicken coop . . . .").

ter.<sup>249</sup> Specifically, form must follow function.<sup>250</sup> Since the *function* of HECs has evolved from one of merely advising on, clarifying, and facilitating decision making to one of actually making the decisions, the *form* of HECs must evolve as well.<sup>251</sup>

### III. THE MULTI-INSTITUTIONAL ETHICS COMMITTEE

I contend that the corruption, bias, disparate expertise, and procedural problems associated with intramural committees are largely a byproduct of their intramural character. In Part IV, I will explain how a multi-institutional ethics committee (MI-HEC) can substantially overcome these four problems. But first, in this Part, I describe the nature and prevalence of MI-HECs.

There are four basic types of MI-HECs. First, some take the form of regional networks of ethics committees—the network model. These committees operate like professional associations, serving as an educational resource for their intramural HEC members. Second, some institutions follow an extramural model. Institutions that are either unable or unwilling to form their own intramural HEC may instead contract with another (usually larger academic) facility to provide those services. Third, some hospitals retain their own intramural HECs but also join with a multi-institutional committee that serves in a quasi-appellate capacity in particularly difficult cases. Finally, some healthcare institutions join together to create a shared multi-institutional committee that they use *instead of* their own intramural HECs.<sup>252</sup>

#### A. *The Network Model*

Intramural HEC members may feel a sense of isolation and a desire to meet with members of other committees to share experiences and to provide encouragement.<sup>253</sup> To meet this need and to help insti-

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249. Cf. McCormick, *supra* note 103, at 153 (“Because these committees are here to stay and are worthwhile, we should face their problems and objections unflinchingly and in their strongest form.”).

250. Cf. IVAR HOLM, *IDEAS AND BELIEFS IN ARCHITECTURE AND INDUSTRIAL DESIGN* 160 (2006); PHILLIP STEADMAN, *THE EVOLUTION OF DESIGNS: BIOLOGICAL ANALOGY IN ARCHITECTURE AND THE APPLIED ARTS* 56, 183 (rev. ed. 2008).

251. Cf. Robertson, *supra* note 116, at 89.

252. See Miller, *supra* note 51, at 207 (describing the “informal, curbside discussion amongst colleagues from different institutions”).

253. See Michael Parker, *The Development of Clinical Ethics Support in the United Kingdom*, 18 NOTIZIE DI POLITEIA 82, 82 (2002).

tutions develop new HECs, many HEC member networks have been established.

Across the United States a number of regional ethics committee networks serve many HEC members.<sup>254</sup> Particularly active among these are (i) the Kansas City Area Ethics Committee Consortium,<sup>255</sup> (ii) the West Virginia Network of Ethics Committees,<sup>256</sup> (iii) the Maryland Healthcare Ethics Committee Network,<sup>257</sup> (iv) the New Hamp-

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254. See Anita Tarzian et al., *The Role of Healthcare Ethics Committee Networks in Shaping Healthcare Policy and Practices*, 18 HEC FORUM 85 (2006). See, e.g., Howard Brody et al., *Medical Ethics Resource Network of Michigan*, 3 CAMBRIDGE Q. HEALTH CARE ETHICS 271 (1992); Patrick M. Dunn, *The Health Ethics Network of Oregon: A Model To Enhance Healthcare Ethics Committee Collaboration*, 4 HEC FORUM 135 (1992); Christopher, *supra* note 47; Fletcher & Hoffmann, *supra* note 17, at 337 nn.38-40; Thomasine Kushner, *Networks Across America*, HASTINGS CENTER REP., Jan.-Feb. 1989, at 24; S. Mass, *Orange County Bioethics Network*, 2 CAMBRIDGE Q. HEALTH CARE ETHICS 109 (1993); B. Minogue, *The Bioethics Network of Ohio (BENO)*, 2 CAMBRIDGE Q. HEALTH CARE ETHICS 107 (1993); T. Sagin, *The Philadelphia Story*, HASTINGS CENTER REP., Jan.-Feb. 1989, at 24; Geoffrey D. Seidel, *Assessing the Need for Bioethics Networks*, 96 PA. MED. 16 (1993); Edward M. Spencer et al., *Ethics Programs at Community Hospitals in Virginia*, 119 VA. MED. Q. 178 (1992); Jay M. Baruch, *What Is the Ocean State Ethics Network?*, [http://www.brown.edu/Departments/Center\\_for\\_Biomedical\\_Ethics/whatis.html](http://www.brown.edu/Departments/Center_for_Biomedical_Ethics/whatis.html) (last visited Mar. 17, 2009) ("there was a need for a collaborative forum" because HECs in Rhode Island were "functioning at varying degrees of sophistication"); Greater Dayton Area Hosp. Ass'n Ethics Consortium, <http://gdaha.org> (last visited Mar. 30, 2009); N. Tex. Bioethics Network, <http://www3.utsouthwestern.edu/ethics/NorthTexasBiomedicalEthicsNetwork.htm> (last visited Mar. 17, 2009). It seems reports of the death of ethics committee networks have been greatly exaggerated. See, e.g., Arthur R. Derse, *Whither Ethics Committee Networks?*, HASTINGS CENTER REP., May-June 1997, at 47.

255. Ctr. for Practical Bioethics, Kansas City Area Ethics Committee Consortium, <http://www.practicalbioethics.org/cpb.aspx?pgID=936> (last visited Mar. 30, 2009) ("[T]he consortium is the largest and longest operating network of its kind in the nation.").

256. W. Va. Univ., West Virginia Network of Ethics Committees, <http://www.hsc.wvu.edu/chel/wvnec> (last visited Mar. 30, 2009) ("[T]he WVNEC is considered to be one of the largest and most successful ethics committee networks."); A.H. Moss, *West Virginia Network of Ethics Committees*, 2 CAMBRIDGE Q. HEALTHCARE ETHICS 108 (1993).

257. Univ. of Md. Sch. Law, Maryland Healthcare Ethics Committee Network, <http://www.law.umaryland.edu/programs/health/mhecnc/index.html> (last visited Mar. 30, 2009).



shire-Vermont Hospital Ethics Committee Network,<sup>258</sup> and (v) the University of Pittsburgh Consortium Ethics Program.<sup>259</sup>

Ethics committee networks primarily provide educational materials and model policies for their member committees.<sup>260</sup> They hold conferences and distribute materials such as newsletters and videos.<sup>261</sup> Some networks provide an even more “integrated and continuous educational program.”<sup>262</sup> In this fashion, a network may enhance the informational and educational resources of its member HECs. The network enables its constituent HECs to better serve their parent institutions, but in so doing it “never supplants” these committees.<sup>263</sup> The individual committee members “retain an autonomous identity within their institutions.”<sup>264</sup>

Networks help intramural HECs address their resource deficiencies and training problems.<sup>265</sup> But networks do not directly address such committees’ independence and composition problems.<sup>266</sup> Moreover, unlike the extramural, quasi-appellate, and joint MI-HEC models, the network model does not engage its constituents with specific cases from member institutions. Consequently, the network model holds comparatively less promise for overcoming the problems of the intramural HEC.<sup>267</sup>

258. Dartmouth-Hitchcock Med. Ctr., Ethics Committee: What We Do, [http://www.dhmc.org/webpage.cfm?org\\_id=512](http://www.dhmc.org/webpage.cfm?org_id=512) (follow “What We Do” hyperlink) (last visited Mar. 26, 2009) (explaining the Ethics Committee represents the HECs of 40 hospitals and other healthcare centers).

259. Unive. of Pittsburgh, Consortium Ethics Program, <http://www.pitt.edu/~cep/> (last visited Mar. 30, 2009).

260. Hoffmann & Tarzian, *supra* note 46, at 50; Miller, *supra* note 51, at 206-07; Nelson, *supra* note 193, at 32; Tarzian et al., *supra* note 254, at 86.

261. *See* sources cited *supra* note 260.

262. Rosa Lynn Pinkus, *The Consortium Ethics Program: An Approach to Establishing a Permanent Regional Ethics Network*, 7 HEC FORUM 13, 14 (1995).

263. Niemira et al., *supra* note 201, at 77.

264. *Id.* Confusingly, some networks, like the Sonoma County Bioethics Network, are referred to as “joint ethics committees.” *See* Texas DADS, *supra* note 173.

265. *See* Greg S. Loeben, *Networking Health Care Ethics Committees: Benefits and Obstacles*, 11 HEC FORUM 226, 227-28 (1999) (“[T]he benefits of HEC networking [include] . . . educational materials and methods . . . policy standardization . . . [and] exposure to problems that other institutions are currently facing, but which have not yet surfaces at one’s own institution.”).

266. *See* Ken S. Meece, *Long-Term Care Bioethics Committees: A Cooperative Model*, 2 HEC FORUM 127, 130 (1990) (envisioning teams “educated jointly” but “meeting individually for consultation on individual cases” such that “[t]he cooperative would only be an educational and policy-review center”).

267. Networks are also useful for non-institutional HECs. For example, in 1993, independent IRBs formed the Consortium of Independent IRBs (CIRB), to provide a

## B. The Extramural Model

Large hospitals and academic medical centers are likely to have a functioning HEC.<sup>268</sup> Conversely, small hospitals<sup>269</sup> and other facilities like nursing homes and dialysis centers are less likely to have an HEC.<sup>270</sup> It may be quite challenging for small institutions, lacking sufficient resources and organizational experience, to form an intramural committee or to work “horizontally” to form a joint—also known as “shared”—committee.<sup>271</sup>

It is often easier for these institutions to work “vertically,” allowing “a recognized ethics center, tertiary care hospital, or state medical society [to] provide the initial leadership.”<sup>272</sup> Indeed, the Joint

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central discussion area concerning public policies and issues. See Heath, *supra* note 131.

268. See Am. Med. Dir. Ass’n, *supra* note 256 (“Smaller facilities may not have the personnel or the volume to maintain an ethics committee.”); Fox et al., *supra* note 59, at 15; Hoffmann Study, *infra* note 47, at 116 (“[L]arge hospitals . . . and teaching hospitals are more likely to have ethics committees than small non-teaching hospitals.”); Gonsoulin, *supra* note 46, at 331-32; Hoffmann, *supra* note 30, at 757 n.70.

269. See *Ethics and Rural Healthcare*, *supra* note 161, at 52; Cook & Hoas, *supra* note 45. See also Hoffmann, *supra* note 30, at 762.

270. See Meece, *supra* note 266, at 127; *How Regional Long-Term Care Ethics Committees Improve End-of-Life Care*, STATE INITIATIVES IN END-OF-LIFE CARE, Jan. 2000, at 1, 1 [hereinafter STATE INITIATIVES] (“Although nursing homes and other long-term care facilities are regularly confronted with wrenching bioethical dilemmas, few have the resources to establish real, in-house ethics committees.”); Am. Med. Dir. Ass’n, *The Role of a Facility Ethics Committee in Decision-Making at the End of Life*, <http://amda.com/governance/whitepapers/ethicscommittee.cfm> (last visited Jan. 18, 2009); Univ. of Fla. Coll. of Med., *Clinical Ethics and Organizational Ethics Consultation Services for Hospitals & Nursing Homes*, [http://chfm.ufl.edu/programs/blmp/blmp\\_consult.shtml](http://chfm.ufl.edu/programs/blmp/blmp_consult.shtml) (last visited Mar. 17, 2009) (“For many hospitals it is simply not cost-effective to maintain an active ethics committee . . . .”); Patricia L. Spath, *What’s Your Complaint Policy*, 6 RADIOLOGY TODAY, Feb. 21, 2005, at 26 (“Smaller facilities may not have the same resources to devote to handling grievances as larger facilities . . . .”). But see Christine M. Weston et al., *The NJ SEED Project: Evaluation of an Innovative Initiative for Ethics Training in Nursing Homes*, 6 J. Am. Med. Directors 68, 71 (2005) (reporting that twenty-seven percent of LTC facilities had an intramural HEC).

271. See Niemira et al., *supra* note 201, at 78-79; Univ. of Fla. Coll. of Med., *supra* note 270 (“For many hospitals it is simply not cost effective to maintain an active ethics committee which meets Joint Commission requirements.”).

272. Niemira et al., *supra* note 201, at 78-79. See Patricia Angelucci, *Ethics Guidance Through Committees*, Nursing Mgmt., June 2007, at 30, 33 (“[C]onsider connecting with institutions of higher learning . . . . [C]ommittees partner with other facilities that have an ethics committee in place . . . .”); HOSFORD, *supra* note 10, at 116 (“[A] small institution . . . representative could attend meetings of a larger one’s bioethics committee, in lieu of having their own.”).

Commission specifically suggested using such outsourcing relationships as a way to satisfy its accreditation standards' ethics mechanism requirement: "Patient rights mechanisms may include a variety of implementation strategies [including] 24-hour access to an external consulting service . . . [or] access to the ethics service of a large medical center in a neighboring town."<sup>273</sup>

A typical extramural MI-HEC entails the smaller facility outsourcing its ethics committee work to the larger facility.<sup>274</sup> The larger facility has resources and experience that the smaller facility could not sustain on its own. Some large institutions have recognized the smaller facilities' need, and have created extramural services suited to serving the smaller institutions. For example, the Wake Forest University Medical Center, recognizing its "importance" to the region, anticipates that its Bioethics Committee will assist "other organizations including some smaller hospitals."<sup>275</sup>

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273. JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGANS., 1994 MANUAL FOR HOSPITALS 10 (1994). Again, there are earlier models for such structures. For example, in the 1950s, the work of Marin General Hospital's therapeutic abortion committee became "accepted so widely that the other three hospitals of the [San Rafael] community now refer all their applications for therapeutic abortion to this committee for review—a most unusual arrangement." Howard Harmond, *Therapeutic Abortion: Ten Years Experience with Hospital Committee Control*, 89 AM. J. OBSTETRICS & GYNECOLOGY 349, 350-51 (1964).

274. See Am. Med. Dir's. Ass'n, *supra* note 256 ("Other options for smaller facilities may include collaboration with . . . local hospital ethics committees"); Texas DADS, *supra* note 173 ("A [long-term care] facility can utilize an external ethics committee (i.e., one that is in a hospital, is community-wide, or part of another [long-term care] facility . . ."); Nelson, *supra* note 193, at 32.

275. Wake Forest University Health Sciences, *Main Ethics Committee By-Laws & Procedures*, <http://www1.wfubmc.edu/bioethics/CommitteeStructure/>. See also University of Pennsylvania Center for Bioethics Mediation Service ("Specific applications at your institution: Using the Service as an alternative or complement to existing ethics mechanisms.") ("For institutions without existing ethics mechanisms, our Service can provide a complete program."). See Jane N. Bolin et al., *An Alternative Strategy for Resolving Ethical Dilemmas in Rural Healthcare*, AM. J. BIOETHICS, Apr. 2008, at 63 (describing program run by Texas A&M Health Science Center); Cleveland Clinic, Bioethics Department, <http://my.clevelandclinic.org/bioethics/default.aspx> (last visited May 4, 2009) ("External agencies [may] request a formal analysis or recommendation about a case."); Columbus Cmty. Hospital, Ethics Committee, <http://www.cch-inc.com/internet/home/columbus.nsf/documents/ethics+committee> (last visited May 4, 2009) ("The committee . . . addresses relevant issues to the hospital, the nursing home, and the community."); Dartmouth Hitchcock Medical Center, Ethics Committee, [http://www.dhmc.org/webpage.cfm?site\\_id=2&org\\_id=512&morg\\_id=0&sec\\_id=0&rgsec\\_id=25602&item\\_id=25602](http://www.dhmc.org/webpage.cfm?site_id=2&org_id=512&morg_id=0&sec_id=0&rgsec_id=25602&item_id=25602) (last visited May 4, 2009) ("The DHMC Bioethics Advisory Committee will consider providing advice if requested by staff of community hospitals and nursing homes."); Med. College of Wis., Services, <http://>

Statutes in Florida, Colorado, and Maryland specifically anticipate that one healthcare facility might use another healthcare facility's HEC.<sup>276</sup> For example, when a guardian in Florida wants to withdraw life-sustaining treatment from a patient, that decision must be confirmed by the HEC.<sup>277</sup> If there is no HEC at the facility, then "the facility must have an arrangement with the medical ethics committee of another facility or with a community-based ethics committee approved by the Florida Bio-ethics Network."<sup>278</sup>

More recently, extramural HECs have been provided not only by another (larger) institution's HEC but also by an academic unit or by an independent organization formed specifically to provide such services.<sup>279</sup> For example, Kansas Health Ethics, Inc. offers consultation services on a sliding fee scale to help resolve healthcare ethics dilem-

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[www.mcw.edu/populationhealth/Services.htm](http://www.mcw.edu/populationhealth/Services.htm) (last visited May 4, 2009) ("The Center for the Study of Bioethics has established and staffs a clinical consultation service for hospitals and health care institutions in the Milwaukee area.").

276. See, e.g., COLO. REV. STAT. § 15-18.5-103(6.5) (2008) ("If there is no medical ethics committee for a health care facility, such facility may provide an outside referral for such assistance or consultation."); FLA. STAT. ANN. § 765.404(2) (2008); MD. CODE ANN., HEALTH-GEN § 19-371(b)(2) (LexisNexis 2008) ("An advisory committee at a related institution may function jointly with a hospital advisory committee.").

277. See FLA. STAT. ANN. § 765.404(2) (2008).

278. *Id.* The University of Florida offers such a service. See Univ. of Fla. Coll. of Med., *supra* note 270. Similarly, Maryland law anticipates that a nursing home ethics committee might function "[j]ointly with a hospital advisory committee." MD. CODE ANN., HEALTH-GEN § 19-371(b).

279. See, e.g., Hamel, *supra* note 61, at 22 n.3 ("Some systems and facilities employ the part-time services of an ethicist who is generally based in a bioethics center or university."); Loras Coll. Bioethics Res. Ctr., Comprehensive Report 1987-2000, <http://www2.loras.edu/~CatholicHE/report.html> (last visited Mar. 17, 2009) ("[The Center] provides consulting services to health care facilities and professionals."); Denver Cmty. Bioethics Comm., <http://www.denverbioethics.org> (last visited Mar. 17, 2009) ("Any individual or institution in the state may present a case to the DCBC."); Ctr. for Health Ethics, Univ. of Mo., Tele-Ethics Consultation Servs., [http://hmi.missouri.edu/ethics/telethics\\_consultation.htm](http://hmi.missouri.edu/ethics/telethics_consultation.htm) (last visited Mar. 17, 2009); MO. LONG-TERM CARE OMBUDSMAN PROGRAM & CTR. FOR PRACTICAL BIOETHICS, LONG-TERM CARE ETHICS CASE CONSULTATION, <http://www.dhss.mo.gov/Ombudsman/LTCCaseConsultation.pdf> (last visited May 4, 2009) (providing a free, neutral, and confidential "mediation service"); St. Louis Univ. Dep't of Health Care Ethics, Faculty Consultation Services, <http://hce.slu.edu/Consultation.html> (last visited Mar. 26, 2009); Markkula Ctr. for Applied Ethics, Santa Clara Univ., Mission, <http://scu.edu/ethics/practicing/focusareas/medical/oconnor/> (last visited Mar. 26, 2009); Vital Decisions, <http://www.vitaldecisions.net> (last visited Mar. 26, 2009) ("If necessary, counselors help with conflict resolution . . .").

mas.<sup>280</sup> Other organizations, such as the Health Priorities Group (formerly Bioethics Consultation Group)<sup>281</sup> and The Ethics Practice,<sup>282</sup> consult with healthcare institutions.<sup>283</sup> Bioethics Services of Virginia, Inc. operates in a similar way.<sup>284</sup> In addition, some HEC networks are planning to move beyond education to “serve as a resource for . . . mediation” in specific cases.<sup>285</sup>

In Ontario, the Consent and Capacity Board (the CCB) operates as an extramural ethics committee.<sup>286</sup> The CCB is a body created by the Ontario government under its Health Care Consent Act.<sup>287</sup> “When ‘in-house’ conflict resolution fails, [the] CCB can mediate. If this mediation fails, [the] CCB adjudicates . . . .”<sup>288</sup> The CCB is, in short, “an independent, quasi-judicial tribunal;” a “neutral, expert board” which, in intractable treatment disputes, can make a “legal, binding decision that can only be reversed on appeal through the courts.”<sup>289</sup>

Here again, the IRB provides guidance in our discussion of HECs. The extramural model is better developed in the research context for IRBs than in the clinical context for HECs. Indeed, over the past decade, there has been an exponential expansion of “independent” IRBs.<sup>290</sup>

280. Kan. Health Ethics, Inc., Ethics Consultation, <http://www.kansashealthethics.org/index.php?topic=ethicsComm> (last visited Mar. 17, 2009).

281. Health Priorities Group, Inc., Services, <http://bioethic.cust.he.net/services.htm> (last visited Mar. 30, 2008).

282. The Ethics Practice provides “clinical ethics consultation and education services to health care providers and health care systems nationally.” Soc’y for Women’s Health Res., About Us, [http://www.womenshealthresearch.org/site/PageServer?pagename=about\\_zoloth](http://www.womenshealthresearch.org/site/PageServer?pagename=about_zoloth) (last visited Mar. 17, 2009) (discussing cofounder of the Ethics Practice, Laurie Zoloth).

283. See, e.g., Dawn Dudley Oosterhoff & Mary Rowell, *Shared Leadership: The Freedom to Do Bioethics*, 16 HEC FORUM 297, 299, 307 (2004) (describing how southwestern Ontario had “consulting-for-fee contracts” and a joint committee); Cmty. Ethics Comm. for Skilled Nursing Facilities, Bioethics Law Project, <http://www.bioethicslawproject.com> (last visited Mar. 30, 2009).

284. Bioethical Servs. of Va., Inc., Services, <http://bsvinc.com/services.htm> (last visited Mar., 26 2009).

285. Baruch, *supra* note 254. See, e.g., Health Care Ethics Consortium of Ga., Membership, <http://www.hcecg.org/membership> (last visited Mar. 30, 2008).

286. Health Care Consent Act, S.O., ch. 2 (1996) (Can.), available at <http://www.canlii.org/on/laws/sta/1996c.2sch.a/20080821/whole.html>.

287. *Id.*

288. Mark Handelman & Bob Parke, *The Beneficial Role of a Judicial Process When “Everything” Is Too Much*, HEALTHCARE Q., Winter 2008, at 46, 48.

289. *Id.* at 50.

290. See INST. OF MED., PRESERVING THE PUBLIC TRUST 40 (2001); Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365, 404 (2005)

Independent IRBs review research proposals (to assure adequate protection of human subjects) for entities that are not affiliated with the IRB.<sup>291</sup> Oftentimes, much research is conducted by those in smaller facilities and physician's offices where the economy of scale precludes forming an IRB. Also, multi-center research is more efficiently reviewed by a single IRB than through duplicative review at each participating site.<sup>292</sup> Accordingly, institutions have developed new models of IRB review, which include schemes whereby one institution relies on the review of another institution's IRB, or whereby multiple institutions rely on the review of an independent IRB.<sup>293</sup>

In contrast to committees based on the network model, the extramural HEC engages with specific cases from member institutions. Since the decision maker is separate and independent from the facility in which the case arose, the extramural model offers promise for overcoming the corruption associated with intramural HECs. Moreover, with both a higher volume of cases and the incentive to maintain its member institution "customers," the extramural HEC can also achieve efficiencies of scale to overcome the intramural HEC's problems of bias, carelessness, and arbitrariness.

### C. *The Quasi-Appellate Model*

Just as ethics committees are a step removed from the medical treatment team, some have proposed what is effectively an ethics com-

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("[T]raditional IRBs are at times being replaced by a relatively new entity, the independent or for-profit IRB."). See, e.g., Chesapeake Res. Review, Inc., <http://www.chesapeakeirb.com> (last updated Mar. 30, 2009); Copernicus Group IRB, <http://copernicugroup.com> (last visited Mar. 30, 2009); Goodwyn IRB, <http://www.goodwynsirb.com> (last visited Mar. 30, 2009); New England IRB, Welcome to New England IRB, <http://www.neirb.com> (last visited Mar. 30, 2009); Quorum Review Inc., An Institutional Review Board, <http://www.quorumreview.com> (last visited Mar. 30, 2009); W. Inst. Review Bd., WIRB Mission, <http://www.wirb.com> (last visited Mar. 30, 2009) (representing the oldest and largest of these IRBs). IRBs, like HECs, have traditionally been intramural entities. And like HECs, IRBs are plagued with many of the same independence, composition, and training problems. See *supra* notes 130-136, 181, 206-208.

291. See Heath, *supra* note 131.

292. See 21 C.F.R. § 56.114 (2009) ("[I]nstitutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.").

293. See NAT'L INST. OF HEALTH ET AL., ALTERNATIVE MODELS OF IRB REVIEW: WORKSHOP SUMMARY REPORT 1 (2005), available at <http://www.hhs.gov/ohrp/sachrp/documents/AltModIRB.pdf>.

mittee for ethics committees.<sup>294</sup> Some hospitals retain their own internal ethics committee but join with others to form a separate, shared committee that hears only particularly complicated cases.<sup>295</sup> Each institution sends representatives to sit on a panel that serves all the member institutions. On this model, an ethics dispute first goes to the intramural HEC; but if it is not resolved intramurally, the case goes to the MI-HEC.<sup>296</sup>

Unaffiliated private hospitals have experimented with quasi-appellate HECs.<sup>297</sup> Several have been formed and implemented. For example, the Vancouver Island Health Authority formed a “regional ethics committee.” While there are five additional ethics committees in the VIHA, the regional committee “deals with issues that cross bounda-

294. See, e.g., DRANE, *supra* note 234, at 163 (“If conflict remains intractable and the decision preferred by the surrogate or patient conflicts with institutional policy, then the health care ethics committee should move the case to a more authoritative/regional committee . . . .”); George P. Smith, *Restructuring the Principle of Medical Futility*, J. PALLIATIVE CARE, Fall 1995, at 9 (proposing a three-tier decisional structure in which the third tier recognizes a right of limited appeal to the courts), available at <http://www.ncbi.nlm.nih.gov/pubmed/7472798>; Truog, *supra* note 100, at 2 (“Some have suggested setting up ad hoc ethics committees with a membership . . . without any financial or social ties to the hospitals they serve, specifically to offer a more legitimate sounding board for difficult cases in which the hospital ethics committee could be seen as having a conflict of interests or biased perspective.”).

295. Michelle Hey, *Shared Corporate Ethics Committee: Two Systems Collaborate to Enhance Ethical Decision Making*, HEALTH PROGRESS, Sept. 1994 (“Cincinnati-based Mercy Health System and Radnor, PA-based Eastern Mercy Health System have formed a Shared Corporate Ethics Committee (SCEC). . . . Local facilities will retain their own ethics committees but benefit from the [system] guidance of the shared committee.”). A quasi-appellate panel could also serve as an extramural committee. Cf. Email from Dr. David Fleming, University of Missouri Center for Health Ethics, to Thaddeus Mason Pope, Associate Professor of Law, Widener University School of Law (June 5, 2008) (on file with author) (“Most, if not all, of the outlying hospitals that we serve do have ethics committees, and we serve to support their efforts with the most difficult cases.”).

296. See Miller, *supra* note 51, at 210-13 (providing a flow chart illustrating the operation of what this Article refers to as the quasi-appellate model). See also KENNETH A. FISHER, IN DEFIANCE OF DEATH: EXPOSING THE REAL COSTS OF END-OF-LIFE CARE 30-31 (2008) (proposing a “three-tiered (local, state, and national) Appropriate Care Committee System”). But see Michael Bevins, *Review of “In Defiance of Death,”* 301 JAMA 108, 109 (2009) (“[T]he idea of appropriate care committees . . . is woefully underdeveloped . . . .”).

297. See Buchanan et al., *supra* note 217 (describing The Colorado Collective for Medical Decisions). See Scannell, *supra* note 111 (describing a proposal for the “creation of an independent organization composed of diverse community and professional representatives who would advise hospitals or help make decisions for their friendless incompetent patients”).

ries.”<sup>298</sup> Similarly, in Fort Wayne, Indiana, three separate institutions formed a “community ethics consensus panel”<sup>299</sup> to handle disputes that could not be resolved by any of the single institutions’ intramural HECs. Today, each institution sends three of its own representatives to serve on the panel. These are joined by a local philosophy professor and a local attorney.<sup>300</sup> The panel provides another level of review when a given conflict cannot be resolved internally.<sup>301</sup>

Perhaps the most notable example of the quasi-appellate model is found in the Veterans Health Administration (VHA). Each VHA facility has its own ethics committee.<sup>302</sup> But there is also a central, national ethics committee available to provide consultation to “field-based ethics programs on request.”<sup>303</sup> However, unlike the Fort Wayne MI-HEC, the VHA central committee only *advises*—it does not approve or reject recommendations or decisions made by individual HECs.

As with the extramural model, the quasi-appellate model has analogues in the U.S. research context. For example, when reviewing proposed research on “vulnerable populations,” a local IRB must seek a second level of review.<sup>304</sup> Similarly, in New Zealand, the 1990 Research Council Act established the Health Research Council Ethics Committee: a national ethics committee “to review the independent

298. Vancouver Island Health Authority, Committees, <http://www.viha.ca/ethics/committees> (last visited Mar. 30, 2009).

299. Lauren Phillips, *A Question of Ethics*, TRUSTEE, Feb. 1997, at 27; Lynne McKenna Frazier, *Panel to Hear Rifts About Life Support*, FT. WAYNE NEWS-SENTINEL, Dec. 14, 1996, at 1A.

300. See sources cited *supra* note 299.

301. Phillips, *supra* note 299. See Denver Cmty. Bioethics Comm., *supra* note 279 (“The DCBC can also serve as a resource to other institutional ethics committees, providing ‘second opinions’ and additional review of cases.”); Univ. of Fla. Coll. of Med., *supra* note 270 (“Even hospitals which maintain an ethics committee may benefit from the consultation services we offer . . .”).

302. U.S. DEP’T OF VETERAN AFFAIRS, ETHICS CONSULTATION, <http://www.ethics.va.gov/activities/consult.asp> (last visited Apr. 2, 2009).

303. *Id.*

304. See AM. ASSOC. OF MED. COLLEGES, TASK FORCE ON FINANCIAL CONFLICTS OF INTEREST IN CLINICAL RESEARCH (2001) (“When the ICOI has determined that compelling circumstances exist . . . the institution should consider the desirability of contracting with an external IRB to provide a second level of review.”). Cf. Standards for Institutional Review Boards for Clinical Investigators, 43 Fed. Reg. 35,186 (Aug. 8, 1978), available at <http://www.hhs.gov/ohrp/documents/19780808.pdf> (permitting the creation of an “appellate IRB”).



ethical assessment made . . . by an approved ethics committee.”<sup>305</sup> While this committee currently provides only “nonbinding second opinions,” New Zealand’s Minister of Health is “attempting to establish an appellate committee.”<sup>306</sup>

#### D. The Joint Committee Model

While a quasi-appellate HEC serves member institutions so that each still retains its own intramural HEC, a joint committee serves institutions that do *not* have their own internal ethics committee. On this model, the joint (or “shared”) committee is the *principal* ethics forum for its participating institutions,<sup>307</sup> each of which sends representatives to form the joint committee.<sup>308</sup> These are also referred to as “regional,” “municipal,” “cooperative,” “inter-institutional,” and “community” ethics committees. Institutions form joint committees for one of two basic reasons: either they cannot form an intramural HEC of their own, or it would be more convenient to use a joint committee.

##### 1. Joint Committees for Institutions Unable to Form Their Own Intramural HECs

Healthcare facilities such as freestanding dialysis clinics, nursing homes, and rural hospitals are unlikely to have their own intramural HECs, as they are too thinly staffed.<sup>309</sup> To address this problem, the American Medical Association advises healthcare facilities lacking ethics committees to “develop flexible, efficient mechanisms of ethics review that divide the burden of committee functioning among collaborating health care facilities.”<sup>310</sup>

305. Health Research Council Act of 1990, 1990 S.N.Z. No. 25, available at [http://www.hrc.govt.nz/root/pages\\_policy/HRC\\_Ethics\\_Committee\\_Terms\\_of\\_Reference.html](http://www.hrc.govt.nz/root/pages_policy/HRC_Ethics_Committee_Terms_of_Reference.html).

306. Tim Dare, *Ethical Review of Research in New Zealand*, ETHICS NOTES, Oct. 2008, at 1, available at <http://www.hrc.govt.nz/assets/pdfs/HRC%20Ethics%20Notes%20FINAL%20221008.pdf>.

307. Nelson, *supra* note 193.

308. *Id.*, at 33 (“Each participating facility would identify one or two professionals to serve on the committee . . . .”); Niemira et al., *supra* note 201, at 78. See MD: CODE ANN., HEALTH-GEN. § 19-372(a)(1)(iv) (LexisNexis 2005) (“Each advisory committee shall . . . [include] the chief executive officer or a designee from each hospital and each related institution represented on that advisory committee.”).

309. See *supra* notes 269-271.

310. AMA CODE OF MEDICAL ETHICS § E-9.1115 (2001). See also Am. Med. Dir. Ass’n, *supra* note 256 (“Other options for smaller facilities may include collaboration with other nursing homes . . . .”); HOSFORD, *supra* note 10, at 116 (“[R]epresentatives of several institutions in a town or small city could associate in a joint bioethics committee.”); Levine, *supra* note 6, at 11 (“[S]everal such . . . small

Similarly, Maryland encourages non-hospital institutions to operate joint committees.<sup>311</sup> A 1990 statute specifically anticipates that a nursing home ethics committee may function “jointly with an advisory committee representing no more than 30 other related institutions.”<sup>312</sup> Pursuant to this statute, the Health Facilities Association helped establish eight joint committees, each composed of four to six facilities.<sup>313</sup>

Other cooperative regional ethics committees have been created for institutions unable to create an HEC individually.<sup>314</sup> For example, the National Kidney Foundation of Kansas and Western Missouri and the Center for Practical Bioethics created a “standing ethics committee” that functions to provide “individual consultations,” among other services.<sup>315</sup> Similarly, the Dubuque Regional Healthcare Ethics Committee established “a service for facilities and agencies in the tri-state area[,] [Iowa, Wisconsin, and Illinois,] which do not have their own ethics committee.”<sup>316</sup>

Perhaps most impressive is the even broader system of joint committees established in New Jersey. While New Jersey licensing regulations require that long-term care facilities have access to a dispute

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community . . . hospitals might together form a committee . . .”). Similarly, CMS recommends that small hospitals satisfy their “utilization review committee” requirement by having the committee “established by the local medical society and some or all of the hospitals in the locality.” 42 C.F.R. § 482.30(b)(1)(ii) (2008).

311. MD. CODE ANN., HEALTH-GEN. § 19-371(b)(3). See also 45 C.F.R. § 84.55(f)(1)(i) (2008) (“The hospital establishes an Infant Care Review Committee (ICRC) or joins with one or more other hospitals to create a joint ICRC.”); 25 TEX. ADMIN. CODE § 405.60(a) (2009) (“The committee may be established multi-institutionally in cooperation with other health care providers, e.g. local hospitals serving the same geographic area.”).

312. MD. CODE ANN., HEALTH-GEN. § 19-371(b).

313. Texas DADS, *supra* note 173 (observing that the institutions which formed the Maryland HEC network “reported that the network helped them gain confidence in making ethical decisions and improving working relationships with their peers”).

314. Heitman, *supra* note 23, at 43.

315. Eugene C. Grochowski & Erika Blacksher, *Collaborative Ethics: A Standing Renal Dialysis Ethics Committee*, 7 *ADVANCES IN RENAL REPLACEMENT THERAPY* 355, 355 (2000). While the standing ethics committee in Kansas City is the only healthcare ethics committee among the fifty-two National Kidney Foundation affiliates, others could be “linked together under the national umbrella.” *Id.* at 357. While the committee may not have actually done much consultation, it was certainly positioned to do so. See Email from Terrence Rosell, Professor of Pastoral Theology and Ethics, to Thaddeus Mason Pope, Associate Professor of Law, Widener University School of Law (May 9, 2008) (on file with author).

316. Loras Coll. Bioethics Res. Ctr., *supra* note 279. See also IOWA ADMIN. CODE r. 641-85.3(2) (2008) (allowing the formation of “multi-county local substitute medical decision-making boards”).

resolution forum like an ethics committee, the “[s]taff of long-term care facilities often do not have the knowledge and experience to address complex ethical issues.”<sup>317</sup> So, starting in 1996, under the direction of the Office of the Ombudsman for the Institutionalized Elderly, New Jersey formed and trained a statewide network of fifteen “Regional Long Term Care Ethics Committees” to serve the state’s nearly 400 long-term care facilities.<sup>318</sup> Many of these regional committees consult on a regular basis.<sup>319</sup>

## 2. Joint Committees for Convenience

While the most common motivation for joint ethics committees is necessity, some are formed for convenience. For example, in Chico, California, healthcare providers formed a joint committee serving both the Enloe and Chico Community Hospitals.<sup>320</sup> Since most physicians had staff privileges at both institutions, the creation of this joint committee was likely motivated by institutional distaste for duplication of effort.

Again, there is an analogy in the research context.<sup>321</sup> Centers engaged in multi-site research sometimes form a consortium by which each agrees to accept review by any other participating institution’s

317. Robert Wood Johnson Found., *A Moral Compass in Navigating Long-Term Care Decisions in New Jersey* (Mar. 2005), <http://www.rwjf.org/reports/grr/035786.htm>.

318. *See id.*; STATE OF N.J. OFFICE OF THE OMBUDSMAN FOR THE INSTITUTIONALIZED ELDERLY, 2006 ANNUAL REPORT 10 (2006), available at <http://www.state.nj.us/publicadvocate/home/reports/pdfs/elderlyombudsmanreport.pdf>. The facilities in each region share a committee, and the committees themselves are linked to the New Jersey Long Term Care Ethics Consortium, which is a forum for “legislative update, . . . continuing ethics education, peer support, and retrospective case review.” Robert Wood Johnson Found., *supra* note 317.

319. STATE INITIATIVES, *supra* note 270, at 2. *See, e.g.*, Ocean County Ethics Comm., <http://oceancountyethics.com> (last visited Mar. 18, 2009); Tri-County Reg’l Ethics Comm., Home, <http://njtrec.org> (last visited Mar. 18, 2009). Indeed, the New Jersey project proved so successful that the project director formed a nonprofit corporation, ElderCare Ethics Associates, to aid other geographic regions in developing similar initiatives. Linda A. O’Brien, *Establishing and Educating a Long-Term Care Regional Ethics Committee: The NJ Model*, 6 J. AM. MED. DIRECTORS ASS’N. 66, 67 (2005).

320. *See* Email from Becky White, Professor of Philosophy California State University, Chico, to Thaddeus Mason Pope, Associate Professor of Law, Widener University School of Law (May 5, 1998) (on file with author). There were four outside members and other members unique to each hospital; the larger of the two hospitals subsequently purchased the smaller.

321. *Cf.* Paul Herbert & Raphael Saginor, *Research Ethics Boards: Do It Once and Do It Well*, CAN. MED. ASS’N J. 597 (2009) (describing increased “centralized ethics review” at the “regional level” and observing: “If all of Europe is collaborating . . . [w]e need to

IRB.<sup>322</sup> Notable examples include the Biomedical Research Alliance of New York,<sup>323</sup> the Multicenter Academic Clinical Research Organization,<sup>324</sup> and the Michigan State University Community Research IRB.<sup>325</sup>

It is important to distinguish one type of joint committee. Often committees that are part of the same corporate health entity may establish committees that serve more than one facility. For example, the Pittsburgh Mercy Health System HEC in Pittsburgh serves three hospitals.<sup>326</sup> There are many other examples.<sup>327</sup> But it is unlikely that the joint committees of entity-related institutions achieve the same degree of independence as the joint committees of unaffiliated institutions.

Since some facilities lack the resources to support an intramural HEC, a quasi-appellate MI-HEC is not a realistic option. For these institutions, the joint MI-HEC model offers the best promise for overcoming problems with the intramural HEC.

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overhaul the ethics review system from an autonomous local review committee process into an interdependent collaboration of local committees.”).

322. Meeker-O’Connell, *supra* note 139.

323. Biomedical Research Alliance of N.Y., Home, <http://www.brany.com> (last visited Mar. 30, 2009)

324. Multicenter Academic Clinical Research Org., <http://www.med.upenn.edu/ohr/aboutmacro.html> (last visited Mar. 30, 2009).

325. Mich. State Univ. Human Research Protection Plan, Research and Creative Endeavor, <http://hr.msu.edu/HRsite/Documents/Faculty/Handbooks/Faculty/ResearchCreativeEndeavor/vi-protection.htm> (last visited Mar. 30, 2009).

326. See Pittsburgh Mercy Health Sys., <http://www.pmhs.org> (last visited Mar. 18, 2009). See also Mercy Health Partners of Nw. Ohio, <http://www.ehealthconnection.com/regions/toledo> (last visited Mar. 18, 2009). Before merging into Catholic Health East, a Philadelphia and a Cincinnati hospital of Eastern Mercy Health System shared an ethics committee. Emails from Sister Patricia Forret to Thaddeus Mason Pope, Associate Professor of Law, Widener University School of Law (May 15 & 18, 2008) (on file with author).

327. E.g., Joanne Davidson, *Children’s Future Will Reap Reward of “Planting” Dinner*, DENVER POST, Apr. 7, 1996, at E07 (describing Dr. Maxine Glaz acting as co-chair of a six-hospital joint ethics committee); Hoffmann Study, *supra* note 47, at 107 (“In two cases, two hospitals shared the same committee . . .”); MedCentral Health Sys., Ethics at MedCentral Health System, <http://www.medcentral.org/default.cfm?id=123> (last visited Mar. 18, 2009) (discussing use of one HEC for a system of two hospitals and other facilities); see also Kendra Rosencrans, *God, Medicine, Money: Religious Secular Union Raises Ethical Issues*, DULUTH NEWS TRIB., Apr. 28, 1996, at 1A; Texas DADS, *supra* note 173 (“Mt. St. Vincent Nursing Home in Holyoke, Massachusetts established an ethics committee that served three LTC facilities . . . under the ownership of Sisters of Providence Health System.”); SMDC Health Sys., Patient Resources: Healthcare Directives, <http://www.smhc.org/patientresources/healthcaredirectives.htm> (last visited Jan. 18, 2009) (“All hospitals within the [System] have access to an ethics committee.”).

#### IV. THE MULTI-INSTITUTIONAL ETHICS COMMITTEE CAN MITIGATE THE PROBLEMS EXISTING IN INTRAMURAL HECs

While they cannot solve all the HEC's problems,<sup>328</sup> MI-HECs are an excellent first step, as they address many of the defects this Article has described above.<sup>329</sup> Indeed, their remedial effectiveness was forecasted by the Joint Commission.<sup>330</sup> Encouragingly, the multi-institutional model appears to be working to address similar problems with IRBs. Given the similarity between HECs and IRBs, MI-HECs should be able to replicate their research-field success in the healthcare ethics arena. We should, therefore, chart a course for HECs based on the prior (and current) voyage of IRBs.

##### A. MI-HECs Mitigate the Risk of Corrupt Decision Making

If a HEC decision maker's deliberation is distorted by pressure and biases, then the typical solution is to get another decision maker.<sup>331</sup> An MI-HEC is just such a source of independent evaluation. The MI-HEC will be less beholden to the peculiar social or professional

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328. Most significantly, HECs need additional procedural protections. See Wilson, *supra* note 67; Wilson, *supra* note 77; Wolf, *supra* note 142; Wolf 1991, *supra* note 47.

329. See *supra* Part II. (describing HEC problems); Thaddeus Mason Pope, *Multi-Institutional Ethics Committees: For Rural Hospitals, and Urban Ones Too*, AM. J. BIOETHICS, Apr. 2008, at 69, 69 (arguing that MI-HECs represent a promising starting point in committee resolution of bioethical conflicts, as they can "significantly ameliorate deficiencies regarding [HEC] resources, competence, and independence").

330. See Banerjee & Kuschner, *supra* note 2, at 143 ("Consideration should be given to an external reviewing mechanism for the oversight of HEC . . .").

331. See generally ABA MODEL CODE OF JUDICIAL CONDUCT (2008); JAMES SAMPLE ET AL., FAIR COURTS: SETTING RECUSAL STANDARDS (2008). Cf. E.P. McDERMOTT & A.E. BERKELEY, ADR IN THE WORKPLACE: CONCEPTS AND TECHNIQUES FOR HUMAN RESOURCE EXECUTIVES AND THEIR COUNSEL (1996) (arguing for bringing in more senior management because they can be more objective than lower-level management directly involved with workplace disputes); Katherine Van Wezel Stone, *Dispute Resolution in the Boundaryless Workplace*, 16 OHIO ST. J. ON DISP. RESOL. 467, 480-81 (2001) (describing the "new wave of in-house dispute resolution systems" as commonly utilizing "decision makers who are outside the employee's normal chain of command").

relationships in place at any single institution.<sup>332</sup> Indeed, sometimes an external HEC is sought specifically because of its independence.<sup>333</sup>

For example, there have been several medical futility cases in which the provider's decision about whether to accede to the surrogate's request for continued treatment was swayed by the family's money and influence.<sup>334</sup> In contrast, a MI-HEC would presumably be less willing to accede to an 86-year-old terminal cancer patient's request for surgery because he "was influential, well-known, and respected in the community."<sup>335</sup> Likewise, the MI-HEC might be more circumspect about denying "recommended vaccinations" to a prema-

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332. See SPIELMAN, *supra* note 85, at 192 (describing problems with in-house dispute resolution programs); Cho & Billings, *supra* note 101, at 157 (suggesting "independence from any single institution, i.e. regional or non-institutional review boards" to "minimize individual and institutional conflicts of interest"); Frazier, *supra* note 299, at A1 ("Airing a case before a community panel might help alleviate concerns that a hospital's recommendation that life support be removed is being made in its own self-interest . . ."); Glantz, *supra* note 134, at 133 ("One objective in encouraging diversity in the composition of committees, both IRBs and IECs, is to keep the committees honest."); Hoffmann, *supra* note 30, at 763 ("Less susceptible to the criticism that it is representing the interests of the institution rather than those of the patient"); *id.* at 785 (arguing that "includ[ing] members from outside the health care institution" having the committee "represent more than one institution" can help overcome the puppet problem); Kimberlee K. Kovatch, *Neonatology Life and Death Decisions: Can Mediation Help?*, 28 CAP. U. L. REV. 251 (2000) (recommending outside mediators); Smith et al., *supra* note 196, at 1274 ("A review committee with significant membership from outside the hospital where the patient in question has been admitted could potentially diminish institutional bias (or its appearance) . . ."); Schuppli & Fraser, *supra* note 146, at 297 ("Other possible solutions are to move to greater independence from the institution—for example by using a regional committee . . ."); Denver Cmty. Bioethics Comm., *supra* note 279 ("Because the DCBC is not attached to any particular institution . . . it offers objective, thoughtful consideration of tough issues.").

333. Before stopping its sale of ethics services for tax reasons, the University of Pennsylvania offered its mediation service as "truly independent." UNIV. OF PA. CTR. FOR BIOETHICS, MEDIATION SERVICE BROCHURE, [http://www.bioethics.upenn.edu/pdf/bioethics\\_mediation.pdf](http://www.bioethics.upenn.edu/pdf/bioethics_mediation.pdf) (last visited Mar. 17, 2009) [hereinafter UNIV. OF PA. BROCHURE]. The Center operated "as an interdisciplinary unit of the University of Pennsylvania School of Medicine with input from a Faculty Advisory Board of academic leaders and an External Advisory Board of key corporate and civic leaders." *Id.* Thus, if another Philadelphia-area hospital had referred a case to the University, its ethics committee would be substantially free from any incentive to appease the medical staff or administration of the referring hospital. *See id.*

334. *Ethics and Rural Healthcare*, *supra* note 161. *See id.* at 136 ("The costs associated with a complicated, un-insured case can compromise the health of an entire community.").

335. *Id.*

ture infant “because his less influential family lacked funds to pay for the procedure.”<sup>336</sup>

Since at least a majority of a MI-HEC’s members would come from institutions other than that of the healthcare provider in a given case, the MI-HEC would not be swayed by extra-ethical factors.<sup>337</sup> A major criticism of intramural HECs is that they cannot “procure an extra-institutional professional appraisal of the medical facts.”<sup>338</sup> But this needed detachment is precisely what the MI-HEC offers. A more diverse HEC better ensures a more unbiased, impartial review of the case.<sup>339</sup>

This is perhaps best illustrated by *In re Torres*.<sup>340</sup> Rudolfo Torres was a patient at the Hennepin County Medical Center. Mr. Torres

336. *Id.*

337. See Bolin *supra* note 275, at 65 (“The virtual ethics committee model allows . . . a neutral committee unlikely to be affected by small town politics.”); M. Fukuyama et al., *A Report on Small Team Clinical Ethics Consultation Programmes in Japan*, 34 J. MED. ETHICS 858 (2008) (“The consultation service offered by our project was . . . independent of any specific medical institution. There was no conflict of interest between the consultants and the clients, and thus we could freely provide candid advice.”); UNIV. OF PA. BROCHURE, *supra* note 333 (“Our Service is designed to avoid problems associated with traditional in-house ethics mechanisms [and] has a number of advantages: . . . [p]reservation of integrity [which] might [otherwise] be compromised . . . by powerful clinicians or hospital administrators [and] . . . [e]nhancement of integrity when the institution acknowledges and manages its potential, perceived, or actual conflicts of interest.”). The court in *In re Quinlan* anticipated that an HEC would “screen out” cases “which might be contaminated by less than worthy motivations of family or physician.” 355 A.2d 647, 669 (N.J. 1976). Similarly, a MI-HEC can screen out cases contaminated by less than worthy motivations of an intramural HEC. Notably, Israeli HECs established under the 1996 Patients Rights Act, which have decision making authority, require an independent chair. See N.S. Wenger et al., *Hospital Ethics Committees in Israel: Structure, Function, and Heterogeneity in the Setting of Statutory Ethics Committees*, 28 J. MED. ETHICS 177 (2002).

338. Wilson & Gallegos, *supra* note 48, at 379.

339. Arthur Caplan, *Comment*, in CRANFORD & DOUDERA, *supra* note 7; Jaffe, *supra* note 11, at 428.

340. 357 N.W.2d 332 (Minn. 1984). There are other, more current examples. Since 1985, New York has authorized the operation of Surrogate Decision-Making Committees to make treatment decisions for unbefriended patients with mental disabilities. Clarence J. Sundram et al., *The First Ten Years of New York’s Surrogate Decision-Making Law: History of Development*, in REPRESENTING PEOPLE WITH DISABILITIES (Patricia W. Johnson et al. eds., 3d ed. 2007). The SDMCs, which have handled over 15,000 cases, consist of twelve volunteers, including a health care professional, an attorney, a family member or former client, and an advocate for persons with mental disabilities. *Id.* See *Inquest into the Death of Paulo Melo* (2008) N.T.M.C. 80, 107-08, 110 (Austl.), available at <http://www.nt.gov.au/justice/ntmc/judgements/2008>

became comatose likely as the result of medical malpractice.<sup>341</sup> His providers determined that the appropriate course of action was to remove his ventilator.<sup>342</sup> Ronald Cranford, chair of the medical center's intramural HEC, recognized the committee's inability to make an independent judgment in the matter because the negligent incident had occurred within its parent institution.<sup>343</sup> As a result, he declined to review the case.<sup>344</sup> Instead, he sought to implement the extramural model, asking the ethics committees of three *other* hospitals to determine whether the withdrawal of life-sustaining medical treatment was appropriate.<sup>345</sup> The Minnesota Supreme Court found these external committees' reports very useful.<sup>346</sup>

Here, as with earlier discussions, the experience of IRBs provides guidance. While many institutions outsource research-related questions to independent IRBs for the sake of efficiency, many also do so to staff the IRB in a way that mitigates conflicts of interest.<sup>347</sup> For example, New Zealand has employed regional committees for nearly twenty years, initially prompted by a scandalous Tuskegee-like<sup>348</sup> study

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12182008ntmc080.htm (encouraging a rural hospital to include outside members on its HEC).

341. *Id.* at 334. At a hearing, "counsel for Mr. Torres and the Hennepin County Medical Center stipulated that Mr. Torres ha[d] a potential cause of action based on negligence against the Hennepin County Medical Center." *Id.*

342. *Id.* at 335.

343. *See id.* at 335-36. Compare the scenario in the text to that of Memorial Hermann Hospital in Houston, which had its *own* HEC review the treating physician's decision to withdraw life-saving medical treatment under similar circumstances. *See supra* text accompanying notes 125-29.

344. *See Torres*, 357 N.W.2d at 335-36

345. Wolf 1986, *supra* note 47, at 13.

346. *Torres*, 357 N.W.2d at 336 n.2 ("[T]hese committees are uniquely situated to provide guidance to physicians, families, and guardians when ethical dilemmas arise.").

347. *See* OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., INSTITUTIONAL REVIEW BOARDS: THE EMERGENCE OF INDEPENDENT BOARDS ii (1998), available at <http://www.oig.hhs.gov/oei/reports/oei-01-97-00192.pdf> (observing that independent boards "provide a detached source of expertise"); *id.* at 5 ("[T]he independent IRBs can operate without being influenced by concerns about the financial well-being or prestige of the institution that employs them or the career interests of colleagues . . . [and] such detachment . . . leads to greater objectivity.").

348. The Tuskegee Study was a troubling research program in which African-American males infected with syphilis, but unaware of it, were solicited and studied—but denied treatment—so that researchers could observe the effects of the disease on living subjects. *See* JAMES JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT: A TRAGEDY OF RACE AND MEDICINE (1981).



involving cervical cancer.<sup>349</sup> In New Zealand, “[i]ndependence from the providers of care and researchers [has come] to be seen [as a] *sine qua non*.”<sup>350</sup>

Commentators have objected to the general proposition that MI-HECs can effectively address committee corruption. First, Richard Saver<sup>351</sup> argues that experience with corporate boards of directors suggests that the MI-HEC will not improve HEC performance. Such adding of more independent directors—directors not otherwise affiliated with the company—to a corporate board does not improve board director performance; likewise (the argument goes), adding committee members to HECs will not ameliorate similar problems in those committees.<sup>352</sup>

But Professor Saver’s argument is inapposite here. The MI-HEC model entails a more significant organizational upheaval than making mere “numerical changes in the insider/outsider mix.”<sup>353</sup> Applying the multi-institutional model works a dramatic change in the very organization of the HEC, delegating the deliberation and decision making to a wholly new and separate committee.<sup>354</sup>

Susan Wolf makes a second objection,<sup>355</sup> namely that MI-HECs are just like HECs in that they are still “dominated by health care professionals employed at the cooperating institutions.”<sup>356</sup> She argues

349. S. R. CARTWRIGHT, REPORT OF THE COMMITTEE OF INQUIRY INTO ALLEGATIONS CONCERNING THE TREATMENT OF CERVICAL CANCER AT NATIONAL WOMEN’S HOSPITAL AND INTO RELATED MATTERS 151 (1988) (attacking HECs as “too closely attached . . . to be trusted” and urging that “the Auckland Hospital Board . . . establish an ethics committee which is able to be more detached”).

350. Donald Evans, *Ethical Review of Innovative Treatment*, 14 HEC FORUM 53, 53-54 (2002).

351. Richard Saver is a law professor at the University of Houston.

352. HOSFORD, *supra* note 10, at 270-71. This is also the position of the Singapore Health Minister Khaw Boon Win. While the minister points to a conflict of interest where committees “sit in the same hospitals where [lucrative live donor] transplants are performed,” he recognizes that this conflict can be managed by “constitut[ing] the ethics committee properly” and “includ[ing] those from outside the hospital.” Hua, *supra* note 113. See *Safeguards Against Organ Trading Already in Place*, STRAITS TIMES, Mar. 25, 2009 (reporting Minister Win as stating that although the HECs have discretion, his ministry must approve HEC composition and processes).

353. Saver, *supra* note 101, at 3.

354. See LORIS A. NESBITT, CLINICAL RESEARCH: WHAT IT IS AND HOW IT WORKS 62 (2004) (arguing that by eliminating their internal IRBs, outsourcing hospitals reduce conflicts of interest and the appearance of bias since the board members will not be friends or colleagues of the researchers).

355. Susan Wolf is a law professor at the University of Minnesota.

356. See Wolf 1991, *supra* note 47, at 838. Similarly, the Dunlop Commission was skeptical when large law firms established an alternative dispute resolution program

that, whereas an intramural HEC is predisposed to protect its sponsoring institution, the MI-HEC's motives are also corrupt—but in favor of the joint and several interests of its various member institutions rather than a single parent entity.

But while MI-HECs do draw their members from much of the same “pool” as intramural HECs, available data does not suggest that professional camaraderie corrupts MI-HEC decisions. For example, while Professor Wolf may be correct to note that corporations are repeat players in ADR forums, “statistics of [such] favoritism *within ADR processes* have yet to be documented.”<sup>357</sup> In addition, independent review of difficult ethics questions has been endorsed by the FDA, the Office for Human Research Protections, and the National Cancer Institute.<sup>358</sup> Even if Professor Wolf is correct in stating that MI-HECs cannot wholly eliminate committee corruption, they can nevertheless materially mitigate it.

#### B. MI-HECs Mitigate the Risk of Committee Member Bias

The MI-HEC's ability to draw from a broad diversity of voices and perspectives addresses the problem of biased decision making among intramural HECs.<sup>359</sup> Diversification of the MI-HEC's membership is analogous to broadening the roster of arbitrators in an ADR setting so that the pool does not favor either party.<sup>360</sup> Just as the HEC was proposed as a check on the idiosyncrasies of the individual provider, the MI-HEC serves as a check on the idiosyncrasies of the individual intramural HEC.<sup>361</sup>

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in which arbitrators for firm employee disputes had to be selected from a panel composed of partners in large firms. U.S. DEP'T OF COMMERCE & U.S. DEP'T OF LABOR, *supra* note 110 (citing *More Law Firms Seek Arbitration for Internal Disputes*, WALL ST. J., Sept. 26, 1994, at B13).

357. Kovach, *supra* note 154, at 1036 (emphasis added). See Lewis L. Maltby, *Private Justice: Employment Arbitration and Civil Rights*, 30 COLUM. HUM. RTS. L. REV. 29, 46 (1998) (reviewing studies finding that “employees prevailed more often in arbitration than in court”).

358. Meeker-O'Connell, *supra* note 139, at 6.

359. See *Ethics and Rural Healthcare*, *supra* note 161, at 137.

360. *Prototype Agreement on Job Bias Resolution*, DAILY LAB. REP. (BNA), May 11, 1995, at D34.

361. MARGARET BRAZIER & EMMA CAVE, *MEDICINE, PATIENTS, AND THE LAW* (2007) (“Given a sufficiently large and diverse committee, there will always be people who represent different ethical viewpoints present and each perspective will, at least, get a chance to make its case.”).

### C. MI-HECs Mitigate the Risk of Careless Decisions

The broader pool of professional and community representatives available to the MI-HEC also addresses the risk of committee carelessness.<sup>362</sup> The MI-HEC can solicit more disciplinary expertise, embrace more disciplinary perspectives, and support more formal training than can an individual intramural HEC.<sup>363</sup> This enhanced expertise in the ethics committee ensures its members receive a more robust education in the subject matter, reducing the likelihood that a decision will be made haphazardly.

An individual healthcare provider or facility might lack the time, money, or expertise required to assemble an adequate HEC.<sup>364</sup> The MI-HEC model can help an institution overcome such a lack of adequate ethics resources by allowing it to benefit from the input and deliberation of a large multidisciplinary body, while only requiring it to contribute a fraction of the committee's cost and personnel.<sup>365</sup> "This model has the potential to be efficient and effective by sharing ethics expertise and financial support."<sup>366</sup> Support can be pooled without unduly taxing any individual institution, allowing more resources to be spent on educating a greater number of members.<sup>367</sup>

362. Cf. Heath, *supra* note 131 ("Recruitment of members for an independent IRB is usually from a broader pool.").

363. Cf. CARTWRIGHT, *supra* note 349, at 151 ("National Women's Hospital is too small an institution [and] lacks the broad scientific and ethical bases needed . . ."); Glantz, *supra* note 134, at 130 (arguing the fact that "[d]ifferent groups have different primary concerns, . . . seems to be a good argument for having people from different fields on each IRB"); HOSFORD, *supra* note 10, at 264 ("Officials of several hospitals, particularly small ones, could establish a joint committee, thus pooling expert people."); Nelson, *supra* note 193.

364. *Ethics and Rural Healthcare*, *supra* note 161, at 135.

365. *Id.* at 137 ("It would also allow hospitals to share training and technical assistance resources."); Hoffmann, *supra* note 30, at 763 (observing that a joint committee is "likely to be better educated," and "could spend more resources on workshops"); Nelson, *supra* note 193, at 32 ("When there are limited resources at one facility to support an ethics committee, another option is a multi-facility ethics committee (MFEC)."). This was probably the goal of the Community Healthcare Ethics Committee, a project of the Nevada Center for Ethics and Health Policy: "to fulfill ethics committee functions for those organizations and facilities that desire or need these services but lack resources to have their own." Craig Klugman, *Model of Ethics Committees in the Public Arena* [http://apha.confex.com/apha/131am/techprogram/paper\\_59968.htm](http://apha.confex.com/apha/131am/techprogram/paper_59968.htm) (last visited May 4, 2009).

366. Nelson, *supra* note 193, at 33; Nyika et al., *supra* note 167, at 190 ("The paucity of resources makes it critical [to] promote synergistic collaborative efforts."). Cf. RICHARD A. BREALEY, *PRINCIPLES OF CORPORATE FINANCE* 870-903 (2007).

367. See Hoffmann, *supra* note 30, at 762 (arguing it would be more efficient to have "community committees or joint committees [because] more resources could be spent

For example, if each of three rural Montana hospitals were individually too small to support their own ethics committees, they could pool their efforts. Each could contribute one-third of the prospective MI-HEC's members and pay one-third of the cost of library materials, educational requirements, clerical support, and other expenses.<sup>368</sup> In short, shifting to "inter-institutional activities" can achieve significant "economies of scale."<sup>369</sup>

#### D. MI-HECs Mitigate the Risk of Arbitrary Decisions

MI-HECs not only mitigate the risk of corrupt, biased, and careless decisions, but they also address the lack of reliable procedures and methods in intramural HECs. Since the MI-HEC serves several institutions, it must operate with greater transparency and accountability. Furthermore, the higher volume of referrals gives the MI-HEC more experience.<sup>370</sup> And with a greater caseload, the MI-HEC will work more formally.<sup>371</sup> More uniformity improves consistency and reliability in decision making.

#### E. Summary of MI-HEC Advantages

Equipped with the collective strength of multiple institutions' financial, professional, educational and disciplinary resources—and detached from what is often the unduly persuasive influence of individual supporting institutions—the MI-HEC can operate as a diverse, accountable, and independent decision making body, ensuring difficult bioethical dilemmas are addressed with enhanced uniformity and

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on educating members and improving the quality of the committee's services"); see also Oosterhoff & Rowell, *supra* note 283, at 303 ("In exchange for financial contribution to the shared costs of the Initiative, similar organizations would receive consultative and educational bioethics services.").

368. Berkowitz & Dubler, *supra* note 59, at 143; Niemira et al., *supra* note 201, at 80 (arguing that MI-HECs "hold the promise of consolidating resources").

369. *Ethics and Rural Healthcare*, *supra* note 161, at 138.

370. See Heath, *supra* note 131, at 15. New Zealand reduced its number of regional committees from fifteen to six to "concentrate expertise." NAT'L ADVISORY COMM. ON HEALTH & DISABILITY SUPPORT SERVS. ETHICS, REVIEW OF THE CURRENT PROCESSES FOR ETHICAL REVIEW OF HEALTH AND DISABILITY RESEARCH IN NEW ZEALAND (2003), available at [http://www.neac.health.govt.nz/moh.nsf/pagescm/970/\\$File/reviewprocesses/ethicalresearch.pdf](http://www.neac.health.govt.nz/moh.nsf/pagescm/970/$File/reviewprocesses/ethicalresearch.pdf). Cf. NESBITT, *supra* note 354, at 62 (outsourcing means economy of scale, and cases go to experts whose sole focus is IRB).

371. Cf. Bashir Jawani, *A Mandate for Regional Health Ethics Resources*, 16 HEC FORUM 247 (2004). One system of MI-HECs operates pursuant to detailed procedures. S.C. DEP'T OF DISABILITIES & SPECIAL NEEDS, ETHICS COMMITTEES—REGIONAL CENTERS (2007), available at <http://www.ddsn.sc.gov/NR/rdonlyres/038AB500-52ED-4878-889A-2017A7DF15C0/0/50208DD.pdf>.

care. Whether an institution resorts to the network model, the extramural model, the quasi-appellate model, or the joint model of MI-HEC constitution, its decision to utilize the MI-HEC should ultimately contribute to an improvement in the quality of its patient care.<sup>372</sup>

## V. OVERCOMING CHALLENGES TO THE FORMATION OF MI-HECS

There is not much debate that MI-HECs can eliminate—or at least substantially mitigate—the problems presented by dependent, insular, and resource-deficient intramural HECs. Yet, there remains an utter dearth of MI-HECs across the United States.<sup>373</sup> So it seems that the greatest challenge lies not in proving the remedial value of MI-HECs, but in proving that these benefits outweigh their costs.

MI-HECs present their own problems and challenges. They take time and effort to form and operate. Ironically, they may even be *too* detached from the institutional context in which cases arise. And there are liability, confidentiality, and communication logistics problems connected with MI-HECs as well.

But these challenges can be readily overcome—indeed, they have *already* been demonstrably overcome by existing MI-HECs. These multi-institutional committees are a viable solution to the intramural HEC problems, but the greatest obstacle to their implementation may be convincing healthcare institutions that those problems exist and are worth addressing.

### A. Classic Obstacles to MI-HECs

#### 1. Transaction Costs

Some have argued that institutions are “unlikely to come together to plan joint committees because of the transaction costs.”<sup>374</sup> “It takes

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372. I thank Professor Peter D. Jacobson for reminding me that the promise of improved performance should be empirically tested by surveying and comparing intramural HECs and MI-HECs across a range of relevant dimensions such as composition and training.

373. The primary exception is for MI-HECs for long-term care facilities in states like Maryland and New Jersey, where they are an appealing vehicle for satisfying regulatory requirements.

374. Hoffmann, *supra* note 30, at 769. See *Ethics and Rural Healthcare*, *supra* note 161, at 135 (discussing potential increase in demand for and cost of expertise and resources); Nelson, *supra* note 193, at 30 (explaining that staff in rural hospitals “have little time to participate on a committee and the facility has limited economic resources to support the committee”); Scannell, *supra* note 111 (“[N]o financial . . . support is available for such an undertaking and structure.”); Smith et al., *supra* note 196, at 1274-75 (“[T]his procedural change would then raise concerns about . . . administrative burden.”). Cf. Caroline McNeil, *Debate over IRBs Continues as*

time and expert personnel to develop and implement a single ethical policy.”<sup>375</sup> Intramural HECs often lack the funds necessary to “find and allocate time in order to resolve present and evolving ethical issues.”<sup>376</sup> While a MI-HEC can reduce some of those costs, it does not obviously produce an overall net savings. Each institution must invest time and resources simply to coordinate with the other member institutions.<sup>377</sup>

But these organizational costs may not be too onerous. Organizations are already in place, such as county medical societies, which can help reduce expense.<sup>378</sup> And costs can be shared by each institution that requests consultation. Moreover, these costs would be a prudent investment, because an effective ethics committee—often achievable only in the MI-HEC form—can reduce operational costs, legal costs, and marketing costs.<sup>379</sup> Ethics committee costs “would be minor compared with the cost of litigation (which hopefully would be avoided).”<sup>380</sup>

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*Alternative Options Emerge*, 99 J. NAT’L CANCER INST. 502, 503 (2007) (“Another barrier to the use of central IRBs is confusion over how local and nonlocal boards can work together.”).

375. Monagle & West, *supra* note 59, at 260; *see also* Fletcher, *supra* note 15, at 871.

376. *Id.*

377. *Cf.* Oosterhoff & Rowell, *supra* note 283, at 309 (describing challenges of a “shared leadership” model, including differences concerning the goals of bioethics and concerns about the overuse of resources).

378. Miller, *supra* note 51, at 211.

379. Nelson, *supra* note 2. *See* Jennifer Bell & Jonathan M. Breslin, *Health Care Provider Moral Distress as a Leadership Challenge*, 10 JONA’S HEALTHCARE L. ETHICS & REG. 94, 95-96 (2008) (arguing that ethics committees can reduce moral distress, increase the quality of patient care, and reduce turnover); Jeffrey Nichols, *When There Is No Ethics Committee*, CARING FOR THE AGES, Oct. 2008, at 13 (“One of the greatest advantages to the physician of the ethics committee process is the time and energy that committee can save him or her in gathering all this information [about the patient].”).

380. DEP’T OF VETERANS AFFAIRS, A BRIEF CASE FOR ETHICS (2007); Caulfield, *supra* note 63; B.J. Heilicser et al., *The Effect of Clinical Ethics Consultation on Health Care Costs*, 11 J. CLINICAL ETHICS 31 (2000); Miller, *supra* note 51, at 211; Nelson, *supra* note 193, at 30 (“[E]thics committees can be economically beneficial for the organization.”). *See* Banerjee & Kushner, *supra* note 2, at 143 (reviewing literature showing “measurable benefits” from ethics committees).

## 2. Locality

It has long been considered important for HECs to be “local.”<sup>381</sup> The same was thought to be true regarding IRBs.<sup>382</sup> For either a HEC or a research review committee to be effective, it must be familiar with the cultural milieu of the institution and the local community.<sup>383</sup> Therefore, “[a]t least one argument against [MI-HECs] . . . is that health care institutions are unique and need to be attuned to the unique characteristics of each institution and to its staff.”<sup>384</sup>

While this argument has some force against the extramural model, in which an institution may have no direct representation on the MI-HEC,<sup>385</sup> it has little weight applied against the quasi-appellate or joint models, which allow each hospital its own representation on the MI-HEC.<sup>386</sup> The quasi-appellate model is independent from each member institution that refers a case. Yet, since each institution has representation, the MI-HEC panel is still in touch with local institu-

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381. An early version of the Patient Self Determination Act required ethics committees. S. 1766, 101st Cong. (1989). But the requirement was dropped because of a desire for local control. See Fletcher, *supra* note 15, at 871; Hoffmann, *supra* note 30, at 753. Some significant opposition to the 1983 Baby Doe rules rested “on the grounds that local ethics review would be more valuable.” Heitman, *supra* note 23, at 411.

382. 21 C.F.R. § 56.107(a) (2008) (“The IRB shall have . . . sensitivity to such issues as community attitudes . . .”); 45 C.F.R. § 46.107(a) (2008). In the IRB context local review is desirable because local members know: (i) the research, (ii) the resources, (iii) the reputation of the investigators, (iv) the capabilities of the investigators, and (v) the attitudes of the community. Also, local members can build a culture of trust. Steven Peckman, *Local Institutional Review Boards*, in 2 ETHICAL AND POLICY ISSUES INVOLVING HUMAN PARTICIPANTS (2001). Local review committees have traditionally been considered better than national or regional committees because they are more familiar with actual conditions surrounding the conduct of the research and can work closely with investigators. See Nat’l Commission, Report and Recommendations: IRBs (1978).

383. See sources cited *supra* note 382; see also OFFICE FOR HUMAN RESEARCH PROTECTION, IRB KNOWLEDGE OF LOCAL RESEARCH CONTEXT (2000). Notably, some objected to intramural HECs as “undesirable bureaucracy not sufficiently close to the clinical situation.” Am. Med. Dir. Ass’n, *supra* note 256.

384. Hoffmann, *supra* note 30, at 762.

385. Even the extramural MI-HEC can overcome the locality objection. Through a regular, ongoing relationship, the MI-HEC will acquire substantial local knowledge. Since physicians are on staff at several hospitals, some MI-HEC members will already have direct local knowledge. See *id.* at 762 n.97.

386. However, on some MI-HEC proposals, the treating facility would have no representation. See, e.g., Buchanan et al., *supra* note 217, at 191 (“Individuals who had a financial conflict of interest with the patient’s ‘home’ facility or managed care plan could not participate on that patient’s panel, and every effort was made to avoid institutional affiliation between panel members and the patient’s site of care.”).

tional culture and possesses “relevant local knowledge.”<sup>387</sup> And since the committee’s functions are not entirely outsourced and the referring institution has some representation on the committee, relevant community norms and values can still be considered.

An equivalent model was suggested which would provide a locality-sensitive solution in the IRB context.<sup>388</sup> For example, the Western Institutional Review Board (one of the largest independent IRBs) utilizes “regional representatives who take the pulse of the local community to determine attitudes and customs that might influence research protocols.”<sup>389</sup> “Routine visits to sites and videos and teleconferences provide the Board with additional information about local conditions.”<sup>390</sup>

### 3. Liability

Lawsuits against ethics committees are rare; but they do occur.<sup>391</sup> Indeed, it is just such a threat that may corrupt an intramural HEC’s decisions and recommendations.<sup>392</sup> In contrast, MI-HECs have a reduced risk of corruption because no single institution has control over the MI-HEC.

Unfortunately, this same lack of control can have a chilling effect on the willingness of a healthcare institution to participate in a MI-HEC.<sup>393</sup> The fear of lawsuits “makes some institutions reluctant to

387. Susan Sturm, *Second Generation Employment Discrimination: A Structural Approach*, 101 COLUM. L. REV. 458, 524 (2001).

388. U.S. DEP’T HEALTH & HUMAN SERVS. ET AL., GUIDANCE FOR INDUSTRY: USING A CENTRALIZED IRB REVIEW PROCESS IN MULTICENTER CLINICAL TRIALS 4-5 (2006), available at <http://www.fda.gov/Cder/guidance/OC2005201fml.pdf> (suggesting as “a sufficient mechanism to ensure meaningful consideration” the participation of an institution in the deliberations of or the provision of information to the central IRB).

389. W. Inst. Review Bd., *supra* note 290.

390. *Id.* See also Heath, *supra* note 131 (describing alternative approaches “for assuring accurate and up-to-date knowledge of local issues and attitudes”).

391. BERNAT, *supra* note 36, at 116-17; Fletcher & Spencer, *supra* note 15, at 270-75; SUSAN B. RUBIN & LAURIE ZOLOTH, MARGIN OF ERROR 355-60 (2000) (five lawsuits against HEC). See Charles Lewis, *Hospital Sued for Keeping Infant Alive*, NAT’L POST, Mar. 14, 2009 (describing a newly-filed \$3.5 million lawsuit in Montreal in which the parents of Phebe Mantha are suing the Montreal Children’s Hospital); S.M. Staubach, *What Legal Protection Should a Hospital Provide, If Any, to Its Ethics Committee*, 1 HEC FORUM 209 (1989).

392. See *supra* Part II.A.

393. Miller, *supra* note 51, at 211; see also Scannell, *supra* note 111 (“[N]o legal . . . support is available for such an undertaking and structure.”). A Community Healthcare Ethics Committee in Nevada dissolved shortly after its formation in significant part because of concerns about liability. Email and Telephone Interview



relinquish control.”<sup>394</sup> Moreover, a MI-HEC could increase an institution’s exposure to liability, assuming it makes the institution more likely to make controversial decisions.

But this legal fear is misplaced. An MI-HEC substantially mitigates liability concerns in four ways. First, MI-HECs increase chances for resolution of treatment conflicts, thus reducing the risk of litigation.<sup>395</sup> Second, in the unlikely event of litigation, the MI-HEC serves a protective role. The original attraction of HECs was the reassurance that they could provide in the face of adverse legal consequences. MI-HECs can do the same job better, since courts are more likely to defer to a broader, more independent committee.<sup>396</sup> Third, MI-HECs are often accorded statutory civil, criminal, and disciplinary immunity.<sup>397</sup> Finally, in the unlikely case of litigation and possibly even liability, MI-HECs can carry insurance.<sup>398</sup>

#### 4. Confidentiality

Some commentators have argued that MI-HECs are problematic because they require institutions to share sensitive information about

with Noel V. Tiano, Nevada Center for Ethics and Health Policy, and Thaddeus Mason Pope, Associate Professor of Law, Widener University (Feb. 4, 2009).

394. McNeil, *supra* note 374, at 502. *Cf.* Winn & Cook, *supra* note 189, at 37 (“[F]acility officials may believe that an institutional ethics committee may actually increase the risk of liability.”).

395. *See* HOSFORD, *supra* note 10, at 314-16; MEISEL & CERMINARA, *supra* note 73, § 3.25[A][3][d]; Monagle & West, *supra* note 59, at 258 (“Bioethics committees reduce, not increase, legal exposure.”). *Cf.* J.T. Wagner & T.L. Higden, *Spiritual Issues and Bioethics in the Intensive Care Unit: The Role of the Chaplain*, 12 *CRITICAL CARE CLINICS* 15 (1986).

396. Peter McShannon, *Panel Discussion: Implementing and Utilizing an Institutional Ethics Committee*, in CRANFORD & DOUDERA, *supra* note 7, at 226, 237 (“The looser the committee, as far as the courts are concerned, the less value and the less deference they would give to a doctor going to that committee.”).

397. *See, e.g.*, Ala. Code § 22-8A-4 (LexisNexis 1975); DEL. CODE § 24-1768(a) (2008) (“[M]embers of other peer review committees . . . whose function is the review of . . . medical care, and physicians’ work, with a view to the quality of care and utilization of hospital or nursing home facilities . . . are immune from claim, suit, liability, damages, or any other recourse, civil or criminal, arising from any act, omission, proceeding, decision, or determination undertaken or performed, or from any recommendation made . . . .”); FLA. STAT. ANN. § 765.404(2) (West 2005); GA. CODE ANN. § 31-39-4 & -7 (2006); HAW. REV. STAT. § 663-1.7(b) (West 2008); MD. CODE ANN., HEALTH-GEN. § 19-374(c) (LexisNexis 2008); MONT. CODE § 37-2-201 (2008).

398. *Cf.* HOSFORD, *supra* note 10, at 116, 316-17; John A. Robertson, *The Law of Institutional Review Boards*, 26 *UCLA L. REV.* 484, 535 (1979).

their problem cases with competitors.<sup>399</sup> Others maintain that most institutions are “unlikely to come together to plan joint committees because of [their] insular views.”<sup>400</sup>

But the issue of whether the HECs are open or closed seems to be a red herring, as not only are a number of MI-HECs *already* operating but also even the intramural HECs *already* have outside members.<sup>401</sup> Additionally, some types of cases necessitating ethically-charged decision making (such as whether to withdraw life support) seem—by their nature—less likely to become the choice morsels fought over by competing institutions, which recognize the mutuality of their stake in managing these disputes discretely.<sup>402</sup> At the very least, those doubting the MI-HECs’ ability to function without compromising confidentiality and institutional competitiveness should recognize that regulatory and common law liability—which may attach to the committee as well as its individual members—may provide safeguards against the misuse or undesired sharing of important data.

### 5. *Distance*

Some have argued that since rural facilities are separated by great distance, a cooperative venture like a MI-HEC would be impractical. It would be very difficult, says the objection, for members from the different constituent institutions to get together for ethics education, policy development, or case consultation.<sup>403</sup>

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399. HOSFORD, *supra* note 10, at 141 (“[O]utsiders might learn confidential information about patients, might hear of failures or bickering among health care providers . . .”); LOEBEN, *supra* note 265, at 230 (“HECs are relatively used to the idea of operating behind closed doors.”); SMITH ET AL., *supra* note 196, at 1274-75 (“[T]his procedural change would then raise concerns about patient confidentiality . . .”). Cf. SZMANIA ET AL., *supra* note 143, at 73; U.S. DEPT. OF VETERANS AFFAIRS, Nat’l Center for Ethics in Health Care, *ECWeb: A Quality Improvement Tool of Ethics Consultation*, <http://www.ethics.va.gov/integratedethics/ecweb.asp> (last visited Apr. 24, 2009) (compiling consults from all VHA facilities but only allowing each facility to view its own data and aggregate nationwide data).

400. HOFFMANN, *supra* note 30, at 769.

401. See STATE INITIATIVES, *supra* note 270, at 3 (“There was initial concern . . . about hanging out our dirty laundry for competitors to see, but . . . the concern didn’t bloom.”); BAYLEY, *supra* note 202, at 362 (“Although neighboring hospitals are often in competition, ethics committees have traditionally been natural allies since many of their goals are not zero sum games . . .”).

402. See sources cited *supra* note 403.

403. NIEMIRA ET AL., *supra* note 201, at 78 (“Distances between institutions . . . are obvious obstacles that must be overcome.”); *id.* at 80 (arguing that “practical issues” such as “distances between members” may limit the usefulness of MI-HECs); OOSTERHOFF & ROWELL, *supra* note 283, at 312-13.

This may have been true just a decade ago, but it is not true today.<sup>404</sup> Technology already available—or soon to become available—in rural healthcare institutions can effectively facilitate the necessary communication. Telemedicine is proving its feasibility and usefulness in the clinical context, for example, by allowing a rural family physician to instantly consult with an urban specialist through live interactive videoconferencing.<sup>405</sup>

Just as telemedicine is addressing the lack of rural physicians, “teleethics” can address deficiencies in rural bioethics.<sup>406</sup> For example, nearly fifteen years ago, the University of Missouri developed the Missouri Telehealth Network to enhance access to care to more than forty underserved Missouri counties.<sup>407</sup> More recently, over the past three and one-half years, the University of Missouri Center for Health Care Ethics has incorporated this very same telemedicine technology for use by ethics consultants to provide consultation services to ethics committees and healthcare providers at rural facilities where such services are not available.<sup>408</sup>

In a very recent medical futility dispute in the remote Northern Territory of Australia, the court recommended establishing “a clinical ethics committee” that would be “independent of the treating doctors and the family.”<sup>409</sup> The court noted that, “given the small population

404. Bayley, *supra* note 202, at 362 (telephone and email may make possible “an ongoing, if geographically distant, buddy relationship”); Pinnock & Crosthwaite, *supra* note 59 (observing that “smaller centres could gain access to ethicists/clinical ethics committees via teleconferencing”).

405. See Arnold R. Eiser et al., *Electronic Communication in Ethics Committees: Experience and Challenges*, 27 J. MED. ETHICS i30 (2001); Kathy Hedberg, *N. Idaho Robot Connects Doctors and Patients*, USA TODAY, Apr. 4, 2009.

406. See Fleming, *supra* note 191, at 250-51, 257. See also Fukuyama et al., *supra* note 318 (“[E]mail was used as the primary means of consultation . . . . Advantages of our method . . . included the ability to request consultation anonymously from anywhere in Japan.”); Nelson, *supra* note 193, at 32-33; L.A. Shaw, *The Use of Email in Clinical Ethics Case Consultation*, 12 J. CLINICAL ETHICS 39 (2001); University of Missouri, *Tele-ethics Consultation Services*, <http://ethics.missouri.edu/Tele-Ethics-Consultation> (last visited Mar. 30, 2009).

407. See Mo. Telehealth Network, <http://telehealth.muhealth.org/> (last visited Mar. 30, 2009).

408. At the 2007 annual meeting of the American Society of Bioethics and Humanities (ASBH), David Fleming and Donald Reynolds reported that the accessibility and feasibility of providing teleethics services have proven to be very effective. See also Bolin et al., *supra* note 275, at 65 (describing a “virtual ethics committee program”).

409. Inquest into the Death of Paulo Melo (2008) N.T.M.C. 80, 107-08, 110 (Austl.), available at <http://www.nt.gov.au/justice/ntmc/judgements/200812182008ntmc080.htm>.

of the Northern Territory, for the committee to have any independence at all from the treating doctors it would probably need to have interstate members (who would need to be available on short notice by telephone or videoconferencing).<sup>410</sup>

### B. *Big Obstacle: Lack of Motivation*

Perhaps the most significant challenge to the expanded use of MI-HECs is enabling healthcare ethicists and committee members to recognize and comprehend the extent of the deficiencies inherent in an intramural HEC.<sup>411</sup> Our discussion thus far, of course, has assumed people *want* an ethics committee.<sup>412</sup> The MI-HEC has gone unappreciated because it sits on the bench, seeing infrequent use.<sup>413</sup> But successful popularization of this unknown resource depends not upon a criticism of the player currently on the field (the intramural HEC), but upon proactive efforts by those in the healthcare ethics field to bring meaningful attention to the *superior* abilities of the pinch hitter (the MI-HEC).

Importantly, the MI-HEC can improve not only the quality of institutions' ethics but also the perception of that quality by both providers and the public. Many have "little idea of what to expect."<sup>414</sup> If healthcare providers were confident that the MI-HEC could handle an issue and bring about positive results, they would be more likely to use the committee.<sup>415</sup> More positive experiences will lead to more usage and more usage, as I have explained in this Article, will lead to more positive experiences. Working virtually in unison, a larger number of MI-HECs can create consistency among institutions, increasing public understanding and trust in committee functions.

Traditional approaches that aimed at improving the HEC have done little to alter the status quo. Education has not worked: problems associated with HECs have continued despite being widely publicized for decades at conferences and in professional literature such as *HEC Forum* and the *Cambridge Quarterly of Health Care Ethics*. Litigation—

410. *See id.*

411. Miller, *supra* note 51, at 214 ("These proposals, though long overdue in terms of need, may even now be premature in terms of acceptance.").

412. Hoffmann Study, *supra* note 47, at 114-15, 118.

413. Fox et al., *supra* note 59, at 13; Pinnock & Crosthwaite, *supra* note 59. *See Ethics and Rural Healthcare*, *supra* note 161; Jessica Gacki-Smith & Elisa Gordon, *Residents' Access to Ethics Consultations: Knowledge, Use, and Perceptions*, 80 *ACAD. MED.* 168 (2005); *Willing, But Waiting*, *supra* note 116; J.P. Orłowski et al., *Why Doctors Use or Do Not Use Ethics Consultation*, 32 *J. MED. ETHICS* 499 (2006).

414. FRY-REVERE, *supra* note 160, at 26.

415. Fry-Revere, *supra* note 222, at 451.

given its cost, complexity, and unpredictability—is not a good method by which to develop cohesive standards;<sup>416</sup> plus, HECs are often statutorily immune or are so endemically postured as to deter most plaintiffs from pursuing claims.<sup>417</sup>

Of the traditional efforts at achieving systemic reform, those centered on utilizing legislation or accreditation standards are most promising, since HECs must be held more accountable as they begin to look more like gatekeepers.<sup>418</sup> Many obstacles to the formation of MI-HECs can be overcome if prospective participants are supplied with the proper incentives by way of responsive lawmaking.<sup>419</sup> But even the legislative approach will gather moss if the valuable benefits of MI-HECs are not effectively demonstrated to providers and the public.

### CONCLUSION

Since the function of HECs has evolved from one of advising, clarifying, and facilitating to one of decision making, the form of HECs must evolve as well. Today, most HECs are intramural committees whose decisions are subject to material risks of corruption, bias, arbitrariness, and carelessness. Reconstituting intramural HECs as network-based, extramural, quasi-appellate, or joint MI-HECs can significantly mitigate these risks.

Unfortunately, material advances in bioethics are often made only in response to crises. Since rural healthcare facilities may most acutely feel the need to fix problems with their ethics mechanisms, they may serve a sort of sentinel or bellwether function. Rural healthcare facilities may serve as the spark to the Joint Commission, state regulators, or others to give definition to the composition and operation of HECs. They may serve as the laboratory in which to test solutions that may later be adapted more broadly.

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416. *Id.* at 454-55. See Timothy D. Lytton, *Using Tort Litigation to Enhance Regulatory Policy Making: Evaluating Climate-Change Litigation in Light of Lessons from Gun-Industry and Clergy-Sexual-Abuse Lawsuits*, 86 TEX. L. REV. 1837, 1837-38 (2008) (“Compared to other forms of regulation, litigation is often unnecessarily complex, protracted, costly, unpredictable, and inconsistent. Moreover, courts are generally less well equipped . . . to evaluate technical information . . . [or involve] public input and accountability . . .”).

417. See, e.g., Fla. Stat. Ann. § 765.404(2) (West 2005); HAW. REV. STAT. § 663-1.7(b) (West 2008); MD. CODE ANN., HEALTH-GEN. § 19-374(c) (LexisNexis 2008).

418. See *supra* text accompanying notes 207-08.

419. See Hoffmann, *supra* note 30, at 769, 789-90 (listing—as examples of such incentives—education, grants, and immunity).