

## Operationalizing the Health Care Benefit Corporation

Terry L. Corbett

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### Recommended Citation

Terry L. Corbett, *Operationalizing the Health Care Benefit Corporation*, 24 J. Health Care L. & Pol'y 267 (2022).

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# OPERATIONALIZING THE HEALTH CARE BENEFIT CORPORATION

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## ABSTRACT

This is the third in a series of articles discussing a proposed new form of legal entity which we have called a “Health Care Benefit Corporation” (“HCBC”) – a variant form of the hybrid “benefit corporation” first proposed by the non-profit organization B Lab. Unlike B Lab’s “Model Act” form of benefit corporation, the HCBC would be specifically tailored to best meet the needs of institutional health care providers and integrated health care delivery systems. As such, it would differ in several significant ways from the B Lab Model, as well as from all current state adaptations thereof. It is proposed as a new

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corporate form that would be particularly useful to those wishing to develop and operate “Accountable Care Organizations” (“ACOs”).

In our first article, in 2015, we explored the evolution of American hospitals into only two predominate forms of legal organization – for-profit and nonprofit corporations. We compared and contrasted the characteristics and performance of hospitals under each of the two corporate forms and analyzed the implications of recent developments in both health law (*e.g.*, the “Affordable Care Act” (“ACA”) and the proposed “Fiduciary Medicine Model” and corporate law (*e.g.*, the proposed “doctrine of mission primacy”). We concluded with a call for a “new organizational paradigm” – the HCBC.

In our second article, in 2019, we delved more deeply into the theoretical underpinnings of the corporation as a legal construct – its governance, existential nature, and social/moral dimensions. We examined several new concepts preceding the benefit corporation, including “corporate social responsibility,” “social entrepreneurship/social enterprise,” and “constituency statutes.” We then fully “fleshed out” the structure of our proposed HCBC and explained how its specifically-tailored features could benefit institutional health care providers.

Now, in this article, we identify and discuss five objectives for operationalizing the HCBC, focusing on: (1) integrated systems, health information technology, and clinical practice guidelines; (2) adoption of exclusive enterprise liability and acknowledgement of broadened fiduciary duties; (3) cost-reductions through liability self-insurance; (4) operating as both a non-capitated provider and nonprofit payer; and (5) creating a “culture of virtue” that sustains the professional integrity of institutional health care delivery and restores patient trust.

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#### FOREWARD<sup>1</sup>

I have never been convinced that competition by itself will improve the efficiency or the effectiveness of care or even that it will reduce the cost of care. I think that commercialization of care is a big mistake. Health care is a sacred mission. It is a moral enterprise and a scientific enterprise but not fundamentally a commercial one. We are not selling a product. We don’t have a consumer who understands

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1. Throughout this article, all internal footnotes in quoted material have been omitted.

everything and makes rational choices – and I include myself here. Doctors and nurses are stewards of something precious. Their work is a kind of vocation rather than simply a job; commercial values don't really capture what they do for patients and for society as a whole.

Systems awareness and systems design are important for health professionals but are not enough. They are enabling mechanisms only. It is the ethical dimension of individuals that is essential to a system's success. Ultimately, the secret of quality is love. You have to love your patient, you have to love your profession, you have to love your God. If you have love, you can then work backward to monitor and improve the system. Commercialism should not be a principal force in the system. That people should make money by investing in health care without actually being providers of health care seems somewhat perverse, like a kind of racketeering.

*Avedis Donabedian*<sup>2</sup>

## I. INTRODUCTION

In a 2015 article,<sup>3</sup> we undertook to examine how the organization and operation of modern American hospitals affects, and is affected by, their initially-selected form of legal entity. We began with a detailed review of the history and evolution of such hospitals from their early beginnings as “donation-supported ‘alms houses’”<sup>4</sup> to their current status as large, institutional direct providers of care in the “Medical-Industrial Complex.”<sup>5</sup> We noted how the advent of health insurance and other third-party payment contributed greatly to the ever-increasing commercialization and capitalization of health care services, and the subsequent bifurcation of essentially all contemporary hospitals into one of only two legal forms of organization – for-profit corporations and nonprofit corporations.<sup>6</sup> We then reviewed available research into the comparative characteristics and performance of these two corporate forms.<sup>7</sup> We concluded, ultimately, that despite the legal features and requirements historically

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2. Fitzhugh Mullan, *A Founder of Quality Assessment Encounters A Troubled System Firsthand*, 20 HEALTH AFFS. 5 (2001) (quoting an interview with Avedis Donabedian).

3. Terry L. Corbett, *Healthcare Corporate Structure and the ACA: A Need For Mission Primacy Through a New Organizational Paradigm?*, 12 IND. HEALTH L. REV. 103, 172 (2015).

4. *Id.* at 109.

5. *Id.* at 116–118.

6. *Id.* at 122–24.

7. *Id.* at 126–30.

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distinguishing the two types of corporations,<sup>8</sup> their operational differences now increasingly appear to be only nominal.

We then shifted focus to the still-continuing debate over the “deontological” nature of health care in the United States – that is, whether it is generally viewed and treated as a simple commodity, a public good, or a basic right of all citizens.<sup>9</sup> The answer to this question, we believe, necessarily informs one’s opinion about which corporate form better serves the needs and objectives of our current health care delivery system.<sup>10</sup> That system, regrettably, has been under attack for several years for well-documented deficiencies in quality, value, efficiency, and accountability – all problems that the 2010 Affordable Care Act (“ACA”) sought to address.<sup>11</sup> Accordingly, we next reviewed and discussed several provisions of the ACA that directly address these deficiencies, and tried to assess how those efforts would impact, and be impacted by, a hospital’s choice of corporate form.<sup>12</sup> One ACA provision in particular stood out – the law’s encouragement that Accountable Care Organizations (“ACOs”) be developed.<sup>13</sup>

From there, we brought three additional academic theses into our analysis: (1) the concept of “mission primacy,”<sup>14</sup> (2) newly-developed “hybrid legal structures,”<sup>15</sup> and (3) a recently-proposed “Fiduciary Medicine Model.”<sup>16</sup>

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8. *Id.* at 103. That is to say, “nonprofit hospitals provide care ostensibly in order to maximize the public good; for-profit hospitals provide care as a means to maximize owner profit. Over time, however, developments in medical science, technology, and business economics have resulted in increased commercialization of both organizational forms, blurring these traditional distinctions.” *Id.*

9. *Id.* at 137.

10. *Id.*

11. *Id.* at 157–58.

12. *Id.*

13. *Id.* at 159 (“ACOs are among the key strategies under the ACA to improve quality and lower cost by promoting organizational structures that will coordinate and integrate the care provided by different service providers in various settings.”).

14. *Id.* at 166 (citing Thomas L. Greaney & Kathleen M. Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 1 (2005)). “Some have argued that the concept of ‘mission primacy’ – a ‘doctrinal recognition’ that a corporation’s ‘articulated mission’ should be its legally-enforceable primary objective (as is profit-maximization for a for-profit corporation) – should be more strictly applied to tax-exempt, nonprofit health care corporations in order to better ensure director fidelity to the organizations’ charitable missions.” *Id.*

15. *Id.* at 168–70 (“[T]hese entities ‘tread [] against the very essence of the for-profit motive’ by defining stakeholder benefit as the primary purpose of the organization, in contravention of which the organization may not act.”); see also *id.* at 169 (citing generally Christen Clarke, *California’s Flexible Purpose Corporation: A Step Forward, A Step Back, Or No Step At All?*, 5 J. BUS. ENTREPRENEURSHIP & L. 301, 307–09 (2013)). We described “the three most currently-prominent forms of hybrid legal structures: the ‘Flexible Purpose Corporation,’ the ‘Low-Profit Limited Liability Company,’ and the ‘Benefit Corporation.’” *Id.* at 170.

16. This was proposed by Dayna B. Matthew, Vice Dean and Professor of Law at the University of Colorado Law School. Matthew’s model embodies a new legal paradigm that she asserts is best suited to ‘implementing and achieving the goals of the ACA’ – ‘to universalize access to health care,’ while reshaping the private and public financing markets ‘and the organizational entities that deliver and control the quality’ of health care services. The basic idea is to extend those fiduciary obligations (*i.e.*,

Integrating these ideas into our assessment of the current state of the American health care delivery system, the objectives of the ACA, and the particular potential of ACOs, we concluded our article with a call for creation of a “new organizational paradigm” – a specific form of benefit corporation which we termed a “Health Care Benefit Corporation” (“HCBC”) – the details of which remained, at that time, to be fully explicated.

Subsequently, in a 2019 article, we attempted to “flesh out” those details.<sup>17</sup> We began by discussing the evolution of the concept of corporations and their governance, focusing more intensely on: the longstanding “shareholder-stakeholder debate;” the three traditional theories of the “existential nature” of the corporation itself (*i.e.*, the Fiction, Aggregate and Real Entity views); and, the (previously-noted) bifurcation of American corporations into for-profit and nonprofit forms. This background prompted us to question the “social and moral dimensions of the modern corporation,” which in turn led us directly to the (relatively) new conceptual constructs of “corporate social responsibility,” “social entrepreneurship/social enterprise,” “constituency statutes,” and lastly the “benefit corporation.”<sup>18</sup> We then undertook a more comprehensive examination of the proposed benefit corporation – the rationale behind it, its founders,<sup>19</sup> its continuing development, and its current status. We identified the fundamentals of the “Model Act” promulgated and promoted by its B Lab originators and reviewed several criticisms made by detractors of the Act. Importantly, we described several recent state “adaptations” of the Model Act, some of which we concluded would more suitably serve as prototypes for our proposed HCBC.<sup>20</sup>

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good faith, loyalty, and due care) that are already well-established in the profession of medicine ‘to all major participants in the health care industry’ who are involved in the direct delivery of health care services to patients. *Id.* at 177 (citing generally Dayna B. Matthew, *Implementing American Health Care Reform: The Fiduciary Imperative*, 59 BUFF. L. REV. 715, 744–45 (2011)).

17. Terry L. Corbett, *The Case For A Health Care Benefit Corporation*, 47 CAP. U. L. REV. 183, 189 (2019).

18. *Id.*

19. *See id.* at 187 n.3 (“The Benefit Corporation began as a ‘project of the non-profit organization B Lab.’ A white paper discussing the need and rationale for model legislation (and containing the model legislation itself) was drafted by principal authors William H. Clark, Jr., of Drinker, Biddle, & Reath LLP and Larry Vranka of Canonchet Group LLC.”).

20. We would here note that some other authors have recently called for health care companies to become benefit corporations. In an article published roughly the same time as our own in 2019, Professors Heled, Vertinsky and Brewer wrote:

In this Article, we suggest that a change in corporate form can be used to more closely align private incentives with public need by changing corporate incentives from the inside. We propose that companies involved in the provision of healthcare products and services should be encouraged or even required to assume alternative business forms that would both enable and require them to consider the needs of a broader range of stakeholders and the public interest in addition to shareholder value. We identify benefit corporations, broadly defined, as one preferred mechanism for achieving this. We conclude that this approach could help to change corporate behavior in ways that improve healthcare outcomes.

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Next, we returned our focus to the health care delivery system. We elaborated further on the “deontology” of American health care as a prelude to discussing the apparent growing need for greater “social responsibility” in the provision of health care services.<sup>21</sup> We identified the broadly-acknowledged continuing “drivers” of recent efforts to reform the delivery system (*i.e.*, escalating cost, system fragmentation, and compromised quality) and described four examples of ongoing reform initiatives that promote ever-increasing “system integration” – Hospitalist Programs, Clinical Co-Management, Patient-Centered Medical Homes, and Provider Clinical Integration.<sup>22</sup> We then expanded upon our earlier discussions of Accountable Care and the ACOs that are now hoped “to integrate, coordinate, and eventually finance the delivery of health care services” under the ACA.<sup>23</sup> Further, we delved more deeply into the topics of mission primacy and fiduciary duty, and included some additional discussion on the related issue of “medical trust.” Finally, we explained our “proposed HCBC legal structure in far-greater detail than our initial article, explaining the specific features necessary for it to provide a viable and preferred

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Yaniv Heled; Lisa Vertinsky; Cass Brewer, *Why Healthcare Companies Should (Be) Come Benefit Corporations*, 60 B.C.L.REV. 73, 74 (2019). These authors go on to say:

For purposes of this Article, we define ‘healthcare companies’ as for-profit business entities involved in the commercial development, manufacture, or distribution of healthcare products and services. Healthcare companies may include pharmaceutical companies and other developers of biomedical technology, distributors and retailers of medical supplies (including retail pharmacies), medical insurance companies, pharmacy benefit management companies, laboratories, and so forth. We acknowledge that healthcare markets are complex and operate in different ways, subject to different constraints, and that these markets are constantly changing, but we argue that private profit incentives largely explain choices made by healthcare companies and that a divergence of private and public interests persists across different parts of the market. Even though we largely focus on for-profit organizations, in Part III we suggest why in many cases benefit corporations may also be preferable to non-profit organizations, although we leave a more detailed comparison and analysis for a separate article.

*Id.* at n.8. While we agree with many of these authors’ contentions regarding the value and desirability of benefit corporations generally (be they the Model Act form or various state statutory adaptations thereof), as well as specifically for what has been called “development-of-care” companies (*e.g.*, pharmaceutical companies, medical equipment companies, etc.) and potentially for “financing-of-care” companies (*e.g.*, health plans and other insurance payers), we remain of the opinion that the Model Act form of benefit corporation is suboptimal for “delivery-of-care” companies (*i.e.*, institutional health care providers and integrated delivery systems). *See* Corbett, *supra* note 17, at 239–40. As discussed at length in our 2019 article, such companies would be best served by a “tailored” form of benefit corporation that has certain specific features: no “general public purpose” requirement, a bifurcated financial structure, and a legally-mandated singular focus on mission primacy and fiduciary duty. *Id.* at 321–26. Such features are intended to respond to the unique deontological character of “delivery-of-care” companies that arises from their inherent ethical (and increasingly, legal) obligations in their direct, “hands-on” provision of health care services. *Id.* at 331–35.

21. Corbett, *supra* note 17, at 244–53.

22. *Id.* at 255–71.

23. *Id.* at 190.

corporate framework for the operation of institutional health care providers.”<sup>24</sup> As we then summarized, the HCBC will essentially:

- Be a “membership corporation” utilizing a “shared governance structure” that includes both organizational and individual members – likely consisting of individual medical professionals (*e.g.*, doctors, nurses, technicians), administrative professionals (*e.g.*, managers, accountants, lawyers), community representatives (*e.g.*, previous/prospective patients, business owners, government employees), and individual representatives of other relevant and related company and/or institutional interests (*e.g.*, medical group practices, medical suppliers, third-party payers, etc.) – who govern a “clinically (and/or financially) integrated health care delivery system” through a “self-electing board” of participating “stakeholders;”
  
- That has a “hybrid” corporate form – comprised of *both* nonprofit and for-profit components – reflecting a “bifurcated financial structure” (based on an *a priori* “apportionment” of nonprofit and for-profit activities) that effectually limits the amount of “private inurement” that can occur (and in turn be deemed taxable), thereby reinforcing a better “calibration” between organizational “mission and margin;”
  
- That is committed to the “primacy” of a “dual organizational mission” – *i.e.*, *both* the ongoing and consistent provision of affordable, high-quality, high-value, and readily accessible health care services *and* targeted profit seeking and distribution (as necessary to attract equity investors and management talent, as well as provide access to taxable capital markets, to ensure the organization’s financial integrity); and
  
- That formally recognizes and accepts its “institutional fiduciary responsibilities” (and corresponding liability) *both* for the professional provision of competent health care *and* for the general accomplishment of its organizationally-mandated dual missions.<sup>25</sup>

We concluded with the hope that the HCBC, so structured, could better serve the legitimate needs and proper interests of the multiple stakeholders in integrated

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24. *Id.*

25. *Id.* at 336–37.

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delivery systems (particularly ACOs), and help rationalize and restore trust in the professional culture of medicine.<sup>26</sup>

Now, in this article, we hope to further advance that objective by suggesting how the HCBC could:

1. Improve care quality by explicitly embracing the ACA's integrated systems approach to a coordinated care model, further facilitating the development and appropriate use of health information technology and evidence-based clinical practice guidelines.
2. Enhance fairness and equity for victims of "iatrogenic injury"<sup>27</sup> by adopting an enterprise liability regime that promotes reconstruction of existing legal standards governing the medical and fiduciary duties and liabilities of integrated system providers.
3. Significantly reduce overhead costs by self-insuring the organization against its prospective medical and fiduciary liabilities.
4. Provide a preferred organizational framework for offering a more cost-efficient, market-competitive private health insurance option priced at cost to interested enrollees.
5. Create and sustain an organizational "culture of virtue" that upholds and reinforces medicine's professional norms and restores patient trust in today's institutional health care delivery systems.

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26. *Id.* at 339.

27. Professor Barry R. Furrow observes:

Patients are harmed frequently in hospitals, in as many as one-third of admissions. They die, suffer surgical injury, become infected, are disabled, are readmitted with problems, lose time from work, or otherwise experience what patient safety experts call 'adverse events,' a term describing the sometimes lethal byproducts of health care. These patient harms, these adverse events, happen because of staff errors, system failures of coordination and management, drug mismanagement, and a hundred other reasons, many of which are discovered after the fact. Health care institutions injure and kill patients one at a time – unlike cruise ship disasters or airplane crashes. The casualties are scattered over almost six thousand hospitals, obscuring the volume of harms that occur. These adverse events come in dozens of forms, caused by a multiplicity of factors.

Barry R. Furrow, *Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 439 (2012) (citing Virginia A. Sharpe & Alan I. Faden, *MEDICAL HARM: HISTORICAL, CONCEPTUAL, AND ETHICAL DIMENSIONS OF IATROGENIC ILLNESS* 4 (1998) (defining an "iatrogenic adverse event" as any "complication resulting from reactions to medication or procedures, physical injury or accident, psychological decompensation, nosocomial infections, and medical or nursing errors – including errors of omission") (emphasis added)).

## II. THE NEED FOR AN INTEGRATED, COORDINATED, AND EVIDENCE-BASED CARE MODEL

As of 2016, the United States had more than 6,000 hospitals – 3,000 nonprofit, roughly 1,300 for-profit, around 1,200 government-owned (at either the federal, state, or local levels), and a remaining few long-term care and psychiatric hospitals.<sup>28</sup> As we noted in our 2015 article:

Generally speaking, the current system has been viewed as competitive (in an unhelpful way), fragmented, and driven by counterproductive financial incentives. These features have resulted in growing concerns over poor quality, spiraling costs, and rising barriers to access – all issues that have been thoroughly addressed and documented elsewhere. There is seemingly broad consensus, professional and academic if not political, that the solution lies with transition to an ‘integrated and coordinated care model’ that is predicated upon ‘systems-based care management’ that will consistently produce efficient, high quality services through greater collaboration among system participants.<sup>29</sup>

### A. *The Systems Approach*

According to Professor P. Greg Gulick, Jr., the term “system” – when applied to health care – can have two different meanings: first, when applied in a “macro” or “national-level” sense, it can mean an aggregation of the taxonomy of companies<sup>30</sup> that comprise the entirety of the broad health care sector and the patients it serves;<sup>31</sup> second, when applied in a “micro” or “delivery-level” sense, it can also properly describe that which we are in fact here focusing on – an aggregation of direct, hands-on providers (*e.g.*, hospitals, physicians, therapists, laboratories, etc.) operating as an integrated delivery system (*e.g.*, an ACO).<sup>32</sup>

Professor Gulick explains how “General Systems Theory” derives from the 1940s’ work of biologist Ludwig von Bertalanffy:

[G]eneral System[s] Theory stands for the premise that ‘it is necessary to study not only parts and processes in isolation, but also to solve the decisive problems found in the organization and order unifying them,

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28. Barry R. Furrow, *The Limits of Current A.I. in Health Care: Patient Safety Policing in Hospitals*, 12 N.E. U. L. REV. 1, 3 (2020).

29. Corbett, *supra* note 3, at 145–46.

30. That is, “development-of-care” companies, “financing-of-care” companies, and “delivery-of-care” companies. Corbett, *supra* note 17, at 239–40.

31. P. Greg Gulick, Jr., *A Systems Thinking Approach to Health Care Reform in the United States*, 21 DEPAUL J. HEALTH CARE L. 1, 1–2 (2019).

32. *Id.*

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resulting from dynamic interactions of parts, and making the behavior of parts different when studied in isolation or within the whole.’ General System Theory recognizes that an imbalance in one part of a system throws the entire system out of balance, so the whole system must be taken into consideration when studying, investigating or reforming the system.<sup>33</sup>

He then describes how application of General Systems Theory over time in the fields of sociology and organizational behavior “has inspired theories such as ‘Systems Thinking,’ which encourages a holistic view of other types of complex systems.”<sup>34</sup> Systems Thinking, he says, “is ‘an approach to problem solving that views ‘problems’ as part of a wider, dynamic system.”<sup>35</sup> He goes on to suggest that much of the failure of health care reform efforts to date is due to a too-narrow focus on “a particular bad act, or agent, or even a particular subsystem,” rather than on the system as a complex whole.<sup>36</sup>

Lastly, Professor Gulick distinguishes a “complex system” from a “complex adaptive system”<sup>37</sup> and opines that the entire U.S. health care system is a complex adaptive system,<sup>38</sup> which he then characterizes:

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33. *Id.* at 64 n.7–8 (citing LUDWIG VON BERTALANFFY, GENERAL SYSTEMS THEORY: FOUNDATIONS, DEVELOPMENT, APPLICATIONS (George Braziller ed., New York 1968)).

34. *Id.* at 2–3.

35. *Id.* at 3.

36. *Id.*

37. He explains the difference as follows:

A *complex system* is ‘one in which the whole is different from the sum of its parts.’ This can be understood by contemplating a chemical reaction in which the characteristics of the substances that are mixed together differ considerably from the resulting compound. Nonlinear systems are always complex. Complex systems form organically from interactions between the various agents within the system and the reactions to these interactions. Complex systems that exhibit the tendency to be self-organizing, the existence of emergent properties, sensitivity to initial conditions, and resistance to change are referred to as *complex adaptive systems*. The defining characteristic of a complex adaptive system is the ability of the agents within the system to receive feedback from external and internal sources and learn from, or adapt to, this feedback. Complex systems are generally composed of other related complex subsystems, which are composed of interrelated and interdependent agents, ‘for which the degree and nature of their relationships is imperfectly known.’

*Id.* at 13 (emphasis added).

38. The U.S. health care system is not just a complex system, but it is a complex adaptive system. A complex adaptive system is ‘a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that one agent’s actions changes the context for other agents.’ In addition to being non-linear, self-organizing, and governed by feedback, complex adaptive systems also share the following characteristics: they are constantly changing, tightly linked, history dependent, counter-intuitive, and resistant to change. Although every complex adaptive system is unique they all exhibit four characteristics, complex adaptive systems are: dynamic, massively entangled, robust, and emergent, (or self-organizing). As will be demonstrated . . . , complex adaptive systems like the U.S. health care system, exhibit all four of these characteristics.

*Id.* at 13–14.

On the national-level, the U.S. health care system has never been referred to as a ‘well-oiled machine.’ There are many well-documented and discussed challenges with the U.S. health care system, including high-costs, difficulty accessing care, and problems with over and under-utilization (and related quality of care issues). There are so many different parts and incentives and causative pathways that thinking of the U.S. health care system as a ‘system’ analogous to a ‘machine’ is the wrong characterization in the first place. Instead, the U.S. health care system should be viewed as a complex [adaptive] system, which is more analogous to a ‘living organism’ with an interrelationship and interdependency between the parts. This re-characterization of the U.S. health care system as a living organism rather than a machine has implications for health care reform. Instead of simply reforming one aspect of the system (repairing a part of the machine), it is necessary to consider a holistic reform that will impact the entire system.<sup>39</sup>

### *1. Who, Exactly, is Taking Care of Me?*

Simply put, while we may be said to have a “complex adaptive system” of health care delivery in this country (at both the macro and micro levels), we remain far from having an “integrated and coordinated care model” that operates at any level to consistently provide high-quality services that are cost-efficient and readily-accessible. Many believe that the fundamental problem continues to be insufficient communication, coordination, and collaboration among our “fragmented” system participants.<sup>40</sup> For example, health care writer Atul Gawande has gone so far as to liken the inefficient way that we deliver health care services to one’s foregoing use of a general contractor “to assemble and supervise a team” when remodeling a home – choosing instead to hire individual tradesmen and paying them for their piecework.<sup>41</sup> Professor William M. Sage makes an analogous point:

[T]his Article posits that prices for health care are too high, quality too unreliable, and innovation too limited in large part because we have been buying and selling the wrong things. In other complex economic sectors, consumers purchase assembled products from

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39. *Id.* at 3–4.

40. In our 2019 article, we spend considerable time discussing system fragmentation as one of the “three principal and closely-interrelated drivers of health care reform” (along with cost and quality). See Corbett, *supra* note 17, at 255–62.

41. *Id.* at 259 (first quoting Elizabeth L. Rowe, *Accountable Care Organizations: How Antitrust Law Impacts the Evolving Landscape of Health Care*, 2012 U. ILL. L. REV. 1855, 1869–70 (2012); and then citing Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, NEW YORKER, June 1, 2009, at 36)).

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which they expect concrete, demonstrable benefits. Producers aggressively manage their supply chains, product performance can be measured, and products can be warranted for safety and effectiveness. In health care, by contrast, most consumers purchase only isolated process steps and components. Physicians strive to deliver reimbursable relative value units (RVUs), not definitive treatment packages. Hospitals coproduce care in vague collaboration with physicians and often have limited leverage over expensive inputs such as medical devices. This causes the health care we receive to be shoddily put together, overly costly to produce, insufficiently responsive to consumers' needs, and difficult to monitor for quality.<sup>42</sup>

Professor Sage goes on to suggest that today's institutionally-provided health care "emphasizes incomplete process steps and isolated components rather than assembled products."<sup>43</sup> While individual physicians still perform certain personal tasks for their patients, most everything else they "order" for their patients – that is, drugs, diagnostic tests, therapeutic services, routine nursing care, evaluation by additional specialists – all are provided by other health care professionals.<sup>44</sup> Each of these professionals, in turn, similarly call upon others for further discrete inputs, too often resulting in an aggregate service experience for the patient that is unstructured and lacking in clinical cohesion.<sup>45</sup> The presence of health insurance and other sources of third-party payment only exacerbates the situation by "aggregating professional process steps and other traditional care components and inputs into assemblages [for payment purposes] that appear coherent but remain disconnected from the efficient solution of complex medical problems."<sup>46</sup>

Nonetheless, "[t]o a surprising degree, even highly sophisticated medical services are still conceptualized as extensions of an individual doctor's traditional black bag and prescription pad."<sup>47</sup> The only part of this "individualistic paradigm" that actually persists in today's health care reality, however, is "the strength of the therapeutic bond between a patient and the individual[s] that patient perceives as his or her expert caregiver[s]."<sup>48</sup> Increasingly, that caregiver is some other professional, some variably-trained

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42. William M. Sage, *Assembled Products: The Key to More Effective Competition and Antitrust Oversight in Health Care*, 101 CORNELL L. REV. 609, 613 (2016).

43. *Id.* at 619.

44. *Id.*

45. *Id.*

46. *Id.* at 630.

47. *Id.* at 618.

48. *Id.* at 619.

paraprofessional, or (more often) one or more *ad hoc* health care “teams” which too-often lack effective cohesion.<sup>49</sup>

## 2. *The Implications of Today’s “Team” Health Care*

It is important to note that medical teams are often formed temporarily from various sources for single episodes of care. Some who become part of the team for a given episode may be independent contractors rather than employees of the healthcare facility where care is provided. Physicians in a particular medical practice may furnish services as team members in a number of diverse contexts. The members of these teams, however, are rarely trained together. They also may come from different disciplines and educational backgrounds. Further, team training in the medical profession tends to be limited and insufficiently grounded in a scientific understanding of the human factors that influence effective teamwork. It may also be haphazard. For example, physicians frequently do not have a good grasp of how hospitals function.<sup>50</sup>

The fact is, and for some time has been, that health care today “requires the coordinated participation of many individuals with different skills and training in one or more settings with advanced physical plants, fixed technologies, consumable supplies, and information resources.”<sup>51</sup> It is for this reason that *ad hoc* teams have evolved somewhat spontaneously in response to our complex adaptive system of health care delivery. However, this expectable response to system complexity has also created increased opportunity for multiple factors to contribute, in inadvertent concert, to medical error.<sup>52</sup> Recognition of this fact has emphasized the need for what has been variously called “root cause” or “contributing factors” analysis when such errors occur:

In more complex systems settings, there are almost always multiple factors contributing to mistakes. No one of these factors alone is the root cause. Errors are a function of natural weaknesses in human cognition and behavior (human factors) interacting with systems errors (latent errors), with the result that any well-intentioned professional who is placed in a poorly designed system is likely to commit an error. Hence, in these settings RCA [Root Cause Analysis]

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49. See John R. Grout et al., *Mistake-Proofing Medicine: Legal Consideration and Healthcare Quality Implications*, 14 MINN. J.L. SCI. & TECH. 387, 402 (2013) (describing the formation of teams in the medical care setting and lack of team training).

50. *Id.* at 402.

51. Sage, *supra* note 42, at 619.

52. See Grout et al., *supra* note 49, at 402–03 (noting the association between lack of team coordination and higher rates of adverse events for patients in hospital settings).

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might be better termed ‘contributing factors analysis.’ Contributing factors include such influences as management decisions, organizational processes, work conditions, workload, supervision, knowledge, ability, and barriers.<sup>53</sup>

It has been noted that one of the best ways to deal with such “medical failings” is to “redesign both the organization of and the equipment used by the medical team” as and when necessary – and that it increasingly is the hospital (or other institutional provider) which is in the best “strategic position” to do so.<sup>54</sup> The question remains, however, who is ultimately accountable and legally liable for the patient’s individual experience when such medical failings result in a bad outcome?

Professor Elliott Fisher – generally credited with “first introducing the modern ACO concept”<sup>55</sup> – spoke to this question in a 2006 article discussing the continuing need for quality improvement and cost control:

A distinguishing feature of many of these efforts, however, is their focus on the individual provider as the locus of both performance assessment and accountability. This focus reflects the historical development, oversight mechanisms, and payment systems that prevail in the U.S. health care system and the interest of providers to be held accountable only for care that is within their direct control. *The limitations of this approach are increasingly apparent.* The provision of high quality care for any serious illness requires coordinated, longitudinal care and the engagement of multiple professionals across different institutional settings. Also, many of the most serious gaps in quality can be attributed to poor coordination and faulty transitions. For these reasons, a recent Institute of Medicine

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53. *Id.* at 420.

54. See Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 413 (1994). The authors explain why such redesign is often necessary:

[T]he inevitable human frailty of individual physicians and the undeniable effectiveness of ‘team’ approaches to reducing patient injury point to the health care enterprise as the most effective mechanism for addressing medical malpractice. The truth is that the individual physician is now typically a member – admittedly a crucial member – of a larger team of medical personnel, all of whom have their own special training and responsibilities for the course of treatment of the same patient. One of the important ways in which things sometimes go wrong within such medical teams is through failures of communication among the physicians, clinicians, nurses, and other staff members (for example, about a patient’s earlier adverse reaction to a particular drug).

*Id.*

55. Corbett, *supra* note 17, at 272.

(IOM) report called for efforts to foster *shared accountability among all providers* for the quality and cost of care.<sup>56</sup>

We will further discuss this idea of “shared accountability” in later sections;<sup>57</sup> for now, let us next examine some particular developments that are impacting team health care.

*a. Health Information Technology, Data Analytics, and Artificial Intelligence*

The Institute of Medicine report, *To Err Is Human* (IOM Report), published in 1998, estimated a maximum of 100,000 patient deaths annually occurred due to medical errors. The IOM Report with its extrapolation of high levels of patient harms – ‘spurred the development of the Patient Safety Movement, which intensified the search for adverse events and means of preventing them.’

Three years later the IOM published *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*, which stressed the importance of health care systems design. It argued that most errors and adverse events in health care are caused by *problems with system processes and not provider error*. The clear implication is that . . . it is time to use AI [Artificial Intelligence] to supercharge the tools for detecting and preventing such errors.<sup>58</sup>

The communication, coordination, and collaboration necessary for safe and effective team health care in today’s increasingly complex medical environment is becoming ever-more dependent on a variety of Health Information Technologies (“HIT”).<sup>59</sup> Central among these technologies available to institutional health care providers and their developing systems is the Electronic Medical Record (“EMR”) – sometimes referred to as the Electronic Health

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56. Elliott Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44, w45 (2006) (emphasis added).

57. See *infra* Part III.

58. Furrow, *supra* note 28, at 19 (emphasis added).

59. See Julianne Sweeney, *Healthcare Informatics*, 21 ONLINE J. NURSING INFORMATICS 1, 1–2 (2017) (defining healthcare informatics and its proliferation in the healthcare field). It should be noted that the proliferation of Health Information Technologies over the last three decades has given rise to an entire academic and professional field of “Healthcare Informatics,” which has been defined as “the integration of health-care sciences, computer science, information science, and cognitive science to assist in the management of healthcare information.” *Id.* (quoting Virginia K. Saba & Kathleen McCormick eds., *ESSENTIALS OF NURSING INFORMATICS* 232, 6th ed. 2015)). It is not our purpose here to delve deeply into this expanding field, but only to examine some of its impacts on system development for effective team health care.

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Record (“EHR”).<sup>60</sup> To maximize their utility, such EMRs must be able “to integrate information from multiple sources, capture data at the point of encounter, and support caregiver decision-making.”<sup>61</sup> According to the IOM, it is critical that EMR capabilities include: “clinical documentation, results management, order entry management, decision support, electronic communication and connectivity, patient support, administrative process support, and population health reporting.”<sup>62</sup>

Despite the “existing and evolving capabilities inherent in advanced EMR technology,” some have described our health care system as remaining “arguably the world’s largest, most inefficient information enterprise.”<sup>63</sup> They see the technology’s potential for reducing medical malpractice going “largely unrealized” due to continuing poor communication and “a lack of understanding of patterns of error resulting from shared information,” rather than from “purely individual human mistakes.”<sup>64</sup> Acknowledging that even the best of technologies are no more than sophisticated tools that require proper application and continuous oversight, several issues continue to present ongoing challenges:

A major issue is deciding who takes responsibility for maintaining and ensuring that EMRs are up to date, given the necessity of shared records. Does a physician have a responsibility to act upon information supplied electronically by a patient and, if so, under what circumstances? Which physician, among various physicians providing care for various ailments, has the responsibility to take action if one of the other physicians enters evidence indicating a potential health-threatening issue? Who is responsible for ensuring patient information is current and correct, and who, if anyone, has the responsibility for periodically updating the system with current patient data, reconciling conflicting data, and deciding on the disposition of information that arrives after a patient is discharged? Which physician, among various sets of physicians providing care for specific ailments, has responsibility for taking action if evidence indicating a potential health-threatening issue is placed in a patient’s EMR? *How far should legal liability extend in a chain of providers?*<sup>65</sup>

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60. See John W. Hill et al., *Law, Information Technology, and Medical Errors: Toward a National Healthcare Information Approach to Improving Patient Care and Reducing Malpractice Costs*, 2007 U. ILL. J.L. TECH. & POL’Y 159, 195 (2007) (noting the importance of EMRs to the future of health care systems and their role to support caregiver decision-making).

61. *Id.*

62. *Id.* (citing INST. OF MED., KEY CAPABILITIES OF AN ELECTRONIC HEALTH RECORD SYSTEM 7 (2003) (available at <http://www.nap.edu/catalog/10781.html>)).

63. *Id.* at 202 (citing Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Healthcare? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFF. 1103, 1103 (2005)).

64. *Id.*

65. *Id.* at 213–14 (emphasis added).

Related to HIT, and in fact further empowered by it to “discover and track the systematic causes of patient harms,” is the science of “data analytics.”<sup>66</sup> Investigation of “iatrogenic injury”<sup>67</sup> used to be “focused on the individual physician as the primary causal agent of patient harm.”<sup>68</sup> Today, the focus has shifted to the hospitals themselves and other direct organizational providers – “the complex institutions where most high-risk care is now delivered.”<sup>69</sup>

Modern data analytics encompasses three separate scientific disciplines: “statistics, the study of data relationships using numbers; artificial intelligence, the use of software and/or machines that display human-like behaviors; and machine learning or deep learning, the use of algorithms learning from data to make predictions.”<sup>70</sup> Taken together, these tools permit modern data analytics to help create “systems by which adverse events are reduced by design, rather than a checklist approach” – e.g., “to move beyond observational reports to the computer tracking of infection rates, high readmissions, and other adverse events by physicians, nurses, surgical teams, and other providers.”<sup>71</sup> Such capability is essential to the previously-discussed “root cause” or “contributing factor” analysis of complex medical errors, and to identify instances where multiple institutional deficiencies combined to harm a patient. Again, it is generally only large, institutional providers who have the financial and technical wherewithal to obtain and effectively use this kind of advanced capability.

Finally, and perhaps most fraught with complicating implications, is the topic of latest-generation artificial intelligence systems such as IBM’s “Watson.”<sup>72</sup> Writer Jessica S. Allain, in a 2013 article, characterized Watson as “a medical supercomputer with borderline artificial intelligence.”<sup>73</sup> A more

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66. Furrow, *supra* note 28, at 4.

67. Professor Furrow notes:

The use of early forms of data analytics to examine patient injury in hospitals is found in the use of statistical analysis based on data collection . . . . Iatrogenic harm, as it used to be called, was studied systematically by three early pioneers in medical data collection on patient safety: Florence Nightingale, Dr. Ernest Codman, and Dr. Elihu Schimmel. . . . The tools they developed laid the foundation for modern data analytics applied to health care.

*Id.* at 7.

68. *Id.* at 5.

69. *Id.*

70. *Id.* at 11 (citing *Data Mining: What it is and Why it Matters*, SAS, <https://www.sas.com/enus/insights/analytics/data-mining.html> (last visited May 27, 2019)).

71. *Id.* at 27.

72. See Jessica S. Allain, *From Jeopardy to Jaundice: The Medical Liability Implications of Dr Watson and Other Artificial Intelligence Systems*, 73 LA. L. REV. 1049, 1049 n.2 (2013) (explaining that Watson was “named after International Business Machines Corporation’s (IBM) founder Thomas J. Watson.”).

73. *Id.* at 1049.

technical description can be found in a 2019 article by A. Michael Froomkin, *et al.*:

Machine learning (ML) is the discipline of automated pattern recognition and making predictions based on patterns that are detected. Neural networks are one of several types of ML. ‘Deep Learning,’ another term of use, refers to neural networks with many layers. ‘AI’ is a more general term applied to automated techniques that produce outputs which appear to mimic human reason or behavior. Thus, deep-learning systems are a subset of neural networks, which are a subset of ML, which is itself a subset of AI. IBM’s *Watson . . . is perhaps the best-known example of a neural-network-based medical diagnostic system.*<sup>74</sup>

Allain characterizes Watson’s considerable array of potential capabilities as including: analysis of patients’ genomes, review of patients’ complete medical records, and searching entire databases of medical knowledge and research to facilitate diagnoses and plans of treatment – all accomplished “in a matter of seconds.”<sup>75</sup> She predicts that Watson eventually “may be able to interface directly with medical equipment and directly treat patients with much less physician interaction.”<sup>76</sup> She notes that “Watson is capable of actually understanding questions posed and giving the user the correct answer” – representing “an extraordinary leap in artificial intelligence, deep analytics, and language processing.”<sup>77</sup>

Just as with robotic surgical systems, cybermedicine,<sup>78</sup> telemedicine,<sup>79</sup> and other emerging medical technologies, it is probably safe to assume that AI systems such as Watson will eventually develop to the point of reasonable cost-effectiveness and wide professional acceptance.<sup>80</sup> The point bears making that the expanded use of telemedicine during the 2020 Covid-19 Pandemic has well illustrated how the acceptance of such new technologies can be hastened by unanticipated circumstances.<sup>81</sup>

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74. A. Michael Froomkin et al., *When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning*, 61 ARIZ. L. REV. 33, 35 n.4 (2019) (emphasis added).

75. Allain, *supra* note 72, at 1049.

76. *Id.* at 1051.

77. *Id.* at 1053.

78. “[G]enerally defined as ‘the discipline of applying the Internet to medicine.’” *Id.* at 1057.

79. “[G]enerally defined as ‘the long-distance practice of medicine via telecommunications.’” *Id.*

80. *Id.* at 1055–60.

81. Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic – United States, January-March 2020*, 69 MORBIDITY & MORTALITY WKLY. 1595, 1598 (explaining how the COVID-19 pandemic has shifted the delivery of health care with a share increase in the use of telehealth).

Nonetheless, the question still to be confronted is how the law will deal with the liability implications of these new and still-evolving technologies. Is Watson essentially no more than a computerized set of clinical practice guidelines, or is it rather an autonomous (albeit non-sentient) “new member” of the health care team? Should medical mishaps caused by, or otherwise attributed to, Watson’s “mistakes” be governed by the law of medical malpractice, vicarious liability, product liability, or something else?<sup>82</sup> As Allain observes: “Watson partially fits into all of these categories, but no single theory of recovery sufficiently covers the liability questions that may arise from a computer system capable of practicing medicine.”<sup>83</sup> Moreover, if Watson is (or eventually becomes) arguably more effective, efficient, and reliable than any individual medical provider or collective team of providers, how does its presence (or even just its availability) affect the applicable standard of care? Such questions will be examined in upcoming sections.

### B. Evidence-Based Medicine

At least two authors have offered specific definitions of “Evidence-Based Medicine” (“EBM”). According to Allain: “[E]vidence-based medicine is the ‘conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.’”<sup>84</sup> Professor Kristin Madison characterizes it more simply as “a term applied to medical decision-making based on ‘good evidence of effectiveness and benefit.’”<sup>85</sup> Unfortunately, such evidence is too often lacking or not utilized: “A much publicized RAND Corporation study of clinical decision[-]making found that American patients

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82. *Id.* at 1060.

83. *Id.* at 1060–61.

84. *Id.* at 1055 n.42 (citing Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J. L. & MED. 361, 385–86 (2001) (citation omitted) (further noting that “[n]ational standards for evidence-based guidelines can be found online through the National Guideline Clearing House, MedScape, AHRQ, organizations for medical specialties, and the U.S. National Library of Medicine Medline source.”).

85. Kristin Madison, *Donabedian’s Legacy: The Future of Health Care Quality Law and Policy*, 10 IND. HEALTH L. REV. 325 (2013) (citing David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9, 14 (2005) (quoting David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9, 14 (2005) (“formally defining evidence-based medicine as a ‘set of principles and methods intended to ensure that to the greatest extent possible, medical decisions, guidelines, and other types of policies are based on and consistent with good evidence of effectiveness and benefit’”)).

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receive only 54.9 percent of ‘recommended care’ when measured against a set of more than four hundred evidence-based best-practice standards.”<sup>86</sup>

Professor Jessica Mantel has observed that “[a] major source of uncertainty in medicine is the lack of authoritative evidence and guidelines on the appropriate course of treatment.”<sup>87</sup> She notes that “less than half of medical decisions [are] supported by adequate evidence regarding an intervention’s effectiveness . . . .”<sup>88</sup> with the result that “clinicians regularly confront ambiguous choices regarding how best to manage their patients’ care.”<sup>89</sup> Adding further to the uncertainty prevalent in medical practice is the inevitable variation among individual patients’ clinical response to a given treatment, “inherent value choices,” and benefit/risk tradeoffs that patients must make, as well as “the complexity and breadth of information physicians must sort through . . . .”<sup>90</sup>

The Patient Protection and Affordable Care Act (“ACA”) of 2010, in Section 6301, attempts to address this situation by mandating “patient-centered outcomes research as a part of the larger goal of developing comparative clinical effectiveness research (CER).”<sup>91</sup> “The section defines ‘comparative clinical effectiveness research’ to mean ‘research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments [and] services . . . .’”<sup>92</sup> The law now putting such focus on CER is expected to “have a profound effect on standardizing physician practice” and promoting best practices generally.<sup>93</sup>

### 1. *Professionally-Acceptable Clinical Practice Guidelines (“CPGs”)*

PPACA, along with the stimulus bill entitled the American Recovery and Reinvestment Act of 2009 (Recovery Act), [*i.e.*, together, the “ACA”] represents a major federal initiative to standardize medical practice – a systematic and well-funded national effort to improve American medicine. Together they pour millions of dollars into government-funded research on *effectiveness, best practices, and*

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86. M. Gregg Bloche, *The Emergent Logic of Health Law*, 82 S. CAL. L. REV. 389, 402 n.33 (2009) (citing Elizabeth A. McGlynn *et al.*, *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2642 (2003)).

87. Jessica Mantel, *The Myth of the Independent Physician: Implications for Health Law, Policy, and Ethics*, 64 CASE W. RES. L. REV. 455, 472 (2013).

88. *Id.* at 473 (citing CONG. BUDGET OFFICE, RESEARCH ON THE COMPARATIVE EFFECTIVENESS OF MEDICAL TREATMENTS: ISSUES AND OPTIONS OR AN EXPANDED FEDERAL ROLE 9 (2007)).

89. *Id.* at 474.

90. *Id.* at 474–76.

91. Barry R. Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1727, 1738 (2011); Patient Protection and Affordable Care Act, 42 U.S.C.A. § 1320e(b)–(c) (2019) (establishing the Patient-Centered Outcomes Research Institute).

92. *Id.*; Patient Protection and Affordable Care Act, 42 U.S.C. § 1320e(a)(2)(A) (2019).

93. Furrow, *supra* note 91, at 1739.

*practice guidelines. This research is backed by new centers and initiatives to disseminate findings and motivate providers to incorporate them into practice.*<sup>94</sup>

“The Institute of Medicine defines CPGs as ‘statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.’”<sup>95</sup> However, the IOM has also said that “‘the quality of CPG development processes and guideline developer adherence to quality standards have remained unsatisfactory and unreliable for decades.’”<sup>96</sup> Professor Laura D. Hermer observes that “[l]ack of unanimity, failure to consistently obtain independent review, commercial conflict of interest, and personal bias all complicate CPG development. Varieties of schema have been developed to address these problems, but none has yet been systematically implemented.”<sup>97</sup>

It is perhaps because many people feel that “[g]overnment-generated practice guidelines and best practices are likely to be an improvement over the currently predominant medical-specialty-created guidelines” that the ACA “requires the HHS Secretary to identify existing and new clinical practice guidelines.”<sup>98</sup> That is exactly what the Agency for Healthcare Research and Quality (“AHRQ”) did up until July 16, 2018 – the date that the Trump Administration effectively defunded the National Guideline Clearinghouse (“NGC”).<sup>99</sup> “According to the AHRQ, it’s possible another organization will take over managing the guidelines clearinghouse. However, ‘it is not clear’ when or if the clearinghouse or something like it will be online again.”<sup>100</sup>

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94. *Id.* at 1736 (emphasis added) (citing American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009)).

95. Laura D. Hermer, *Aligning Incentives in Accountable Care Organizations: The Role of Medical Malpractice Reform*, 17 J. HEALTH CARE L. & POL’Y 271, 281 (2014) (quoting INST. OF MED., CLINICAL PRAC. GUIDELINES WE CAN TRUST 4 (Robin Graham et al. eds., The National Academies Press, 2011)).

96. *Id.* at 283 (again citing INST. OF MED., CLINICAL PRAC. GUIDELINES WE CAN TRUST 4 (Robin Graham et al. eds., The National Academies Press, 2011)).

97. *Id.*

98. Furrow, *supra* note 91, at 1741.

99. Andrew Bergman, *Explained: The Shutdown of the National Guideline Clearinghouse and the Independent Efforts to Launch a Replacement*, SUNLIGHT FOUNDATION (July 20, 2018, 04:29 PM), <https://sunlightfoundation.com/2018/07/20/explained-the-shutdown-of-the-national-guideline-clearinghouse-and-the-independent-efforts-to-launch-a-replacement/>. “On Monday, July 16, [2018] the Agency for Healthcare Research and Quality (AHRQ) shut down its National Guideline Clearinghouse (NGC), formerly hosted at [www.guideline.gov](http://www.guideline.gov), a website that had gotten about 200,000 visitors per month, according to AHRQ, and, for almost 20 years, had been medical professionals’ go-to resource for finding and understanding medical guidelines.” *Id.*

100. Lauren Vogel, *Trump Administration Shatters Clinical Guidelines Database*, 190 CANADIAN MED. ASS’N J. E841, E841 (2018).

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In view of this obvious setback, another observation of Professor Hermer becomes all the more relevant: “The use of best practices could arguably be both complemented and furthered by *reforming medical malpractice law* to expand the use and importance of appropriately-developed clinical practice guidelines (CPGs) in medical malpractice cases.”<sup>101</sup>

### III. RECONSTRUCTING MEDICAL/FIDUCIARY DUTIES AND LIABILITY

Professor M. Gregg Bloche has opined: “Medical tort law’s approach to health care quality and value is a relic of past, disproven premises about the practice of medicine.”<sup>102</sup> He explains:

*Tort law* can make another contribution to health care quality and value by incorporating state-of-the-art, *systems approaches* to the management of medical services. This will require *moving beyond blame for individuals* and toward *shared duties* to disseminate and adopt *evidence-based protocols, coordinate diagnosis and treatment* in complex cases, employ *information systems* that avert mistakes, and report and learn from errors. For example, a doctor’s failure to prescribe beta blockers or aspirin to a heart attack patient upon discharge from the hospital should be treated not just as negligence on her part, but as *breach of duty by the hospital* – if the hospital has not made these medications part of its post-heart-attack protocol and adopted monitoring practices to minimize the risk of their omission. And a nurse’s misunderstanding of a doctor’s hard-to-read handwritten order, resulting in a fatal overdose, should be understood not merely as the nurse’s (or the doctor’s) negligence, but as the hospital’s breach of its duty to employ reasonably safe information systems.<sup>103</sup>

In a 2008 article, Professors Michelle M. Mello and David M. Studdert discuss the results of “a large empirical study of closed malpractice claims” that they conducted from 2001-2006 – the “Malpractice Insurers Medical Error Prevention and Surveillance Study (“MIMEPS”).<sup>104</sup> The study had three major goals: (1) to determine “the prevalence of medical error among claims;” (2) to discover “the failures and breakdowns in care” that resulted in the claims; and, (3) to identify “promising prevention measures.”<sup>105</sup> The study resulted in three key findings implicating, if not outright contradicting, traditional tort doctrine:

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101. Hermer, *supra* note 95, at 281 (emphasis added).

102. Bloche, *supra* note 86, at 462.

103. *Id.* at 468 (emphasis added).

104. Michelle M. Mello & David M. Studdert, *Deconstructing Negligence: The Role of Individual and System Factors in Causing Medical Injuries*, 96 GEO. L.J. 599, 601 (2008).

105. *Id.*

first, that “the causality of medical injuries is multifactorial and weblike” (contrary to the customary notion of a “causal chain”); second, that in making causality determinations in complex medical situations, it is difficult to separate individual failures from the operative system environments in which they occur (raising doubts about “medical malpractice doctrine’s heavy focus on individual liability”); and third, “the patterns of etiologic factors” indicate that effective “opportunities for injury prevention” most likely exist “at the organizational level” (rather than the individual level).<sup>106</sup> Accordingly, the authors argue:

Like most branches of tort law, medical malpractice is largely premised on the notions that injuries arise from individual carelessness or lack of expertise, that culpable actors can be readily identified, and that their negligence can be deterred by setting damages sufficiently high to induce medical professionals to take due care.

The emerging science of patient safety takes a very different view of the occurrence and prevention of medical injury. This field, which draws heavily from the traditions of industrial organization and complex-systems engineering, emphasizes the role of ‘system failures’ in causing injuries, rejecting simple characterizations of error as individual physicians’ carelessness or incompetence. A ‘system’ in this context is ‘a set of interdependent elements,’ both human and non-human, ‘interacting to achieve a common aim.’ *In other words, the concept refers to the interrelationships among health care providers, the tools they use, and the environment in which they carry out their work.* The system view of accident causation asserts that it is misguided to prioritize, and dead wrong to focus exclusively on, lapses by individual health care providers because most medical outcomes, including those that flow from errors, are essentially *the product of organizational structures and processes.* It is a view that resonates with providers at the front lines of care.<sup>107</sup>

From all of this, the authors conclude that a “*realigning*” or “*reorientation*” of tort doctrine “*to expand corporate or enterprise liability is needed.*”<sup>108</sup>

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106. *Id.*

107. *Id.* at 600 (emphasis added).

108. *Id.* at 601 (emphasis added).

### A. Redefining Medical Malpractice

The typical defendants in U.S. medical malpractice lawsuits are healthcare providers *targeted for individual acts of negligence*, either directly or through the doctrine of respondeat superior. However, according to the Institute of Medicine (“IOM”), blaming an individual does little to prevent medical errors and improve patient safety, because most errors can only be prevented by identifying and resolving systemic failures. Although individual provider negligence should be, and is, addressed through the tort system, *healthcare organizations are rarely held accountable for acts of systemic or organizational negligence*. As a result, the malpractice system fails to promote the systemic change in healthcare organizations needed to improve patient safety.<sup>109</sup>

According to Professor James F. Blumstein, the “central message” of the above-noted IOM report<sup>110</sup> “was that ‘errors are caused by faulty systems not by faulty people.’”<sup>111</sup> Such assertion “is in considerable tension with many traditional assumptions and premises of medical malpractice doctrine” and “pose[s] direct challenges to traditional medical malpractice norms and understandings.”<sup>112</sup> Specifically, Blumstein notes that the systems approach advocated by the IOM deemphasizes “individual responsibility or accountability through legal liability”:

... Many of the strategies . . . , such as protections from discovery for error-reporting and the elimination of identifying characteristics from data collected, would make imposition of legal liability more difficult or impossible. Indeed, the systems approach advocated by the IOM, in essence, *views traditional medical malpractice doctrine, itself justified as a form of quality assurance as well as a mechanism for victim compensation, as something of an impediment to achieving patient safety.*<sup>113</sup>

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109. Mindy Nunez Duffourc, *Repurposing the Affirmative Defense of Comparative Fault in Medical Malpractice Cases to Improve Patient Safety*, 16 IND. HEALTH L. REV. 21, 21 (2018) (emphasis added).

110. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Krohn, et al. eds., 2000).

111. James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace*, 11 ANNALS HEALTH L. 125, 138 (2002) (citing Lucian L. Leape, *Foreword: Preventing Medical Accidents: Is “Systems Analysis” the Answer?*, 27 AM. J. L. & MED. 145, 145 (2001)).

112. *Id.* at 139.

113. *Id.* (emphasis added.)

Traditionally (and still currently), medical malpractice law is governed by state-specific common law and judicial rules that treat it as a particular species of the tort of negligence.<sup>114</sup> Generally speaking, every state jurisdiction requires the plaintiff in a medical malpractice action to establish four common law elements as regards their alleged medical injury:

1. Duty – as defined by the applicable “standard of care”
2. Breach – of that standard, as demonstrated by expert testimony
3. Proximate cause – establishing the legal relationship between the breach and the alleged injury
4. Damages – the medical injury resulting in compensable harm<sup>115</sup>

Because of the obvious tension between the IOM approach and the “existing regime of medical malpractice liability doctrine,” Blumstein urges “some hard rethinking” characterized by “constructive dialogue and flexibility” to reach a needed “doctrinal hybrid.”<sup>116</sup> With that advice in mind, we will proceed with our discussion using the traditional medical malpractice construct as our analytical framework.

*1. What was the Duty and by Whom was it Owed?*

First, let us begin by openly acknowledging our bias. Blumstein has characterized two “competing visions of medical care – the professional model and [the] economic model.”<sup>117</sup> While these two models are not mutually exclusive, they can be distinguished by their principal attributes. The professional model: dictates that medical diagnosis and treatment be based solely on scientific evidence and criteria without empirical or normative regard of financial considerations, and be “available to all patients on the basis of medical need.”<sup>118</sup> The economic model, in contrast: “advocates the virtues of pluralism in the marketplace and the desirability of choice based on individual preferences

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114. See generally, Peter P. Budetti and Teresa M. Waters, *Medical Malpractice Law in the United States*, HENRY J. KAISER FAM. FOUND., May 2005, at 1–2 (explaining how medical malpractice developed through state common law).

115. See Blumstein, *supra* note 111, at 130 (describing the common law elements of medical malpractice); see generally Budetti & Waters, *supra* note 114, at 1–4 (explaining medical negligence in a malpractice action).

116. See Blumstein, *supra* note 111, at 141.

117. *Id.* at 125.

118. See *id.* at 126–27, 130 (explaining the underlying assumptions of the professional model and its effect on patient care).

and stratified resource availability.”<sup>119</sup> We subscribe to, and advocate for, the professional model.<sup>120</sup>

Second, let us note the extent to which we have now argued that health care delivery in this country has moved well beyond the purview of individual practitioners providing discrete medical services for which they can be held singularly responsible for an eventual bad outcome.<sup>121</sup> From the perspective of tort law, the issue is increasing shifting to who – among many involved health care delivery participants – owes relevant duties to the patient.<sup>122</sup> That is to say, the ubiquitous and complex nature of team-provided health care today necessarily raises issues of defendant indeterminacy when things go wrong, and often requires resort to various theories of alternative liability in order to determine proper accountability.<sup>123</sup>

*a. The Standard of Care for Medical Negligence*

Traditionally, in a legal action for the tort of medical negligence, the relevant duty is defined by the medical profession’s “standard of care.”<sup>124</sup> The law presumes “that, as a scientific matter, a standard of practice exists and that, as an empirical matter, practitioners conform their conduct to that standard.”<sup>125</sup> According to Blumstein, the standard is “doctrinally embodied” in the ““*customary practices* of the medical profession”“ as “established by appropriate expert medical testimony.”<sup>126</sup> In contrast to an ordinary, non-professional negligence case – where a defendant’s compliance with “customary” conduct is relevant to, but not dispositive of, a jury’s determination of negligence – “the professional standard governing medical liability is based on professional norms and on the ‘assumption that science has established a single or unitary standard of practice and that unitary standard is in fact uniformly implemented in the medical profession.’”<sup>127</sup>

However, critics argue it is fallacious to maintain that “there exists one single correct medical response to every clinical problem” and “that this single correct response is, and should be, determined without reference to cost” and

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119. *Id.* at 130.

120. That is not to say, of course, that we in any way disavow the critical importance of informed consent, patient-centered care, shared decision-making, and/or a patient’s right to self-determination in refusing any recommended medical treatment or supportive care.

121. *See supra* Part II Section A.1–2.

122. *See supra* Part II Section A.2.

123. *See supra* Part II Section A.2.

124. *See supra* text accompanying note 115.

125. James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice Safe Harbors as a New Role for QIOs*, 59 VAND. L. REV. 1017, 1023 (2006).

126. *Id.* at 1023–24 (emphasis added).

127. *Id.* at 1024.

other considerations.<sup>128</sup> This disagreement has spilled over into continuing debate about the proper development and use of *clinical practice guidelines*:

[T]he goal is to ‘develop ‘evidence-based’ diagnostic and therapeutic recommendations for each medical condition.’ That is, the response of the adherents of the professional/scientific paradigm has been to develop better science to restore the confidence in the scientific ideal.<sup>129</sup>

Those seeking to restore the scientific ideal would tend to favor formulation and adoption of *clinical practice guidelines* as a regulatory technique for establishing uniformity in clinical practice as conceptualized under the professional/scientific ideal. Advocates of a pluralistic approach, which would be sensitive to concerns of cost-consciousness and to consumer/payer preferences as reflected in private contracting would view the role of such guidelines differently – as grounds for specifying different levels or styles of service through private choice.<sup>130</sup>

While we have admitted our bias in support of evidence-based clinical practice guidelines, we acknowledge the considerable criticism that many in the medical profession have voiced against what they consider to be promotion of “cookbook medicine” that improperly impinges on their professional autonomy.<sup>131</sup> Others have been critical of CPGs, and the customary practice standard generally, on the grounds that both stifle desirable advancement of medical innovation.<sup>132</sup> They argue that “innovating” physicians risk deviating from “custom,” thus causing potential malpractice exposure for “unreasonable behavior” regardless of outcome.<sup>133</sup> As a result of such criticisms, the use of “customary practice” as a legal defense is starting to diminish:

Already, a dozen states have expressly rejected deference to medical customs and another nine, although not directly addressing the role of custom, have rephrased their standard of care in terms of the *reasonable physician*, rather than compliance with medical custom.

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128. See *id.* at 1024 n.35 (citing Gail B. Agrawal & Mark A. Hall, *What If You Could Sue Your HMO? Managed Care Liability Beyond the ERISA Shield*, 47 ST. LOUIS L.J. 235, 285 (2003)).

129. Blumstein, *supra* note 111, at 136 (emphasis added).

130. *Id.* at 136–37 n.60 (emphasis added).

131. See Blumstein, *supra* note 125, at 1035 n.91.

132. See Froomkin et al., *supra* note 74, at 54–55.

133. *Id.* at 55.

Even more important than the raw numbers is the trend revealed by the decisions. The slow but steady *judicial abandonment of deference to medical custom* began in earnest in the 1970s, continued in the 1980s, and retained its vitality through the 1990s. Showing no signs of exhaustion, this movement could eventually become the majority position.<sup>134</sup>

Thus, some have said that the malpractice standard of care “is being normalized and brought into alignment with the ordinary tort duty of care, permitting courts to hold that even widespread medical practices can be negligent.”<sup>135</sup>

Yet, another issue in the still-ongoing debate is the way in which malpractice standards are established. As previously noted, the “customary practice standard” – and for that matter, the “reasonable physician standard” – are both necessarily established *after the fact* (i.e., *ex post*), by the fact-finder, during a trial.<sup>136</sup> For the most part, CPGs – if offered at all – have been admitted as no more than one piece of evidence relevant to the question of the asserted standard, to be considered along with expert testimony adduced by both sides.<sup>137</sup> Rarely have they been successfully offered as an already-established and broadly-accepted standard systematically developed *in advance* (i.e., *ex ante*) by one or the other professional organization.<sup>138</sup> Put differently, CPGs have generally been viewed and treated in most jurisdictions as “evidence” of the standard of care, not themselves “defining” the standard of care.

Difficult questions remain: Is it even possible to develop CPGs that can or should serve as *ex ante* dispositive standards governing determinations of liability for medical negligence? Is the practice of medicine a science or an art; or both, in some indeterminate and constantly-shifting proportions? To again quote Blumstein: “In a fundamental way and in many areas of practice, the widespread existence of clinical uncertainty calls into question a cornerstone of medical malpractice law – the assumption that there is a professionally[-]determined and scientifically[-]validated standard of care.”<sup>139</sup> Similarly, as Professor Hermer observes:

Finally, there are simply many circumstances in which, at least for the foreseeable future, no definitive guidelines will – or can – exist. These issues make it unlikely that CPGs could, on their own, provide a

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134. *Id.* (emphasis added) (quoting Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164 (2000)).

135. *Id.* at 55–56.

136. Blumstein, *supra* note 125, at 1028.

137. *Id.* at 1029.

138. *Id.* at 1028.

139. *Id.* at 1027.

satisfactory and sufficient response to the problems inherent in our medical malpractice regime at present, or anytime in the near future.<sup>140</sup>

*Nonetheless, we believe that CPGs have an important role to play – a role that the HCBC, as a new form of corporate health care entity, can best facilitate.* Professor Hermer has presaged this role in her discussions of CPGs in the context of ACOs:

Accordingly, if an ACO wants physicians to buy-in to the standards it adopts or promulgates, it will need to be able to convince physicians that they will not suffer increased liability by following cost- and waste-conscious CPGs that the ACO might promulgate. Physicians may be skeptical, however. Short of *ACOs offering indemnification to physicians for following the CPGs that they adopt*, our medical malpractice system would have to change by, for example, permitting CPGs to be used as a shield in malpractice suits. Yet this would, at minimum, entail addressing many of the problems raised by guideline development, choice, and uses that were discussed earlier. . . . As a different solution, it may instead be time once again to consider adopting *exclusive enterprise liability*, at least in the context of ACOs.<sup>141</sup>

As will become clear in our discussions in later sections, we believe that the HCBC is well structured to develop its own CPGs, indemnify its physicians and staff for following them, and to assume legal accountability for outcomes through acceptance of exclusive enterprise liability. The question of duty, however, does not end there.

*b. The Need to Recognize Broader Fiduciary Duties*

“Malpractice” is defined as “a dereliction of *professional duty* or a failure to exercise an ordinary degree of *professional skill* or learning by one (such as a physician) rendering *professional services* which results in injury, loss, or damage.”<sup>142</sup> Accordingly, any *professional member* of a health care “team” who either negligently or intentionally acts, or fails to act, in violation of the

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140. Hermer, *supra* note 95, at 284.

141. *Id.* at 293 (emphasis added).

142. *Malpractice*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/malpractice> (last visited Jan. 30, 2021) (emphasis added).

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requirements of their “scope of practice” as set forth in their applicable State Practice Act,<sup>143</sup> can be deemed to have committed medical malpractice.<sup>144</sup>

As we have discussed at length in our previous two articles, such professional duties have come, over time, to be recognized as *fiduciary*. As Professor Thomas L. Hafemeister and Joshua Hinckley Porter note:

[T]he steady historical expansion of hospitals’ services and their corresponding legal duties to patients has reached a point in today’s medical environment where hospitals have assumed, and patients expect them to assume, a more central role in the delivery of health care than ever before – a role that increasingly can be seen as fiduciary in nature.<sup>145</sup>

The previously-noted Fiduciary Medicine Model proposed by Professor Dayna B. Matthew essentially formalizes this recognition and extends such fiduciary duty to *all* participants on the health care team (*professional and non-professional alike*), as well as to the organization employing (or otherwise engaging) them itself.<sup>146</sup> Consistent with our discussion in Part II Section A.2., Professor Matthew acknowledges the implications of today’s “team-provided” health care and (in our opinion) properly characterizes the team’s collective responsibility as being fiduciary in nature.<sup>147</sup> Further, she provides a cogent rationale for an evolving doctrine of *institutional accountability*, which we have previously discussed:

*Accountability* is an obligation or willingness to accept responsibility or to account for one’s actions.’ Moreover, ‘[f]iduciary law, embodied in common law duties, statutory standards, and equitable principles, is the primary legal mechanism for assuring accountability in American corporations.’ Inasmuch as institutional delivery-of-care

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143. See generally, *Assessing Scope of Practice in Health Care Delivery: Critical Questions in Assuring Public Access and Safety*, FED’N OF STATE MED. BD. (2005), <https://www.fsmb.org/siteassets/advocacy/policies/assessing-scope-of-practice-in-health-care-delivery.pdf> (discussing the importance of ‘collaboration’ and ‘accountability’ in the health care sector by declaring their effectiveness in “providing safe and competent health care”).

144. See generally, *What is Medical Malpractice?* AM. BD. OF PRO. LIAB. ATT’Y, [www.abpla.org/what-is-malpractice](http://www.abpla.org/what-is-malpractice) (last visited Mar 8, 2021) (proclaiming that a medical malpractice claim must: (1) be “[a] violation of the standard of care”; (2) include “[a]n injury [that] was caused by the negligence”; and (3) prove that “[t]he injury resulted in significant damages”).

145. Thomas L. Hafemeister & Joshua Hinckley Porter, *Don’t Let Go Of The Rope: Reducing Readmissions By Recognizing Hospitals’ Fiduciary Duties To Their Discharged Patients*, 62 AM. U. L. REV. 513, 525 (February, 2013).

146. Dayna B. Matthew, *Implementing American Health Care Reform: The Fiduciary Imperative*, 59 BUFF. L. REV. 715, 762 (2011).

147. *Id.* at 744–45.

providers – most of whom adopt the corporate form of organization – have come to be increasingly recognized as having fiduciary duties to the patients they serve, it should come as no surprise that “*accountability*” has become a central tenet of health care reform. In fact, the concept is ‘imbedded in one of the principal proposed reform mechanisms, the Accountable Care Organization. Indeed, the very name suggests that this new, integrated, coordinated-care organization itself has a fiduciary obligation to the patients it serves . . . .’ To quote Professor Marc A. Rodwin: ‘Public policy and market forces are creating pressures for greater physician and provider accountability. And accountability is the core of the fiduciary ideal.’<sup>148</sup>

Professor Matthew’s proposed model has much of interest – more of which we have already discussed in some detail in our previous two articles.<sup>149</sup> For present purposes, suffice it to say that the most significant contribution of her proposal, in our opinion, is the way in which it would expand liability *beyond just the involved licensed medical professionals and institutions* to now include essentially all participants in the “team-delivery” of health care services. While it may remain debatable whether or not an unlicensed team member or organization can commit “medical malpractice” as heretofore defined, *there is growing consensus that unlicensed, non-professional individuals and institutions can and should be held accountable for concomitant tortious (either negligent or intentional) breach of fiduciary duties to patients.*<sup>150</sup> As we will continue to discuss, the best way to effect such accountability would be *through institutional acceptance of enterprise liability for both medical negligence and breach of fiduciary duty.*

## 2. *What was the Breach and How did it Occur?*

Professor Grout *et al.* observe that the term “malpractice” is usually taken to mean the circumstance wherein a patient has been harmed by a physician or other health care provider (“HCP”) and sues them for negligence.<sup>151</sup> While true, it should be noted that this is not exclusively the case – that is, although rare, malpractice cases can “present claims of intentional or reckless wrongdoing, as opposed to negligence.”<sup>152</sup> Nonetheless, most malpractice claims are in fact brought as negligence claims for alleged “medical errors,” which they define as “an HCP’s act of ‘commission or . . . omission . . . that would have been judged

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148. See Corbett, *supra* note 17, at 303.

149. *Id.* at 303–06; Corbett, *supra* note 3, at 176–78.

150. See, e.g., Furrow, *supra* note 28, at 50 (discussing the fiduciary duties of members of a hospital’s board of directors for ensuring patient safety).

151. Grout *et al.*, *supra* note 49, at 397.

152. *Id.* at 397 n.43 (citing KENNETH R. WING, LAW AND THE PUBLIC’S HEALTH 290–91 (6th ed. 2003)).

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wrong by skilled and knowledgeable peers at the time it occurred.”<sup>153</sup> They go on to say: “Given the process nature of healthcare, the key question for liability purposes will often be whether an HCP’s actions or omissions deviated so much from those that are usual and customary as to constitute a ‘process variation.’”<sup>154</sup>

Simply put, such “medical errors” or “process variations” constitute the alleged “breach” that must be shown to establish negligence. It is important to recognize, however, that such breaches are not necessarily singular events involving one person. Sometimes, one or more persons may have had a role in the same medical error; other times, one or more persons may have been involved in a series of medical errors that collectively result in harm to a patient. Thus, the “negligence liability environment” – particularly in the “team” context in which care is typically delivered today – increasingly involves the prospect of “*individual-error, group-error and[or] system-error.*”<sup>155</sup> In the complex institutional setting in which today’s team health care is delivered, each of these types of error can and does occur – interacting in a montage that some have analogized to a “spider web”:<sup>156</sup>

First, *most errors are multifactorial* and often involve both cognitive/knowledge and system/process failures. Second, most care is delivered through a series of frequently complex processes that are often plagued with a lack of consistency and a cultural dependence upon individuals. These considerations lead to variability in the quality of delivery. Third, medicine involves both art and science and requires subjective judgment, especially in the art component. Given that subjectivity, *the predominant culture influences both behaviors and outcomes.* Underlying the medical culture is a host of behavioral issues that contribute to medical errors through various psychological and epistemological influences. When combined with the customary defensive responses by HCPs to systemic failure and the absence of a comprehensive, centralized system for measuring, tracking, and reporting errors, the three considerations identified above operate as barriers to reducing the incidence of medical errors.<sup>157</sup>

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153. Compare *id.* at 395, with Mello & Studdert, *supra* note 104, at 603 n.18 (citing INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 54 (Linda T. Kohn *et al.* eds., 2000)) defining medical error as: “the failure of a planned action to be completed as intended (*e.g.*, error of execution) or the use of a wrong plan to achieve an aim (*e.g.*, error of planning).”

154. Grout *et al.*, *supra* note 49, at 395 n.33 (citing JOHN D. BANJA, MEDICAL ERRORS AND MEDICAL NARCISSISM 6 (2005)).

155. *Id.* at 400 (emphasis added).

156. See *id.* at 401 n.67.

157. *Id.* at 401 (emphasis added).

Needless to say, this multiplicity and interactivity of possible breaches underlying any given negligence claim presents plaintiffs with a growing challenge in the traditional medical malpractice construct.

3. *What was the Causal Relationship Between the Breach and the Alleged Injury?*

The next requirement for a plaintiff seeking accountability is to establish that the breach (or breaches) at issue were the “proximate cause” of the alleged medical injury. Again, the complexity added by today’s team health care – with its corresponding addition of multiple and interacting potential breaches – makes this required relational proof equally if not more confounding.

In the traditional malpractice construct, once a breach of the standard of care has been demonstrated it remains to be shown whether a “sufficient causal link” existed between that breach and the plaintiff’s injury.<sup>158</sup> That is, that the breach was either the “but for” cause of, or was a “substantial factor” in, the injury.<sup>159</sup> As Professor Hill *et al.* explain:

The causation requirement has two parts: *actual cause* and *proximate cause*. Both parts must be established. Actual cause is established under the “but for” or substantial factor tests . . . . Depending upon the test used in the jurisdiction whose law controls, proximate cause exists if the harm experienced by the plaintiff was a foreseeable consequence of the defendant’s breach or was a natural and probable consequence of the breach. If actual cause exists in a medical malpractice case, proximate cause is likely to exist as well. With HCPs typically furnishing medical treatment to persons who were already ill or injured, the patient whose condition was worsened as a result of negligent medical treatment may have a valid malpractice claim for the harm associated with the worsened condition, even though the HCP was neither the initial nor sole cause of the condition that warranted treatment.<sup>160</sup>

According to Professor Nancy Lee Firak, the difference between actual (*factual*) and proximate (*legal*) causation is that the former is an issue of “what happened,” the latter is an issue of “what law ought to do about it.”<sup>161</sup> Thus, the

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158. Hill *et al.*, *supra* note 60, at 167–68.

159. *Id.*

160. *Id.* at 168 n.49 (emphasis added).

161. Nancy Lee Firak, *The Developing Policy Characteristics of Cause-in-Fact: Alternative Forms of Liability, Epidemiological Proof and Trans-Scientific Issues*, 63 TEMP. L. REV. 311, 311 (1990) (citing Malone, *Ruminations on Cause-in-Fact*, 9 STAN. L. REV. 60, 60 (1956)).

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bifurcation is intended to keep factual questions separate from policy questions.<sup>162</sup> Professor Firak elaborates:

Since the bifurcation of causation, cause-in-fact is intended to be a scientific, objective inquiry into the actual causes of events, and proximate cause is intended to reflect policy limits on liability. Cause-in-fact is the critical first threshold to liability. Without an affirmative showing of cause-in-fact, there is no inquiry into proximate cause. Because of the practical problems of proof, however, the goal of maintaining objectivity in the cause-in-fact inquiry has always been elusive.<sup>163</sup>

Further complicating the overall causation question is the legal doctrine of “superseding” or “intervening” causation, which health care organizations will often raise as an affirmative defense to comparative negligence allegations against them – arguing that an *individual* “provider’s medical malpractice was a superseding cause of a plaintiff’s injuries, especially if the organizational negligence alleged involves administrative decisions [that were] remote in time and not easily connected to the provider’s act of malpractice.”<sup>164</sup> In today’s institutional health care environment, it is increasingly necessary and often difficult to distinguish acts that are “administrative” and “not easily connected” from acts that are clinically-related to ongoing treatment.

The fact is, the traditional medical malpractice construct requires the plaintiff to present “factual evidence that ‘singles out from the crowd’ the person who in fact caused the plaintiff’s injury and the trier-of-fact [to measure] the credibility of the plaintiff’s evidence against a standard of persuasion known as the preponderance of the evidence rule.”<sup>165</sup> However, as Professor Firak goes on to explain:

[T]he preponderance of the evidence rule, as traditionally understood, does not relieve a plaintiff from the requirement of identifying, from among all others, *the one* who caused the injury. While the preponderance of the evidence rule may occasionally result in a wrong answer to the question of whether the named defendant was the cause-in-fact of plaintiff’s injury, this standard was never intended to allow a plaintiff to prove cause-in-fact with a showing of only a statistical

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162. *Id.*

163. *Id.* at 314.

164. See Duffourc, *supra* note 109, at 37–38 (emphasis added).

165. See Firak, *supra* note 161, at 315 (citing E. Wayne Thode, *Tort Analysis: Duty-Risk v. Proximate Cause and the Rational Allocation of Functions Between Judge and Jury*, 1977 UTAH L. REV. 1, 2 (1977)).

probability that the identified defendant is the one who caused his or her injury.<sup>166</sup>

It is becoming increasingly clear that achieving accountability in today's team health care environment requires resort to alternative forms of liability. Accordingly, our purpose in the next section is not to discuss the usual issue of how a plaintiff establishes and proves damages, but rather the issue of who properly should be held to account for those damages.

#### 4. *Who Should be Held Responsible for the Patient's Damages?*

Increasingly, in "nontraditional tort cases," problems of defendant identification have resulted in relaxation of the "traditional cause-in-fact requirement" in favor of one or the other alternative form of liability:

There are several alternative forms of liability now recognized by the courts, including *alternative liability* (sometimes called alternate liability), *industry-wide liability* (sometimes called enterprise liability), *concert of action liability* (sometimes called the concerted action theory), *market-share liability*, and *risk contribution* (or risk share) *liability*. All of these different theories of liability represent precedent-setting departures from the traditional cause-in-fact requirement. Yet all are quite limited in their scope of application.<sup>167</sup>

Where "indisputedly innocent plaintiffs" have been unable to prove exactly who caused their injury, policy considerations have dictated that "defendants who created risks of the type that caused the injury" should be held accountable.<sup>168</sup> The principal reason, then, that alternative forms of liability have developed is to provide recourse to innocent plaintiffs confronted with indeterminate defendants.<sup>169</sup> Instead of focusing on the factual question of "what happened," such forms are said to focus more on the question of what the law ought to do about it.<sup>170</sup> Thus, they respond "to questions about facts with answers about policy."<sup>171</sup>

While medical malpractice cases can hardly be called "nontraditional," it is nonetheless true that malpractice plaintiffs are indisputably innocent and often (particularly today) unable to prove who, *individually*, caused their injuries. Thus, more than ever, alternative forms of liability in medical malpractice cases

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166. *Id.* (emphasis added).

167. *Id.* at 316 (emphasis added).

168. *Id.*

169. *Id.* at 340.

170. *Id.*

171. *Id.*

“makes both scientific and policy sense” – “scientific sense because the defendant’s [defendants’] conduct [collectively] created the type of risk that caused injury to the plaintiff,” and “policy sense because the plaintiff is not at fault in being unable to identify the proper [individual] defendant.”<sup>172</sup>

*a. Liability when Tortfeasors Indeterminate*

According to Professor M. Stuart Madden and Jamie Holian, *alternative liability* originated as a “burden-shifting approach to tortfeasor indeterminacy” in the 1948 California case of *Summers v. Tice*.<sup>173</sup> In that case, the plaintiff could not prove which of two negligently-shooting hunters actually injured him, only that “it was equally likely that each was the source of the bullet.”<sup>174</sup> In response to the plaintiff’s “source indeterminacy” problem, the California Supreme Court shifted the burden of proof to both defendants “to prove that they did not cause the plaintiff’s injury.”<sup>175</sup> If neither could do so, then each “would be jointly and severally liable.”<sup>176</sup> The “primary limitation” on this alternative liability approach is that “all of the potential tortfeasors must be before the court.”<sup>177</sup>

*Concert of action liability* is a second way that courts have dealt with tortfeasor indeterminacy. The theory “posits that when a group of actors agree, whether explicitly or tacitly, to proceed in risk-creating behavior, each of the actors will be jointly and severally liable if that behavior results in injury to another.”<sup>178</sup> The usually-cited paradigm case – the holding of which was limited

172. *Id.* at 334.

173. M. Stuart Madden & Jamie Holian, *Defendant Indeterminacy: New Wine Into Old Skins*, 67 LA. L. REV. 785, 790 (2007) (citing *Summers v. Tice*, 199 P.2d 963, 964 (Cal. 1948) (noting evidence did not clearly show which of the two defendant hunters’ shots struck plaintiff, finding that pellets lodged in the plaintiff’s eye and lip as a result of shots fired by ‘defendants[,] and each of them’ was a sufficient finding that defendants were jointly liable and that negligence of both was the cause of injury).

174. *Id.*

175. *Id.* The authors go on to note:

“Underlying the court’s decision were such factors as: (1) the plaintiff’s inability, through no fault of his own, to identify the tortfeasor; (2) the joint culpability of the defendants, in that both fired negligently at a target they had not determined to be prey; and (3) the defendants’ superior position, when contrasted to that of the plaintiff, to prove which one caused the injury.”

*Id.* (citing *Summers*, 199 P.2d at 967).

176. *Id.* at 791.

177. *Id.*

178. *Id.* at 792. The authors explain:

The analogy often used is that of two automobile or motorcycle drivers pulled up at the same stoplight. By a nod or by simple eye contact, they affirm that they will race each other when the light turns green. If their joint race ends up hurting a third party, both drivers or riders will be liable for the harm. This will be true even if it is clearly only one vehicle that injured the plaintiff, such as, *e.g.*, only one of the two vehicles skids out of control and injures a pedestrian.

*Id.* at 792 n.33.

to its facts – is the 1982 decision in *Bichler v. Eli Lilly & Co.*<sup>179</sup> The case involved all of the producers of the miscarriage drug DES, who sought quick Food and Drug Administrative approval by cooperating “together in pooling information, agreeing on the formula for the drug, and adopting packaging models,” while having “tacit knowledge” that there had been inadequate testing to prove the drug’s effectiveness.<sup>180</sup> The court concluded that because all of the producers had engaged in “conscious parallel activity,” the plaintiff had the option of proceeding against “any joint tortfeasor.”<sup>181</sup> That is,

[a]lthough the evidence showed that the pharmacy from which the plaintiff’s mother purchased the DES stocked a generic DES product of four or five different producers, and although the plaintiff admittedly could not prove that Lilly produced the pill that caused her injury, she was not required to include additional producers as defendants.<sup>182</sup>

A third way that courts have dealt with tortfeasor indeterminacy is through *industry-wide liability* (sometimes called “enterprise liability”). “The pioneer case in this area was the 1972 case of *Hall v. E.L Du Pont De Nemours & Co.*”<sup>183</sup> While Madden and Holian credit *Hall* as “establishing the enterprise liability theory,” we will explain in the next section how “enterprise liability” has come to have meanings different from that described in *Hall*.<sup>184</sup> *Hall* involved multiple children “injured by blasting caps manufactured by six different manufacturers.”<sup>185</sup> Because of the explosion, it was impossible to identify which manufacturer’s caps caused the injuries.<sup>186</sup> Accordingly, the plaintiffs argued that since all six of the manufacturers followed long-standing industry practices of not placing warnings on the blasting caps and of delegating the responsibility for warnings about the known risks to a trade association, all the manufacturers could be held jointly liable under an alternative form of liability.<sup>187</sup>

The court agreed, holding that the defendants’ “joint adherence” to the industry labeling practice caused a risk for which the defendants jointly shared

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179. See Firak, *supra* note 161, at 318–19 n.39 (citing *Bichler v. Eli Lilly & Co.*, 436 N.Y.S.2d 625 (N.Y. App. Div. 1981), *aff’d*, 436 N.E.2d 182 (N.Y. 1982)) (describing the seminal case regarding paradigms).

180. *Id.* at 319.

181. *Id.*

182. *Id.*

183. *Hall v. E.L Du Pont De Nemours & Co.*, 345 F. Supp. 353 (E.D.N.Y. 1972).

184. See Madden & Holian, *supra* note 173, at 792 n.35.

185. Firak, *supra* note 161, at 317.

186. *Id.*

187. *Id.* at 317–18.

responsibility.<sup>188</sup> “The court decided that if the plaintiffs could prove that it was more likely than not that they were injured by caps manufactured by one of the named defendants, they would satisfy the causation element of their cases.”<sup>189</sup> Put differently, “the court held that if the blasting cap manufacturers and their association had ‘joint or group control of the risk,’ liability could be imposed on each of the manufacturers without the need to show which manufacturer had produced the caps that caused the injuries.”<sup>190</sup>

A fourth and similar alternate form is *market-share liability*, which arose from another DES case in which the Supreme Court of California “found that all existing alternative forms of liability, including alternative liability, concert of action, and enterprise liability, were inappropriate.”<sup>191</sup> In the 1980 case of *Sindell v. Abbott Laboratories*,<sup>192</sup> multiple plaintiffs “were unable to prove which of more than one hundred DES manufacturers had produced the pills” that were alleged to have caused their injuries.<sup>193</sup> To address the plaintiffs’ inability to prove cause-in-fact, the court adopted a new theory: “if the plaintiffs join as defendants a number of manufacturers who together provided DES to a substantial share of the relevant market, each defendant will be held liable for the proportion of the judgment represented by its share of the market.”<sup>194</sup> The *Sindell* decision created a new “burden-shifting approach” that was intended to

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188. *Id.* at 318.

189. *Id.*

190. Madden & Holian, *supra* note 173, at 793. The authors go on to say:

. . . The enterprise liability theory is thus a hybrid theory combining elements of alternative liability and concert of action. More specifically enterprise liability: (1) incorporates the alternative liability requirement that, in regard to the plaintiff, each actor is at fault; and (2) provides that the group’s pursuits through their trade association provide circumstantial evidence of a concert of action.

The most significant limitation on the enterprise liability approach . . . is the court’s quite specific comment that the theory was only suited to claims involving a small group of defendants.

*Id.*

191. Firak, *supra* note 161, at 320.

192. *Sindell v. Abbott Laboratories*, 607 P.2d 924, 939–40 (Cal. 1980), *cert. denied*, 449 U.S. 912 (1980).

193. Firak, *supra* note 161, at 320.

194. *Id.* The author goes on to note:

The *Sindell* court was not clear on whether plaintiffs would recover 100% of their damages, or only that percentage of damages that was equal to the market shares of the defendants. That is, it is not clear whether defendants’ relative market shares would satisfy 100% of plaintiffs’ damages. This question raised the possibility that the named defendants, whose combined share of the market was less than 100%, could nevertheless be liable to plaintiffs for 100% of their injuries. That issue was later resolved in *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988), in which the California Supreme Court decided that the liability of the defendants would be several and limited only to the actual market share each held, even where the consequence would be that the plaintiff would not recover 100% of her damages.

*Id.* at 320 n.59 (citing *Brown v. Superior Court*, 751 P.2d 470, 485 (Cal. 1988)).

conform to the specific facts of the case and others like it.<sup>195</sup> Professor Firak notes that “market share liability has been severely criticized” for undermining “traditional cause-in-fact prerequisites,” with few jurisdictions adopting the approach “and then almost exclusively in DES cases.”<sup>196</sup>

A fifth and final way that courts have dealt with tortfeasor indeterminacy is through *risk contribution liability*.<sup>197</sup> In a 1984 Wisconsin DES case, *Collins v. Eli Lilly*,<sup>198</sup> the court rejected alternative liability, concert of action liability, and enterprise liability as inappropriate in a DES case.<sup>199</sup> However, the court also rejected the market share approach of the *Sindell* decision on the basis that “the large number of producers, the long period of time of production, the fluid nature of the market, and the lack of accurate records made it practically difficult for a plaintiff to precisely define and prove any individual defendant’s market share.”<sup>200</sup> To prevent the plaintiffs from going prospectively uncompensated, the court instead adopted a law review- suggested “risk contribution theory”<sup>201</sup> that “allows a plaintiff to proceed against a single [or multiple] defendant[s], even if that defendant held an insignificant percentage of the market, and to recover from that defendant in proportion to the amount of risk it created to all consumers.”<sup>202</sup> Professor Firak explains:

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195. Madden & Holian, *supra* note 173, at 797. The authors go on to describe the approach as follows:

Burden-shifting would be fair and warranted, Justice Mosk wrote, upon a plaintiff’s predicate showing that: (1) the injury causing substance caused his injury; (2) the injury causing product was fungible; (3) the plaintiff could define a relevant market for the injury causing product; and (4) the plaintiff had joined as defendants a substantial share of the defendant producers that had sold DES during the pertinent time period, *i.e.*, the time during which the mother was pregnant and taking DES. Upon satisfaction of this evidentiary burden, the burden would shift to the defendants to demonstrate individually that they had not produced the DES that the mother had taken. Upon such a showing, a defendant would not be liable. Defendants unable to exculpate themselves would be liable for any plaintiff’s proven harm in an amount proportionate to the defendant’s share of the market during the relevant time period.

*Id.*

196. Firak, *supra* note 161, at 321.

197. *Id.* at 321–23.

198. *Collins v. Eli Lilly*, 342 N.W.2d 37, 47 (Wis. 1984), *cert. denied*, 469 U.S. 826 (1984).

199. Firak, *supra* note 161, at 321.

200. *Id.* at 322.

201. *Id.* at 322 nn.61 & 74. Risk contribution theory was first proposed in Robinson, *Multiple Causation in Tort Law*, 68 VA. L. REV. 713, 752 (1982) (stating that sensible deterrence theory “suggests that if one tortfeasor can be identified, and his or her contribution to risk of injury can be established, all other things being equal, that tortfeasor should be held liable to extent of contribution”). The *Collins* court adopted a modified form of the Robinson proposal. See Glen O. Robinson, *Probabilistic Causation and Compensation for Tortious Risk*, 14 J. LEGAL STUD. 779, 782 n.13 (1985) (arguing for a risk-based theory of liability).

202. Firak, *supra* note 161, at 322–23.

According to the risk contribution theory, the wrongful conduct is the creation of a risk to the market-at-large rather than the injury the defendant may have inflicted on the plaintiff. In other words, creation of a risk of the kind that caused plaintiff's injury is enough to meet the cause-in-fact requirement under this theory of liability.<sup>203</sup>

While each of the above-described alternate forms of liability is helpful in providing recourse to plaintiffs confronting defendant indeterminacy in a variety of circumstances, they all do so only by creating avenues to joint and/or several liability against one or more prospective defendants.<sup>204</sup> None of these approaches, however, provides for singular and complete liability against an organizational or corporate defendant where only a possibly-indeterminate subset of individual actors within the organization or corporation are causally responsible for causing the harm, or creating the risk of that harm occurring.<sup>205</sup> That is the circumstance presented by today's team health care. As we have now discussed at some length, the very nature of today's institutionally-provided team health care potentiates a complex montage of interacting individual, group, and system errors that sometimes results in harm.<sup>206</sup> In such circumstance, a need for single-point organizational accountability remains. For this, we must look to viable theories of "institutional liability."

*b. Institutional Liability for Medical Negligence*

The IOM found that psychologist James Reason's error research, which explains why damage-causing failures occur in complex systems, including aviation and nuclear power, could also be used to understand medical errors. Reason's 'Swiss Cheese Model,' recognizes that complex system failures are usually the result of multiple weaknesses in the process chain. These weaknesses, called 'latent failures,' do not individually cause damage. However, latent failures acting together can lead to damage at the end of the process chain. When damage occurs, the final error, which Reason terms the

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203. *Id.* at 323. Professor Firak further explains that the *Collins* court emphasized that: [T]he plaintiff need not prove that a defendant produced or marketed the precise DES taken by plaintiff's mother. Rather, the plaintiff need only establish by a preponderance of the evidence that a defendant produced or marketed the *type* (e.g., color, shape, markings, size, or other identifiable characteristics) of DES taken by the plaintiff's mother; the plaintiff need not allege or prove any facts related to the time or geographic distribution of the subject DES.

*Id.* at 323 n.77.

204. *Id.* at 317–19.

205. *Id.*

206. *See supra* Part II. Section A.1–2.

‘triggering event’ or ‘active failure’ is easily identified, while the latent failures go unnoticed.

As predicted by Reason’s Swiss Cheese Model, when failures occur in a healthcare system, an individual provider’s actions or inactions (active errors) are easily identified following a patient injury. As a result, individual providers become the targets of medical malpractice litigation, while the systemic failures go unnoticed and unaddressed. According to the IOM, isolation of individual provider negligence as the cause of the patient injury will not effectively prevent future errors, because (1) the provider’s negligence can be caused or induced by a combination of latent errors unlikely to repeat, and (2) failing to address the latent errors allows them to accumulate making the system more error-prone. Likewise, targeting only individual providers in medical malpractice litigation fails to identify latent errors, fails to hold healthcare organizations accountable for systemic failures, and promotes a culture of individual blame in healthcare, all of which threaten patient safety.<sup>207</sup>

The door to institutional liability for medical negligence first began to open with the 1957 New York Court of Appeals decision in *Bing v. Thunig*,<sup>208</sup> which predicated a finding of hospital vicarious liability “based on the negligence of its healthcare provider employees through the doctrine [of] respondeat superior.”<sup>209</sup> Prior to that decision, hospitals in the United States – most of which were (and remain) nonprofit organizations<sup>210</sup> – “were generally immune from liability for the allegedly negligent conduct of their nurses and physicians under the charitable immunity doctrine.”<sup>211</sup> However in *Bing*, the court articulated “a modern view of hospitals” that dictated a different result:

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207. Duffourc, *supra* note 109, at 22–23 (citing James Reason, *Human Error: Models and Management*, 320 *BMJ* 768, 769 (2000)).

208. 143 N.E.2d 3 (N.Y. 1957)

209. Duffourc, *supra* note 109, at 24 (citing *Bing*, 143 N.E.2d at 8). The doctrine of respondeat superior is defined as “the doctrine making an employer or principal liable for the wrong of an employee or agent if it was committed within the scope of employment or agency.” *Respondeat Superior*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/legal/respondeat%20superior> (last visited Feb. 5, 2020).

210. See generally Corbett, *supra* note 3, at 109–20 (discussing how the ACA changed institutional health care in the United States and how an increase in Americans with health insurance will lead to a decrease in the need for charity care).

211. Jane Elaine Ballerini, *The Apparent Agency Doctrine in Connecticut’s Medical Malpractice Jurisprudence: Using Legal Doctrine as a Platform for Change*, 13 *QUINNIPIAC HEALTH L. J.* 317, 321 (2010). The author goes on to explain: “The justification for the exemption was based on the characterization of non-profit hospitals as charities and on widespread presumptions about the hospital-physician relationship.” *Id.* at 322. That is to say, physicians caring for patients in hospitals have historically been viewed as independent contractors, working under their own initiatives and being

The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact. Present-day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment. They regularly employ on a salary basis a large staff of physicians, nurses and internes, as well as administrative and manual workers, and they charge patients for medical care and treatment, collecting for such services, if necessary, by legal action. Certainly, the person who avails himself of 'hospital facilities' expects that the hospital will attempt to cure him, not that it[ 's] nurses or other employees will act on their own responsibility.<sup>212</sup>

In 1965, the Illinois Supreme Court decided *Darling v. Charleston Community Memorial Hospital*, redefining "the legal relationship between hospitals and patients."<sup>213</sup> There, the court "recognized for the first time a legal cause of action for negligence based upon a duty owed by the hospital directly to the patient rather than one that was imputed through the doctrine of respondeat superior."<sup>214</sup> Arguably, a doctrine of *hospital corporate negligence* was born.<sup>215</sup> Health care law author Mindy Nunez Duffourc provides a succinct summary of the "Corporate Negligence Doctrine:"

The elements of a prima facie case of corporate negligence are: (1) derivation (*sic*) [deviation] from an accepted standard of care, (2) actual or constructive notice of the defects or procedures that created the harm, and (3) negligent conduct that was a substantial factor in bringing about the plaintiff's harm. The scope of the corporate negligence doctrine is generally limited to actions that involve *administrative* and *managerial* decisions, as opposed to *medical*

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solely responsible for their own conduct. *Id.* at 323. As long as hospitals chose their physicians with "due care," they were deemed to have no control over and no liability for such physicians' actions. *Id.*

212. Duffourc, *supra* note 109, at 24 (quoting *Bing v. Thunig*, 143 N.E.2d 3, 8 (N.Y. 1957)).

213. *Id.* at 25.

214. *Id.* (citing *Darling v. Charleston Cmty. Mem'l Hosp.*, 200 N.E.2d 149 (Ill. App. 1964), *aff'd*, 211 N.E.2d 253 (Ill. 1965)). The author goes on to explain that: "the *Darling* court sanctioned the use of industry accreditation standards, state-licensing standards, and the hospital's own regulations to determine the applicable legal standard of care owed by the hospital. The most important of these standards is the Joint Commission on Accreditation of Healthcare Organizations Accreditation's ("JCAHO") Manual, which is used by courts to evaluate the applicable standard of care in corporate negligence claims." *Id.*

215. *Id.* (emphasis added). In a 1994 article, Abraham and Weiler noted that, "[t]hus far, 21 states have adopted hospital corporate liability." Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 390 n.34 (1994).

decisions; however, courts and legislatures in different states have interpreted the scope of the doctrine in varying degrees. The doctrine encompasses duties to select and retain competent physicians, maintain appropriate facilities and equipment, train and supervise employees, and implement appropriate protocols and procedures.<sup>216</sup>

As Duffourc notes, the scope of *Darling*'s corporate negligence doctrine focused primarily on a hospital's administrative and managerial, as opposed to medical, decisions and actions.<sup>217</sup> The general legal view at the time continued to be that patients' "attending staff physicians" were independent contractors for which the hospital had no direct or "conventional agency" liability.<sup>218</sup> By the 1970s, however, many state jurisdictions "created new modes of 'imposing liability on hospitals for the malpractice of physicians with whom they were affiliated but whom they did not employ.'"<sup>219</sup> Since then, "apparent agency" increasingly has become "a prominent theory of hospital liability" as today's team-delivered institutional health care is seen for what it is – "an integrated system that binds physician and provider services to the corporate control of hospitals and other health care entities (e.g., MCO[s], HMO[s], IPA[s])."<sup>220</sup>

According to a 2010 article by Ballerini, "about half of the states apply agency principles to hold hospitals vicariously liable for the conduct of their physicians, regardless of their status as employees or independent contractors."<sup>221</sup> In this way, hospitals and other organizational health care providers are coming to be held liable for *medical*, as well as administrative and managerial, misfeasance. As Ballerini concludes: "the modern hospital is viewed as an *entrepreneurial venture, as well as a health care provider*, and patients are not forced to distinguish between employed and independently contracted providers when seeking reimbursement for medical negligence."<sup>222</sup>

In sum, then, institutional liability for medical negligence has increasingly come to encompass not only *imputed* liability under respondeat superior and

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216. Duffourc, *supra* note 109, at 26 (emphasis added).

217. *Id.*

218. See Ballerini, *supra* note 211, at 340.

219. *Id.*

220. See *id.* (emphasis added). The author goes on to note: "Apparent agency is '[a]n agency created by operation of law and established by a principal's actions that would reasonably lead a third person to conclude that an agency exists.' The theory is based on the Restatement (Second) of Torts section 429 . . ." *Id.*

221. Ballerini, *supra* note 211, at 342. The author identifies these states as including: "Alaska, Arizona, California, Delaware, Florida, Georgia, Illinois, Kentucky, Maryland, Michigan, Mississippi, Missouri, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Washington, Wisconsin, and Wyoming." *Id.* at 342 n.152.

222. *Id.* at 343–44 (emphasis added) (citing Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 387 (1994)).

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apparent agency, but *direct* liability for an organizational health care provider's failure to meet the standard of care applicable to a "reasonable" like-provider. Such failures may well now include individual-errors, group-errors, and system-errors that today's team-delivered health care potentiates.<sup>223</sup> Moreover, such liability increasingly will extend to institutional providers other than just hospitals. As Professor Furrow opines:

[E]ven if *ACOs* and *other entities* operate without a hospital as part of the organization, they are now health care providers, subject to liability just as a hospital or managed care organization, on both vicarious liability and direct negligence principles. *Corporate negligence principles will likely apply to integrated organizations that manage care*, whether a patient home, an ACO, or some other delivery form that PPACA creates. American courts have proved willing to look beyond the hospital form in deciding whether a health care entity might be liable for corporate negligence. . . . The entity would, like an HMO, 'involve [itself] daily in decisions affecting [its] subscriber's medical care. These decisions may, among others, limit the length of hospital stays, restrict the use of specialists, prohibit or limit post-hospital care, restrict access to therapy, or prevent rendering of emergency room care.' The entity must have general responsibility for 'arranging and coordinating the total health care of its patients.' It must take 'an active role in patients' care.'

. . . PPACA – with its millions of dollars in demonstration grants and its new mandates – will foster new entities that are far more likely to coordinate care than are current health care providers. These new entities will take on new responsibilities that will make them appropriate defendants in tort litigation. . . . It may be that finally *enterprise liability* ['a proposal often discussed but never adopted'] will make sense as *integration and coordination intensify, and outcomes and performance data are generally available to all.*<sup>224</sup>

*c. Demise of the "Corporate Practice of Medicine" Doctrine*

Having now made the point that institutional/corporate liability for medical negligence has become increasingly well-established, it is appropriate to make the corollary point that the common law "corporate practice of medicine doctrine" has become increasingly moribund. That is the doctrine that

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223. See Grout et al., *supra* note 49, at 400 (explaining the importance of "mistake proofing" individual errors, group errors, and system errors).

224. Furrow, *supra* note 91, at 1773–74 (emphasis added).

“recognized practicing physicians as distinct from conventional employees in a business enterprise.”<sup>225</sup> Professor Robert I. Field explains:

The doctrine is based on the notion that as professionals bound by a code of ethics and licensing rules, physicians must honor a fiduciary duty to their patients, and as such, should be accountable not to the financial imperatives of a commercial employer but to their patients directly. This reasoning led to the legal principle that physicians should not render services as employees within corporate structures, but only in practices that they themselves controlled or that were controlled by professional colleagues. The doctrine thereby blocked the development of practice arrangements through corporations managed by nonphysicians. This result granted the profession substantial leeway to adopt its own business structure free from outside interference. However, once again, by gaining legal authority to control their actions, physicians also positioned themselves as the only accountable parties when their services failed to meet expectations.<sup>226</sup>

Needless to say, the doctrine today runs counter to multiple trends in the continuing evolution of the health care delivery system. As we have now emphasized: physicians are not the only hands-on direct providers of medical and related health care services owing “a fiduciary duty to their patients;” physicians today practice in a multitude of settings, in a number of different employment and/or affiliation relationships with unlicensed individuals and/or corporate organizations; and, physicians are clearly not “the only accountable parties when [those] services [fail] to meet expectations.” As Professor Gabriel Scheffler has observed:

As the practice of medicine has evolved from solo practitioners to large integrated health care organizations, the doctrine has ceased to be enforced in most states. The Supreme Court dealt the AMA a major setback in 1982 when it affirmed a Federal Trade Commission order that the AMA’s ethical restraints on the corporate practice of medicine violated the Federal Trade Commission Act. In addition, many states have carved out explicit exceptions to the doctrine, including for non-profit health care organizations, health care organizations owned and

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225. Robert I. Field, *The Malpractice Crisis Turns 175: What Lessons Does History Hold for Reform*, 4 DREXEL L. REV. 7, 28 (2011).

226. *Id.* at 28–29.

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managed by licensed physicians, health maintenance organizations (HMOs), and medical schools.<sup>227</sup>

She goes on to conclude:

Over the years, many scholars have argued in favor of abolishing the corporate practice of medicine doctrine altogether. These critics argue that the original justifications undergirding the doctrine no longer apply in a world in which *the delivery of health care is increasingly team-based*, and where managed care companies exert influence over how care is delivered. Rather than serving to promote quality, they argue that the corporate practice of medicine doctrine in fact degrades the quality of health care by making our health care delivery system more fragmented. Critics argue that the corporate practice of medicine doctrine contributes to this fragmentation by preventing health care organizations from exerting control over physicians' decisions and making it more difficult for health care organizations to implement patient-safety initiatives.<sup>228</sup>

All of the above, then, segues well into our next discussion – the enterprise liability model for organizational health care providers.

*B. Enterprise Liability Redux*

In her 2014 article, Professor Hermer states:

*Enterprise liability* would move the locus of liability from physicians and other individual health care providers to the enterprise in which or for which they work. It was most recently suggested in the 1990s, when health maintenance and other managed care organizations were ascending and were conceptualized as the 'enterprise' in question. Although hospitals had originally been proposed as the liability-bearer, the prospect that a health care system based on managed care would come into being through the Clinton health reform proposal in the 1990s prompted some to suggest that managed care organizations should instead assume liability. William Sage, Kathleen Hastings, and Robert Berenson argued, for example, that *enterprise liability* for managed care entities paid through capitation would make managed care entities bear the costs of substandard or inadequate care that they

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227. Gabriel Scheffler, *The Dynamism of Health Law: Expanded Insurance Coverage as the Engine of Regulatory Reform*, 10 U.C. IRVINE L. REV. 729, 740 (2020) (citing Adam M. Freiman, *The Abandonment of the Antiquated Corporate Practice of Medicine Doctrine: Injecting a Dose of Efficiency Into the Modern Health Care Environment*, 47 EMORY L. J. 697, 706–08 (1998)).

228. *Id.* at 741 (emphasis added).

might otherwise be tempted to deliver in an effort to reduce expenses and increase profits. Managed care plans, they argued, have the ability to coordinate providers, manage health care delivery, and oversee quality, making it both economically and practically efficient for them to bear liability.

The Clinton health reform plan was never enacted, so the health coverage landscape that Sage and his co-authors contemplated did not come into being. With the ACA, we now have a different landscape. Health plans are not being asked to tightly manage and oversee care; rather, groups of providers are, via clusters of demonstration projects involving care coordinated through delivery or financing innovations. ACOs constitute one such demonstration project, and *arguably are the best suited of the different proposed models to support a system of enterprise liability.*<sup>229</sup>

In our 2019 article, we observed that ACOs and our purposed HCBC share an “affinity of purposes.”<sup>230</sup> That affinity derives from the fact that both strive to “transform the current fragmented delivery system into an integrated and coordinated care model that consistently produces improved quality, greater accessibility, and lower cost” by effecting “greater collaboration between and among [ ] disparate system participants.”<sup>231</sup> While we do not envision the HCBC form necessarily being used exclusively for the operation of ACOs, we do suggest that it would be ideally-suited for such purpose – and thus for adoption of enterprise liability, as Professor Hermer urges.

We must first, however, clarify what is meant (or at least what *we* mean) by “enterprise liability” in this context. It is *not* just another name for “industry-wide liability,” as Madden and Holian seemingly proclaim in their 2007

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229. Hermer, *supra* note 95, at 293–94 (emphasis added). In a 1997 article, Professor William M Sage explained:

Despite its theoretical promise, the Clinton Administration’s enterprise liability proposal fell flat. The concept came into public view as a ‘trial Balloon’ of the Administration’s health care task force in April 1993, immediately floated into a storm of opposition, and quickly proved leaden. Intended both as a policy-based imposition of responsibility on managed care plans in recognition of their expanded role, and as a political benefit to doctors who would be liberated from the threat of individual lawsuits, enterprise liability provoked a reaction that took its proponents by surprise. In retrospect, the criticism related less to the proposal *per se* than to what its announcement indicated about the direction of change in the American health care system.

William M. Sage, *Enterprise Liability and the Emerging Managed Health Care System*, 60 LAW AND CONTEMP. PROBS. 159, 169 (1997).

230. Corbett, *supra* note 17, at 337.

231. Corbett, *supra* note 3, at 165–66.

article.<sup>232</sup> Neither is it a “no fault” or “strict liability” approach, such as Professor Furrow discusses in a 2012 article – a “pure enterprise-liability approach” wherein “a compensation obligation arises from the mere occurrence” of a harm-causing adverse event, without any need for showing “avoidability” or “error” (*i.e.*, negligence).<sup>233</sup> Rather, it is a model based on a policy proposal originally developed by Professors Kenneth S. Abraham and Paul C. Weiler in the late 1980s – the rationale for which they articulated in a 1994 Harvard Law Review Article.<sup>234</sup>

### *1. The Enterprise Liability Model of Abraham and Weiler*

The current ferment over reform of our health care system has led to a rethinking of the relations between this country’s health care and civil justice systems. Since the time when the traditional individual liability approach to malpractice crystallized, the manner in which health care is delivered has changed enormously. From a group of isolated individual practitioners who used hospitals as workshops for themselves and hotels for their patients, the system has evolved to the point where care is now delivered mainly under the auspices of large enterprises such as health insurers, hospitals, and HMOs. Yet the liability regime has remained geared to an older world of individual delivery of health care, a world that is on the verge of disappearing. The time has come to renovate our system of liability to make it better suited to a new world dominated by health care enterprises. The enterprise liability model we have developed is designed for precisely this purpose.<sup>235</sup>

Early in their article, the authors note that tort law scholars have sought to expand tort liability for personal injury to “the enterprise in the best position to make risk/safety tradeoffs” for more than fifty years.<sup>236</sup> Even in 1994, they saw their proposal as constituting “a significant but logical extension of trends that have been evolving over several decades in both the allocation of legal responsibility for negligently caused patient injuries and the increasingly

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232. See Madden & Holian, *supra* note 173, at 792–793. The authors there characterize enterprise liability as being: “. . . a hybrid theory combining elements of alternative liability and concert of action. More specifically enterprise liability: (1) incorporates the alternative liability requirement that, in regard to the plaintiff, each actor is at fault; and (2) provides that the group’s pursuits through their trade association provide circumstantial evidence of a concert of action.” *Id.* at 793.

233. See Barry R. Furrow, *Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 470–71 (2012).

234. See Abraham & Weiler, *supra* note 54, at 381.

235. *Id.* at 436.

236. *Id.* at 384.

commercialized organization of health care.”<sup>237</sup> For all of the reasons we have now discussed, their assertion is all the more true today.

They provide a succinct summary of their concept’s essential elements:

Under our proposal, as under present-day vicarious, agency, and corporate liability theories, the *malpractice* of physicians and *other health care personnel would remain a prerequisite to the imposition of liability on the hospital*. In contrast to these existing forms of liability, however, hospitals under enterprise liability would be the *exclusive bearers of medical liability for all malpractice claims* brought by hospitalized patients – regardless of the provider’s status as employee, independent contractor, or holder of admitting privileges, and regardless of the site of the provider’s malpractice. In turn, *physicians would be insulated from, or at least insured against, personal liability* to injured patients, in the same way as are nurses and other medical staff working for hospitals under the current legal regime.<sup>238</sup>

A few points from this summary warrant particular emphasis: first, their proposal is *not* for a “no fault” or “strict liability” approach – a showing of negligence (*i.e.*, malpractice) is still required; second, they anticipate arrangements through which the (hospital) enterprise would become the sole (“exclusive”) party who could be held liable for a patient’s medical malpractice claim; third, the enterprise liability extends to the malpractice of “other health care personnel,” not just physicians; and fourth, they contemplate use of appropriate means to protect physicians from “personal liability” (*i.e.*, “insulated from, or at least insured against”) – just as the hospital’s employed personnel have traditionally been under conventional institutional liability insurance coverage.<sup>239</sup>

Although ACOs were not even on the horizon at the time of Abraham and Weiler’s 1994 article, their expectations for the future were nonetheless prescient:

As the cost of care becomes even more important to all health care providers because of the manner in which competition is shaping the process of health care delivery, both physicians and hospitals will increasingly find themselves linked in *health care provider ‘networks’* designed to assure the most cost-efficient provision of care. Such networks will be supervised by the enterprises that contract with patients, who likely will be purchasing coverage in sizable groups with correspondingly greater market power. The economic interests

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237. *Id.* at 385.

238. *Id.* at 393–94 (emphasis added).

239. *Id.*

of different individual and *enterprise health care providers* will be linked, and their relationships increasingly regulated by a series of contracts between and among patients, individual physicians, hospitals, HMOs, and insurance companies. The transformation of health care delivery from a free-standing professional pursuit into an *integrated economic enterprise* will then be one step closer to completion; accordingly, *the old justifications for focusing malpractice liability on individual physicians will have largely disappeared.*<sup>240</sup>

*This is an entirely accurate description of the present environment that has brought about the ACA, it's ACOs, and now our proposed HCBC.* Moreover, we agree with their contention that “enterprise medical liability” (“EML”) “would be a more sensible system of compensating injured patients, a more economical method of administering such compensation, and a more effective vehicle for prevention of medical injury than the current system of individual liability for malpractice.”<sup>241</sup>

Near the end of their article, Abraham and Weiler “sketch the outlines of an EML ‘experiment.’”<sup>242</sup> They suggest a legislative approach, wherein a state legislature authorizes “hospitals to elect EML on the following terms:”

- (a) Any hospital electing EML would be liable to its patients for malpractice by any affiliated physician, nurse, or other individual provider, whether or not the provider was a hospital employee. The hospital would assume liability for all patients treated by its affiliated physicians, whether or not those patients were ever admitted to the hospital.
- (b) Patients would be given clear notice, both by the physician’s office and by the EML hospital’s admitting branch, of the hospital’s expanded liability and the resulting immunity of its affiliated physicians.
- (c) Individual health care providers would be relieved of liability for malpractice, with an exception for injuries caused by a health care provider who acted with intent to cause harm or with reckless indifference to the welfare of the patient.

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240. *Id.* at 398 (emphasis added).

241. *Id.* at 399.

242. *Id.* at 426.

(d) All individual physicians relieved of malpractice liability by a hospital's election of EML would be obligated to pay the hospital an annual surcharge in order to reimburse the hospital for the anticipated increase in its malpractice insurance costs. The surcharge would take into account the anticipated reduction in malpractice insurance costs charged the physician.

(e) The amount of the surcharges would be set by agreement between each participating hospital and its affiliated physicians. Surcharge levels would be reviewable by the state's Commissioner of Insurance on the same basis that the Commissioner may now review medical malpractice premium levels. In most states new rates can be filed and may be used unless the Commissioner formally objects. Ideally, each physician could designate a single hospital to be his or her 'primary' hospital and pay a surcharge to that hospital alone. Alternatively, separate surcharge rates could be set for physicians affiliated with more than one hospital so that these providers would not be required to pay excessive duplicate surcharges.

(f) As another alternative, hospitals and affiliated physicians, through negotiations with health insurers and other third-party payers, could arrange adjustments in the charges for services and reimbursement rates payable for medical and hospital services to take account of the shift in liability resulting from elective EML.

(g) Hospitals electing EML would be required, to the extent that they had not already done so, to set up peer review mechanisms to ensure that quality care is provided. Such peer review mechanisms would have to include procedures for revoking the admitting privileges of physicians who fail to comply with the hospital's standards.<sup>243</sup>

While we would not necessarily agree with the inclusion of each of these "terms" exactly as they propose, we do agree with their broad strokes. We also agree with the idea of a state-legislated "enabling statute" to effectuate an organizational health care provider's adoption of enterprise medical liability. However, we have an additional suggestion. We have already addressed in our 2019 article the fact that "enabling legislation" to create the HCBC must occur at the state level (albeit with necessary waivers from, or exceptions to, certain federal laws governing taxes and health care operations);<sup>244</sup> we would accordingly argue that the state enabling legislation for effectuating enterprise

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243. *Id.* at 427–28.

244. Corbett, *supra* note 17, at 326–27.

medical liability should be included (expressly or by reference) into that state's HCBC legislation itself, thereby making EML a constitutive part of the HCBC's statutory structure.

In addition, we would urge that such statute require that any organization adopting the HCBC form accept enterprise liability for any breach of its *institutional fiduciary duties to its patients*, as well as for any breaches of fiduciary duties arguably owed by any of its *non-professional staff*. That is to say, under the “broader fiduciary duties” of the Fiduciary Medicine Model that Professor Matthew (and we) advocate, one does not have to be a “licensed medical provider” – technically susceptible to a “medical malpractice” claim for violating an applicable “professional standard of care” – to have actionable fiduciary duties to patients.<sup>245</sup> Thus, the *administrative, managerial, and/or other systemic errors* of unlicensed personnel that result in harm to patients should also create grounds for the HCBC's enterprise liability *for fiduciary breach* (itself an actionable tort<sup>246</sup>).<sup>247</sup>

## 2. Continuing Academic Support for Enterprise Medical Liability

Since Abraham and Weiler's 1994 article, a number of health law scholars have continued to endorse the idea of enterprise medical liability. In a 1996 article, author Jack K. Kilcullen, after discussing the rationale for imposing liability on a manufacturer in a product liability case, wrote the following:

Enterprise liability can address similar problems posed by medical care. Medical treatment is the product of a network of trained individuals, many of whom have no contact with the patient. *Thus, the individuals may not have a traditional duty of care toward the patient, yet their negligence can have devastating consequences.* In addition, patients lack the bargaining power to negotiate all aspects of treatment, where, for example, they may consent to procedure without full comprehension of the procedure and its risks. Consequently, the medical enterprise is superiorly placed to manage both the risk and to distribute its costs in compensating anyone injured from its well-intended efforts.<sup>248</sup>

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245. See generally Matthew, *supra* note 146 (proposing the Fiduciary Medicine Model to expand and refine fiduciary law in health care policy).

246. See generally Deborah A. DeMott, *Breach of Fiduciary Duty: On Justifiable Expectations of Loyalty and Their Consequences*, 48 ARIZ. L. REV. 925 (2006) (expounding on the notion of loyalty to inform fiduciary duty in tort law). See previous discussion at *supra* Part III Section A.1.b. about fiduciary breach itself being an actionable tort.

247. See *supra* Part III. Section A.1.b.

248. Jack K. Kilcullen, *Groping for the Reins: ERISA, HMO Malpractice, and Enterprise Liability*, 22 AM. J. L. & MED. 7, 14–15 (1996) (emphasis added). The author later goes on to say: The sheer complexity of modern health care, both administratively and technologically, is as James would describe:

Furthermore, in a 1997 article, Professor William M. Sage noted:

A considerable part of the debate over enterprise liability comes down to the question of the appropriate unit for accountability in modern health care. Traditionally, control – and therefore blame – rested with individual physicians. Today, however, there is increasing evidence that most errors in health care delivery, while human in proximate cause, are ultimately the result of faulty institutional processes. In this respect, health care is beginning to mirror other industries more than adherents to a purely professional model would like to admit. . . .<sup>249</sup>

Additionally, in 2002, Professor Thomas R. McLean wrote:

If in the twenty-first century health care delivery is to be based upon a multidisciplinary team approach to control health care costs, patients will be receiving a greater proportion of their health care from individuals with less formal training than the current physician providers. Assertions that as a group, physician extenders provided the same quality of health care as physicians are unsupported by hard statistical data. Moreover, collaborative multidisciplinary health care delivery, because it inserts another caregiver between the physician and the patient, of necessity increases the complexity of our health care system, thereby increasing the potential number of handoff errors. Thus, the unassailable corollary of implementation of collaborative multidisciplinary medicine to cut health care costs is that it will be less safe than our autonomous physician-based approach. . . .

In short, to ensure that the standard of medical care is not lowered by a national decision to facilitate collaborative multidisciplinary health care delivery, the country must be prepared to move to enterprise liability for health care delivery.<sup>250</sup>

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[A]n enterprise . . . beneficial to many, which takes a more or less inevitable accident toll of human life and limb . . . where the accident victims are as a class economically ill-equipped to carry the burden of serious accident losses. The impact of such losses on the individual in terms of human hardship is often crushing and the repercussions of this blow reach far beyond the individual and pose a significant social problem.

*Id.* at 47 (citing James Fleming, Jr., *General Products – Should Manufacturers Be Liable Without Negligence?*, 24 TENN. L. REV. 923, 923 (1957)).

249. Sage, *supra* note 229, at 195.

250. Thomas R. McLean, *Crossing the Quality Chasm: Autonomous Physician Extenders Will Necessitate a Shift to Enterprise Liability Coverage for Health Care Delivery*, 12 HEALTH MATRIX 239, 291, 295 (2002). The author also notes:

*Crossing the Quality Chasm* is not the first report to Congress advocating the adoption of enterprise liability, which is a method to shift liability for adverse events, occurring during the delivery of health care, from the individual physician to the business organization that provided

Moreover, in a 2008 article, Professor Philip G. Peters, Jr. urged:

Exclusive hospital enterprise liability has the potential to revive the dormant deterrent power of tort law. The reasons are simple. *Unlike individual physicians, hospitals are experience-rated repeat players* who have the vantage point and the resources needed to recognize and implement systematic improvements in the process of delivering health care. Adoption of enterprise liability would align the incentives of tort law with the goals of modern patient safety advocates who emphasize the need to shift our focus from the blaming of individual wrongdoers to the design of systems that anticipate and prevent human error. *Exclusive enterprise liability would also reduce the disruption caused by the insurance cycle*, spare high-risk specialists from shouldering a disproportionate share of health care's liability costs, reduce litigation costs that arise in multi-defendant lawsuits, and dampen the extraordinary anger of practicing physicians. The time has come to adopt hospital enterprise liability.<sup>251</sup>

In addition, Peters also observed:

Because the benefits of enterprise liability far outweigh its disadvantages, many respected health law scholars endorsed it. They include Clark Havighurst, Paul Weiler, Troyen Brennan, Michelle Mello, David Studdert, Tom Baker, and William Sage. Although these scholars differed on a number of issues, like the choice between

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the medical service. However, although enterprise liability is conceptually no more than a natural extension of corporate liability, enterprise liability is a slippery concept because of polymorphic definitions. However, if enterprise liability is defined as a system under which a business organization that provides a medical service is the exclusive bearer of liability for all medical negligence, *regardless of the provider's status*, then enterprise liability is the superior method by which to assign liability if physician extenders are to be granted greater autonomy. Moreover, by focusing all litigation against a single party, it is hoped that enterprise liability is a more just and cost efficient system than the traditional indemnity medical malpractice system.

*Id.* at 275–76 (emphasis added).

251. Philip G. Peters, Jr., *Resuscitating Hospital Enterprise Liability*, 73 MO. L. REV. 369, 370 (2008) (emphasis added). He goes on to say:

Lawmakers should recognize that hospital enterprise liability will shift legal responsibility onto actors who are better positioned to detect opportunities for safety improvement and better financed to act upon those insights. Because hospitals are experience-rated or self-insured, enterprise liability will create a greatly enhanced financial incentive to undertake those safety improvements. At the same time, the shift of liability from individual physicians to hospital systems is likely to loosen current physician resistance to promising patient safety initiatives. For all of these reasons, we urgently need to modernize the law of malpractice liability by making hospitals exclusively liable. Lives, not to mention lawsuits, literally hang in the balance.

*Id.* at 385.

hospitals and managed care organizations as the responsible ‘enterprise,’ they agreed on the need for institutional, rather than individual, responsibility. They shared the belief that health care quality would improve if organizations had a legal incentive to minimize medical accidents.<sup>252</sup>

As our final example, in her 2013 article writer Jessica S. Allain suggests that the continued proliferation of artificial intelligence systems like Watson provides further impetus for a system of enterprise liability:

The law currently is a conglomeration of legal regimes that do not clearly apply to artificial intelligence systems. As a result, different courts could apply different theories to similar cases, leading to inconsistent results. A streamlined method for assessing liability against artificial intelligence systems will likely encourage this technology’s use. For instance, removing doubts about who will be liable and to what extent the responsible party will be financially responsible if these systems malfunction will likely encourage hospitals to adopt this emerging technology. Additionally, cases involving Watson will necessarily involve a team of supporting physicians. Distinguishing fault and causation between the actors for a traditional comparative fault analysis can be a very complex inquiry. A regime based on enterprise liability combining elements of medical malpractice, products liability, and vicarious liability will adequately address the legal challenges raised by Watson while ensuring fairness and consistency between courts.<sup>253</sup>

Additional examples of continuing scholarly support for enterprise liability could be given, but would only serve to belabor the point.<sup>254</sup> In view of the continuing evolution of the health care delivery system into ever-larger and more complex clinically and/or financially-integrated organizational providers, adoption of enterprise medical liability is now more than ever a compelling idea for which the HCBC would (by design) be particularly well-suited.

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252. *Id.* at 375; see also Philip G. Jr. Peters, *Health Courts*, 88 B.U. L. REV. 227, 278-286 (2008) (providing a detailed discussion of the advantages of enterprise liability).

253. Allain, *supra* note 72, at 1073.

254. See, e.g., Thomas R. McLean, *Cybersecurity - An Argument for Enterprise Liability*, 23 J. LEGAL MED. 167, 169 (2002) (arguing that adopting enterprise liability for cybersurgery would “provide consistent compensation to worthy plaintiffs”); Mello & Studdert, *supra* note 104, at 620 (arguing that “doctrinal realignment” of the tort system “requires the development of a more robust role for enterprise liability”); Mantel, *supra* note 87, at 515–17, 517 n.275 (citing several other authors and their arguments in favor of enterprise medical liability).

#### IV. THE HCBC AS LIABILITY AND HEALTH INSURER

We have argued that the HCBC is a preferred legal form for large, integrated health care delivery systems wishing to improve quality and accessibility while simultaneously lowering costs and restoring patient trust – all objectives shared in common with ACOs under the ACA. Accordingly, while we would not necessarily expect all HCBCs to operate as ACOs, we would hope that many ACOs would see the value in operating as HCBCs. In any event, both entities will be confronted with the question of how to best deal with the issue of their own ongoing institutional medical and fiduciary liability:

There are many questions that remain unanswered in terms of ACO malpractice liability: Will ACOs maintain liability insurance? Will they self-insure? What will be the most popular legal structure of the statutory options available? In other words, *will most ACOs organize as corporations, partnerships, limited liability companies or some other state recognized legal structure?* Will individual ACO physicians and providers serve as employees, independent contractors or in some other legal capacity? How will liability work with regard to the governing board of ACOs? *How will liability be distributed between individual ACO providers and the ACO entity for malpractice committed by an individual ACO physician or provider?* How will the concept of joint and several liability function within the ACO context? These are all open questions that will have to be answered in the future.<sup>255</sup>

In our opinion, an institutional health care provider's adoption of the HCBC form and formal acceptance of exclusive enterprise liability for its prospective malpractice and fiduciary liabilities would arguably go a long way toward accomplishing our quality, accessibility, fairness, and trust objectives; however, to the extent that such providers simply rely on the commercial insurance market for liability coverage, minimizing the overhead costs associated with such coverage remains another matter.

##### A. *The HCBC as Liability Insurer*

It is not our intent to enter the decades-long and still-continuing debate over whether or not the existing medical malpractice system is plagued by “frivolous” lawsuits that require and justify caps on plaintiffs’ damages and/or other kinds of limitations on plaintiffs’ ability to adjudicate claims. We again openly acknowledge our bias – that such “reform” efforts are misplaced and have little

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255. Christopher Smith, *Between the Scylla and Charybdis: Physicians and the Clash of Liability Standards and Cost Cutting Goals within Accountable Care Organizations*, 20 ANNALS HEALTH L. 165, 195 (2011) (emphasis added).

salutary effect on overall system performance or costs. Rather, we wish to more closely and critically examine the still-predominating for-profit, third-party, commercial liability insurance system – and suggest a more cost-effective approach. We again begin with the observations of Professor Philip G. Peters, Jr.:

Liability insurance premium levels go through periodic peaks and troughs that are called ‘*the insurance cycle*.’ Although the magnitude of the peaks can be exacerbated by underlying trends in the number of claims being filed and the size of settlement payouts, *the cycle itself is fueled by factors that are not related to claims experience*. The cycle typically involves a period of relative stability or even shrinking of real premium levels as insurers compete on the basis of price to increase their market share and to obtain funds to invest until claims against their insureds are resolved. *When changes in the investment returns, reserve levels, or legal markets warrant an increase in premiums*, insurers have historically been loath to be the first to do so. As a result, corrections are delayed until *price increases are essential to the company’s survival*. When the correction occurs, it must account for years of inappropriately low premiums. This correction of accumulated under-pricing caused the sharp premium spikes that occurred in the mid-1970s, mid-1980s, and early 2000s and prompted physicians to march on state capitals across the country. *It is no coincidence that the periodic escalation of angry demands for medical malpractice reform always follows a spike in the cycle*. Any malpractice reform that hopes to end these crises must temper the impact of these inevitable premium spikes on individual physicians.<sup>256</sup>

As Abraham and Weiler point out, malpractice liability is governed by state law; insurance premiums are “subject to state regulation;” the commercial insurer’s “risk pool for purposes of loss-prediction and premium-setting” is limited to the number of physicians practicing in the state; and, the insurers divide those physicians into “risk classes” based on their specialties, regardless of their personal claims experience.<sup>257</sup> Consequently, “a comparatively small number of physicians comprising each pool is charged with the aggregate cost of this risk.”<sup>258</sup> As a result, high-risk specialists incur higher premiums than other physicians in the same area.<sup>259</sup> Moreover, when premiums inevitably increase, they do so sharply – resulting in unforeseen reductions in income and cash-flow

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256. Peters, *supra* note 251, at 386–87 (emphasis added).

257. Abraham & Weiler, *supra* note 54, at 401.

258. *Id.* at 401–02.

259. *Id.* at 402.

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problems for many physicians.<sup>260</sup> “These shocks in the market for malpractice coverage produce not only economic effects, but *also political repercussions that generate ill-designed tort reform of various sorts.*”<sup>261</sup>

As indicated in our initial quote of Professor Peters, an exclusive enterprise liability approach is preferable since, unlike physicians, hospitals are “experience-rated repeat players” (as would be other institutional providers, like ACOs and our proposed HCBC); moreover, “[e]xclusive enterprise liability would also reduce the disruption caused by the insurance cycle . . . .”<sup>262</sup> As Abraham and Weiler argue:

EML would be a superior compensation system from the standpoint of both physicians and claimants. For physicians, shifting liability from individual physicians to hospital enterprises could ameliorate the effect of sharp changes in premium levels that result from the small size of insurer risk pools. Each liability-bearing enterprise would serve, in effect, as a large pool consisting of the risks posed by all the doctors and nurses for whose malpractice the enterprise would be liable. For claimants, and especially those who suffered severe and permanent injuries, EML would virtually eliminate the risk that a large judgment would go unrecovered.

In addition, EML could prove to be a superior insurance system from the standpoint of hospitals. Though some hospitals now self-insure their liability for malpractice, this practice probably would be rendered more feasible by enterprise liability, because the increased number of events for which hospitals would be liable would render their annual claims experience even more predictable. Moreover, whether a hospital self-insures or purchases market insurance, hospitals are better able to plan and budget for the variable costs of malpractice insurance than are individual physicians or small practice groups.<sup>263</sup>

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260. *Id.*

261. *Id.* (emphasis added). The authors go on to note:

For example, during both the medical malpractice ‘crisis’ of the mid-1970s and the liability ‘crisis’ of the mid-1980s, physicians and other potential defendants were often successful in persuading state legislatures to enact their favored tort reforms. For catalogues of the results, see Joseph Sanders & Craig Joyce, ‘*Off to the Races*’: *The 1980s Tort Crisis and the Law Reform Process*, 27 HOUS. L. REV. 207, 218-23 (1990), and Comment, *An Analysis of State Legislative Responses to the Medical Malpractice Crisis*, 1975 DUKE L.J. 1417 *passim*.

*Id.* at 420 n.78.

262. Peters, *supra* note 251, at 369–70.

263. Abraham & Weiler, *supra* note 54, 403–04 (emphasis added).

Although now made more than 25 years ago, Abraham and Weiler's arguments remain persuasive today.

*1. The Self-Insurance/Captive Option*

In a 2012 article, Professor Eleanor D. Kinney notes:

In recent years, healthcare providers have increasingly used captive insurance companies for their medical liability coverage. Over the past several years, an increasing number of individual hospitals and consortia of hospitals and physicians have begun to self-insure in a variety of ways. In 2003, the American Hospital Association estimated that forty percent of its member hospitals were self-insured. A more recent industry survey conducted by AON Risk Solutions and the American Society for Healthcare Risk Management 'found that 73 percent of systems surveyed will self-insure the combined hospital-physician malpractice risk.'<sup>264</sup>

According to Kinney, the Captive Insurance Companies Association "defines captive insurers as follows:"

Captive Insurance Company – A risk-financing method or form of self-insurance involving the establishment of a subsidiary corporation or association organized to write insurance. *Captive insurance companies are formed to serve the insurance needs of the parent organization and to escape uncertainties of commercial insurance availability and cost.* The insureds have a direct involvement and influence over the company's major operations, including underwriting, claims, management policy, and investments.<sup>265</sup>

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264. Eleanor D. Kinney, *The Potential of Captive Medical Liability Insurance Carriers and Damage Caps for Real Malpractice Reform*, 46 NEW ENG. L. REV. 489, 498 (2012) (citing, *Healthcare Industry Faces Unprecedented Change in Hospital Landscape*, AON (Oct. 18, 2011), <http://aon.mediaroom.com/index.php?s=43&item=2414>).

265. *Id.* at 495–96 (emphasis added) (citing *Captives Glossary*, CAPTIVE INS. COS. ASS'N, <http://www.cicaworld.com/Resources/CaptivesGlossary.aspx> (last visited Mar. 30, 2012)). Professor Kinney goes on to note:

There are two primary forms of captives: *single-parent captives* and *group captives*. In a single-parent captive, also known as a pure captive, a parent company forms an insurance company to insure its own risks. In a group captive, multiple, non-related organizations form or participate in an insurance company to insure risks common to the group. Other classifications of captives include an association captive, a 'rent-a-captive,' a sponsored or 'protected cell' captive, and a risk retention group ("RRG").

*Id.* at 497 (emphasis added).

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Professor Kinney emphasizes the principal advantage of captives for institutional health care providers: since the provider is the “only insured entity” – able to direct all underwriting, claims, and investment decisions – they can better “take steps to limit medical liability claims” free of a commercial carrier’s competing interests in “*serving shareholders or other insureds*,” that is, because commercial carriers “*are incentivized to contest medical liability claims in pursuit of profits or revenue*” they “have little incentive to work with provider patient safety programs in compensating patients for medical injury.”<sup>266</sup> In addition, she suggests that those providers wishing to develop ACOs under the ACA (with its “multiple provisions that encourage providers to integrate their quality improvement, patient safety, and care delivery activities”) “could greatly benefit by the flexibility accorded by captive insurance companies managing liability.”<sup>267</sup>

Not surprisingly, Professor Hermer also endorses the benefits of captives for ACOs, particularly within the context of enterprise liability.<sup>268</sup> In her previously-quoted 2014 article, she writes:

*ACOs will need to have the capacity to exercise a certain amount of control over participating health care providers in order to more reliably meet quality and cost targets. Given the need for such control, it makes sense that the enterprise should bear the financial risk of negligent medical errors, rather than the individual practitioners acting as a part of it. . . .*<sup>269</sup>

. . .

*ACOs would be aided in [their] pursuits by self-insuring or insuring via a captive insurance company, rather than by purchasing coverage on the market. While self-insurance had once been more commonly used by larger health care entities, the use of captive insurers created by one or more business entities (parents) solely to insure the risk of that entity or entities has grown substantially in recent years. The parent pre-funds losses by paying premiums to the captive, which the IRS considers a tax-deductible business expense to the parent. Thus, rather than deducting losses as they are paid, which would be the case under a self-insured model, the parent takes the deduction up-front. Excess premiums can be held in reserve and invested to fund future losses, or distributed to the parent as profit.*<sup>270</sup>

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266. *Id.* at 500 (emphasis added).

267. *Id.* at 499.

268. Hermer, *supra* note 95, at 295–96 (explaining why placing liability on the ACOs rather than on participating physicians would accomplish multiple important goals).

269. *Id.* (emphasis added).

270. *Id.* at 297–98 (emphasis added).

Professor Hermer then goes on to note the difference between “*enterprise liability*” and “*enterprise insurance*,” and to explain why enterprise liability is the preferred approach for ACOs:

Given that many of the innovations discussed above do not require the institution of enterprise liability but instead can be done through our present liability regime, one might ask why one might prefer enterprise liability over, for example, *enterprise insurance*, where an ACO would simply provide malpractice coverage to its participating physicians through a captive, self-insurance, or otherwise. Enterprise insurance is widely used by academic medical centers to cover their faculty. It has been less common elsewhere in the health care industry, but that may be in part because physician employment has not been as common outside of academic medicine until more recently. As consolidation continues in the health care sector, it is likely that enterprise insurance will also become more common. Not only does enterprise insurance offer improved financial benefits to larger health care entities with an employed physician staff, but it also allows for better risk- and quality-management.

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*Yet an ACO’s control over both risk and quality could improve further through assumption of enterprise liability, rather than enterprise insurance. As the ACO would bear the burden of litigation, it would possess not merely institutional authority, but also moral authority for deterring errors and enforcing quality measures. This would be particularly important, given that most ACO participants will not provide services exclusively to ACO patients, but also to others, both within and outside the context of the ACO. If an ACO provided only enterprise insurance, it would possess fewer means by which to enforce quality standards for care provided outside the ACO. . . .*<sup>271</sup>

Accordingly, the HCBC – with or without operating an ACO – could and should adopt enterprise liability for the same reasons, while simultaneously minimizing the cost of its medical and fiduciary liability coverage by self-insuring through its own captive.

#### *B. The HCBC as Health Insurer*

We believe, then, that the HCBC could improve its risk management and quality control, and reduce its insurance costs, by becoming its own enterprise liability insurer with direct control of “underwriting, claims, and investment decisions” while eliminating the additional cost burden of an outside commercial carrier’s profit requirements. In like fashion, we believe that the HCBC could

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271. *Id.* at 298–99 (emphasis added).

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similarly maintain quality, improve accessibility, and further lower costs (to its patients, if not to itself ) by becoming a state-licensed and regulated health insurance provider of its own non-HMO, non-capitated, indemnity plan<sup>272</sup> – operating essentially as a *nonprofit*<sup>273</sup> Preferred Provider Organization (“PPO”).<sup>274</sup> As has been said, “much of what is called health insurance is primarily the provision of administrative services: managing enrollment, verifying eligibility, contracting with health care providers, and processing claims”<sup>275</sup> – all functions that the HCBC could readily accomplish.

*I. A Non-Capitated Provider/Payer*

In order to best explain our concept of the HCBC serving as *both* provider and payer, we need to compare and contrast an earlier proposal for “*health plan enterprise liability*” with current understandings of enterprise liability for an ACO. In his previously-cited 1997 article, Professor Sage discusses not only the Abraham and Weiler “hospital-based model” of enterprise liability, but also the “health plan-based model” that was proposed by President Clinton’s 1993 Task Force on National Health Care Reform.<sup>276</sup> In explaining the latter, Sage says:

As both a logical and a practical matter, *adoption of enterprise liability during the 1993-94 health care reform debate relied on the concurrent passage of universal health coverage based on managed competition.* This legislatively created managed health care system would have been composed of ‘*health plans,*’ that is *integrated organizations that combined health care financing with the provision of services.* Health plans might have been unitary corporations or contractual networks, and could have been owned or controlled by any combination of physicians, hospitals, insurers, and other health care entities. *Regardless of their structure, however, health plans would have received a fixed annual payment, and would have been responsible for organizing and delivering necessary care to enrollees.*<sup>277</sup>

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272. An “Indemnity Plan” is defined as “[a] type of medical plan that reimburses the patient and/or provider as expenses are incurred.” *Definitions of Health Insurance Terms*, U.S. BUREAU OF LAB. STAT., <https://www.bls.gov/ncs/ebs/sp/healthterms.pdf> (last visited Feb. 1, 2021).

273. Again, using Professor Kinney’s words, free of a commercial carrier’s competing interests in “serving shareholders or other insureds.” Kinney, *supra* note 264, at 500.

274. A “Preferred Provider Organization (PPO) Plan” is defined as “[a]n indemnity plan where coverage is provided to participants through a network of selected health care providers (such as hospitals and physicians). The enrollees may go outside the network, but would incur larger costs in the form of higher deductibles, higher coinsurance rates, or non-discounted charges from the providers.” *Definitions of Health Insurance Terms*, U.S. BUREAU OF LAB. STAT., <https://www.bls.gov/ncs/ebs/sp/healthterms.pdf> (last visited Feb. 1, 2021).

275. Sage, *supra* note 42, at 697.

276. Sage, *supra* note 229, at 162–66.

277. *Id.* at 164 (emphasis added). Professor Sage went on to note:

Of course, the “concurrent passage of universal health coverage based on managed competition” that Sage described was not forthcoming – at least as then envisioned. What happened instead was a growing disillusionment with “managed care” generally and capitated HMOs in particular. The eventual result was the 2010 Affordable Care Act with its promotion of Accountable Care Organizations (ACOs) – which are not, at least for now, required to operate on a “fixed annual payment” basis (*i.e.*, capitation).<sup>278</sup> As we discussed in our 2019 article:

‘The accountable care organization superficially resembles Independent Practice Associations and Physician Hospital Organizations, entities that sprang into being during the heyday of managed care. The ACO is seen as having the potential to harness some of the positive characteristics of managed care – such as a measure of financial risk assumed by physicians, the ability to coordinate care, and the infrastructure of an integrated delivery system – without the negative characteristics, such as a loss of physician autonomy, potentially harmful financial risk to physicians, *or incentives to stint on care. This is because it remains a fee-for-service system, retaining independent proprietorships, and any financial incentives to stint on care can be counterbalanced, or outweighed, by incentives to improve patient outcomes.*’<sup>279</sup>

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In an environment where health care is planned, managed, and provided by a ‘system’ instead of being rendered by unaffiliated, individual practitioners, *holding health plans primarily accountable for instances of medical malpractice* is appealing for three reasons. First, health plans already would be primarily responsible for cost containment. Legal liability for negligent health outcomes therefore should make health plans reluctant to cut costs by reducing quality, especially when weighing aggregate budgetary concerns against the health needs of individual patients. Second, unlike torts that involve strangers (such as automobile accidents or toxic spills), medical malpractice arises between parties who have a pre-existing relationship, which health plans could formalize and extend. Health plans enroll beneficiaries using detailed insurance agreements, and rely on contractual relationships with providers to allocate financial risk, determine the price of services, and assure cost-consciousness. *As a whole, these agreements could form the basis for quality improvement activities, communication of grievances, and efficient dispute resolution.* Third, health could be subjected to significant direct regulation and oversight. *In the Clinton bill, for example, health plans were required to comply with national standards on the accessibility and impartiality of grievance procedures; to collect, process, and publish comprehensive information on clinical performance; and to work closely with purchasing alliances as well as with state and federal authorities to ensure access to and quality of care.*

*Id.* (emphasis added).

278. See Corbett, *supra* note 17, at 271–84, for a more complete discussion of ACOs and the concept of Accountable Care in general.

279. *Id.* at 274 (emphasis added and in original) (quoting Jackson Williams, *The “Shared Accountability” Approach to Physician Payment: Four Options for Developing Accountable Care Organizations*, 7 IND. HEALTH L. REV. 85, 190 (2010)).

Although it has been suggested that HMOs ‘are the most recognizable ACO precursors,’ there is an important distinction between the two models: ‘HMOs focus on the modification of reimbursement only’ (i.e., by ‘provid[ing] comprehensive health care to [voluntary enrollees] . . . that is financed by fixed periodic payments determined in advance’), whereas ACOs ‘address modification of both delivery structure and reimbursement.’ Health care author Wasif Ali Khan argues that ACOs avoid the “‘chicken or the egg’ conundrum,” which has historically ‘sidetracked and derailed’ previous efforts at healthcare reform; that is, *an ACO is a ‘healthcare delivery and cost-control model’* that simultaneously reforms both.<sup>280</sup>

From our perspective, these differences are critical: the HCBC is a new legal form for a clinically-integrated, institutional, direct care provider that we propose be subject to exclusive enterprise liability for all instances of medical negligence and/or fiduciary breach that might occur in its delivery of medical and related health care services. The HCBC *itself* will be the provider-entity properly subject to liability – *not* any health plan reimbursing it. That is to say, our suggestion that the HCBC undertake to operate as a “state-licensed and regulated health insurance provider of its own non-HMO, non-capitated, indemnity plan – operating essentially as a *nonprofit* Preferred Provider Organization (‘PPO’)” – is *not* to suggest that such PPO should be the locus of enterprise liability. It is for this reason that we advocate for a variation of the Abraham and Weiler “hospital-based model” of enterprise liability rather than the never-pursued “health plan-based model” proposed under the Clinton Administration.<sup>281</sup> Our singular purpose in suggesting that the HCBC provide an indemnity insurance product is to create more control – and thus improved risk management and quality assurance opportunities for the organization – while simultaneously creating an individual insurance product for its patients (and others) that could be very cost-competitive on the ACA Insurance Exchange (perhaps even as a private, cost-competitive alternative to a “public option”). Liability would properly continue to reside with the HCBC as the “institutional provider” of medical and supportive health care services.

## 2. *The ERISA Problem*

As something of an aside, while we have no real desire to wade into the murky morass of ERISA<sup>282</sup> jurisprudence, we do feel obliged to acknowledge

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280. *Id.* at 275 (emphasis added and in original) (citing Wasif Ali Khan, *Accountable Care Organizations: A Response to Critical Voices*, 14 DEPAUL J. HEALTH CARE L. 309, 310 (2012)).

281. See Abraham & Weiler, *supra* note 54.

282. 29 U.S.C. § 1001 et seq.

and comment on its continuing deleterious effects on the health care delivery system. To this end, we will point to the work of a few health law scholars who have braved the morass with more fortitude than we possess.

As Professor P. Greg Gulick, Jr. well summarizes:

Around the time *employer-based health insurance* became the predominant source of health care financing in the U.S., Congress enacted the ERISA to address abuses in the administration and investment of pension plan assets. *The intent of ERISA was to regulate pension plans and was not necessarily intended to regulate health benefit plans to the extent that it has*; however, non-pension benefits, that is, health benefits, were included in this sweeping piece of legislation. Since health benefits were part of employee benefit plans, the federal government gained unexpected authority over health benefit plans by virtue of changes made to ERISA. While ERISA gives the Department of Labor and Internal Revenue Service authority over employer-sponsored health plans (both self-funded and to a lesser extent, fully-insured plans), *this statute does not provide nearly as many consumer protections as state laws that regulate comparable health insurance coverage*. ERISA added to the complexity of the health care system by regulating otherwise identical health plans differently and created the incentive for plans to self-fund, which drew people out of the insurance risk pool. *ERISA is an example of reductionist reform. Although the stated intent of ERISA was to address abuses of pension plans, it inadvertently created a secondary health insurance market that impacted and influenced the way the health care system has evolved and operates.*<sup>283</sup>

Health law writer Christopher Smith succinctly explains how and why the effect, if not the intent, of ERISA is essentially to protect Managed Care Organizations (“MCOs”) from tort liability for adverse outcomes, leaving

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283. Gulick, Jr., *supra* note 31, at 23 (emphasis added) (citing Amy B. Monahan, *Federalism, Regulation or Free Market? An Examination of Mandated Health Benefit Reform*, 2007 U. ILL. L. REV. 1361, 1362 (2007)). The author goes on to note:

A self-funded health plan, in which employers fund the costs of health claims incurred by their employees, can offer nearly identical benefits to fully-insured health plans, in which the employer pays a premium for health insurance and the health insurer takes the risk (pays the claims). *However, the self-funded plan is subject to federal law (ERISA) and the fully-insured plan is subject to state law*. Although the benefits offered are nearly identical, the fully-insured plan has to include benefits mandated by state law while the self-insured plan does not.

*Id.* at 23 n.135 (emphasis added).

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plaintiffs with “few, if any, remedies” except focusing “their grievances against their physicians.”<sup>284</sup>

*Ironically, even though the MCO exerts extensive control over the physician’s treatment decision, . . . (ERISA) preempts most state law claims against many MCOs, and therefore, the physician usually remains solely liable for any adverse outcome. Most MCOs generally avoid any form of liability for their coverage decisions. ERISA applies to MCOs that are employer-sponsored health plans and preempts state law malpractice claims against those MCOs, while also failing to provide for a federal tort remedy against them. This is a bit of an oversimplification of the confusing and complex liability standards and case law governing the application of ERISA to MCO liability, but for purposes of this article it is sufficient to note three summarizing principles from the ERISA statute and guiding case law. First, plan beneficiaries can bring ERISA claims in federal court for breach of contract and collect breach of contract damages against ERISA covered MCOs, but there are no ERISA tort claims or ERISA tort damages to be had against ERISA covered MCOs. Second, ERISA preempts plan beneficiaries’ state tort claims against ERISA governed MCOs as to any claims involving eligibility decisions or administration of benefits decisions. Lastly, ERISA preempts tort claims founded upon MCO coverage decisions involving both treatment and plan benefit decisions, provided the patient’s treating physician was not involved in the utilization review decision and/or ‘the medical judgment was made by a utilization review physician who never saw the patient.’<sup>285</sup>*

Given the extent to which Americans continue to rely on “employer-sponsored health plans,” ERISA preemption of state law medical liability claims becomes “a nontrivial problem, since”:

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284. See Smith, *supra* note 255, at 175–76 (noting the importance of how plaintiffs are forced to focus their complaints against physicians rather than ERISA-compliant MCOs due to the lack of remedies). As Professor Sage further explains:

Because of ERISA, persons injured by the conduct of managed care organizations may be unable to bring causes of action such as wrongful death, professional negligence, intentional infliction of emotional distress, or bad faith breach of insurance contract. If they decide to sue, they must do so in federal court, possibly without the benefit of a jury trial. Most importantly, their maximum potential recovery is the value of the health care benefit wrongfully denied plus attorneys fees in many cases. Neither extracontractual compensatory nor punitive damages may be awarded.

Sage, *supra* note 229, at 180.

285. Smith, *supra* note 255, at 175–76 (emphasis added).

[M]any firms, especially larger ones, self-insure: in 1997, a survey of seven states showed that employers self-insured in 13% of all firms, 56% of firms with 500 or more employees, 25% of firms with 100-499 employees, and 3% of all firms with fewer than 100 employees. A more recent study using a different methodology suggests this number has grown significantly in our decade; *self-insured plans that escape the [state law] mandates now cover an estimated 55% of all workers and 77% of workers in large companies.*<sup>286</sup>

In our opinion, health plan coverage denials can be, and arguably have been in many instances, tantamount to negligent violations of the medical standard of care – for which ERISA preemption often has left meritorious claimants without just recourse. This result is the antithesis of our aims for the HCBC – *a clinically and financially-integrated organizational provider that embraces enterprise liability for both medical negligence and fiduciary breach, while reducing its costs to the maximum extent possible through the elimination of outside third-party profits in the direct provision of health care services.* As Jack K. Kilcullen observed nearly 25 years ago:

Enterprise liability speaks loudly on the question of how to allocate the costs of compensating injury caused by defective medical care, much as it has incorporated itself into modern manufacturing of goods. It provides the conceptual basis within modern economics for the archetypically American premise that the free market will be the primary source for meeting essential human needs. *By contrast, ERISA's preemption of liability of health care plans, but not the individual physician, is an outdated government incentive that disrupts competition and robs consumers of well-established remedies. It removes a powerful incentive to provide quality service at a time when the government itself has failed to shoulder that responsibility directly through a national health care program.*<sup>287</sup>

#### V. CREATING A “CULTURE OF VIRTUE” IN INSTITUTIONAL HEALTH CARE

“Did you ever expect a corporation to have a conscience, when it has no soul to be damned, and no body to be kicked?”

*Edward, 1<sup>st</sup> Baron Thurlow, Lord Chancellor of England*<sup>288</sup>

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286. I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467, 1545 (2010) (emphasis added).

287. Kilcullen, *supra* note 248, at 50 (emphasis added).

288. Michael B. Metzger & Dan R. Dalton, *Seeing the Elephant: An Organizational Perspective on Corporate Moral Agency*, 33 AM. BUS. L.J. 489, 541 n.5 (1996) (citing THE OXFORD DICTIONARY OF QUOTATIONS 697 (4<sup>th</sup> ed. 1992)).

What we seek for the HCBC is what Professor Ronald J. Colombo has called “*a corporate culture that fosters virtue.*”<sup>289</sup> In this instance, we see such a culture as one that maintains medicine’s professional norms and commitment to excellence, while reinforcing and sustaining a recognition of the broad scope of fiduciary responsibility necessarily attendant to the team-delivery of health care services. Such culture is essential, we believe, to the restoration of equity of care and patient trust in today’s institutional health care delivery system.<sup>290</sup>

Professor Colombo explains:

‘Corporate culture is the body of shared beliefs, values, expectations, and norms of behavior that shape life in the organization and account for certain observable artifacts.’ Corporate culture *is essential to virtue and morality* because ‘it is a vehicle for imparting and maintaining the moral principles and the values, good and bad, that animate life in the organization.’ Scholarship has increasingly documented the ‘impact of organisational culture on the ethical standards and moral practices of people in organisations.’<sup>291</sup>

As he goes on to note, “*to the extent that a corporation’s focus is on excellence – the excellence of its product and the excellence in its treatment of its various constituencies – the corporation is fertile for the development, growth, and exercise of virtue.*”<sup>292</sup> Professor Colombo thus urges creating “an

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289. See Ronald J. Colombo, *Toward a Nexus of Virtue*, 69 WASH. & LEE L. REV. 3, 69 (2012) (emphasis added) (explaining the tremendous impact organizational culture has on the moral and ethical standards and practices of individuals in corporations).

290. See Corbett, *supra* note 17, at 306–10.

291. Colombo, *supra* note 289, at 69–70 (emphasis added).

292. *Id.* at 71 (emphasis added). Professor Colombo advocates for “virtue ethics,” as derived from Aristotle’s *Nicomachean Ethics*:

Hailing from the fourth century B.C., *Nicomachean Ethics* posits that “*eudaimonia*” (best translated as authentic flourishing, as opposed to mere transient pleasure or satisfaction) requires virtue as its predicate. And since Aristotle famously observed that man is a social animal, virtue is not simply a matter of individual concern, but rather a concern of society as a whole. As indicated, an individual’s excellence (or lack thereof) usually has repercussions for all those around her. In the parlance of modern economics, one could say that an individual’s private morality imposes very public externalities – indirectly if not directly.

*Id.* at 11–12 (citing ARISTOTLE, *NICOMACHEAN ETHICS* (Roger Crisp ed., Cambridge Univ. Press 2000)). Professor Colombo goes on to discuss how virtue is “developed:”

Aristotle wrote that moral virtue cannot be acquired via instruction alone but rather needed to be developed through choice and action. Indeed, virtue has been commonly defined as the “habit” of doing good, and habits are learned via repeated doing. This comports well with common experience. Countless individuals know what they ought to do yet fail to actually do it. The gulf between knowledge and willpower can be wide, and a person of virtue is someone who has effectively bridged that gulf. To take the analogy one step further, the

environment where the practice and development of virtue [is] actively encouraged by the corporation.”<sup>293</sup>

The virtue that Professor Colombo exhorts, we contend, reflects the essence of “institutional morality;” and, as we have previously said, we believe “‘institutional morality’ is a coherent and legitimate concept – the idea that the corporation functions as a ‘real person in society’ with corresponding obligations to attend to the effects its presence and activities have upon a broad range of others.”<sup>294</sup> Moreover, as Professor Jeffrey Nesteruk observes:

[T]he corporation is an environment in which individuals make choices and take actions and like other environments, it is not neutral in nature. The context it creates affects the choices and actions which occur within it, influencing their development and character. It is thus important to consider the corporation not only as an actor, but as an environment which structures the relationships and choices of other actors, those individuals who work in and with the corporate organization. In particular, the corporation affects the character of such individuals’ ethical decision-making.<sup>295</sup>

As to corporate health care organizations (“HCOs”) specifically, we agree with Professor Mantel:

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bridge is built by repeatedly acting in accord with one’s conscience. Conversely, the bridge is damaged each time an individual ignores the dictates of conscience and chooses instead to act at odds with what she believes to be right.

*Id.* at 14.

293. *Id.* at 69.

294. Corbett, *supra* note 17, at 321. That is not to say that we subscribe to the notion of “corporate moral personhood.” Rather, we share the view that corporations are “intentional systems and secondary moral agents.” See Patricia H. Werhane, *Corporate Moral Agency and the Responsibility to Respect Human Rights in the UN Guiding Principles: Do Corporations Have Moral Rights*, 1 BUS. HUM. RTS. J. 5, 17 (2016). As Professor Werhane explains:

[C]orporations are *eliminable* moral agents, because even as distinct abstract entities they do not and cannot act independently of those who act on their behalf. Corporations, then, like other collectives, depend on the ‘strings’ pulled by others, even though those strings appear to be pulled by *corporate missions* and goals, *organizational culture*, a dominant logic, and *other organizationally structured phenomena* that trace their origins to individual decision-making and behavior. . . .

. . . Rather, a corporation, particularly one of any size, is a socially-constructed non-physical phenomenon. It cannot act on its own, but this does not diminish its collective nature and the non-redistributable content of much of its behavior and *decisions for which we hold a corporation responsible*.

*Id.* at 15 (emphasis added). As we stated in our 2019 article: “The real question, then, appears not to be so much whether a corporation can have a ‘moral character of its own,’ but rather whether it is inclined to act like it does and whether such inclination depends solely on its nonprofit verses for-profit status.” Corbett, *supra* note 17, at 207.

295. Jeffrey Nesteruk, *Legal Persons and Moral Worlds: Ethical Choices within the Corporate Environment*, 29 AM. BUS. L. J. 75, 82 (1991).

Because HCOs are heterogeneous organizations, differences in their organizational cultures may lead to differences in physician behavior and, ultimately, differences in the *quality, modality, and cost of care* provided to patients. Of particular concern are organizational cultures that bias physicians' clinical decision making in ways that lead to the provision of inexpert or inefficient care or the withholding of necessary care. *The challenge for health scholars and policymakers, then, is to determine how best to promote more virtuous organizational cultures that minimize these risks while respecting community standards of compassion and fairness.*<sup>296</sup>

We believe that a properly-operationalized HCBC can help meet this challenge.

*A. The Effect of Organizational Culture*

*An organization's culture manifests itself both formally and informally. At the more visible level are an organization's formal structures, processes, and espoused values. These include the organization's financial-incentive structures, methods of performance assessment, mission statement, and ethical guidelines. Of greater influence, however, is an organization's informal culture, that is, the 'taken for granted beliefs, perceptions, thoughts and feelings.' Together, an organization's formal and informal culture significantly influence its employees' decisions, perhaps even more than the professional norms and personal values an employee brings to the workplace.*<sup>297</sup>

Professor Mantel argues that physicians practicing within HCOs become subject to "an organizational dynamic that powerfully influences" their clinical judgments.<sup>298</sup> Through a process that "largely occurs" outside their "conscious awareness," they gradually adapt "to the HCO's 'way of doing things.'"<sup>299</sup> In her previously-cited 2013 article, she spends considerable time discussing the cognitive psychology behind this process – how physicians, when inevitably confronted with "medical uncertainty" and "difficult value trade-offs," come to be "guided by *cognitive frameworks*, or *schemas*, that organize their knowledge, assumptions, and values."<sup>300</sup> These schemas "provide the 'personal decision rules' that physicians use to make clinical decisions, particularly in conditions of

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296. Mantel, *supra* note 87, at 506 (emphasis added).

297. *Id.* at 485 (emphasis added)

298. *Id.*

299. *Id.* at 505.

300. *Id.* at 460 (emphasis added).

uncertainty.”<sup>301</sup> Professor Mantel argues that schemas thus “play a central role in the balance physicians strike among the competing considerations in the patient-care setting . . . enabling them to make choices in the face of uncertainty and ambiguity.”<sup>302</sup> She further notes the importance of this role in “directing a physician’s cognitive processing” in the absence of “clear clinical guidelines.”<sup>303</sup>

While Professor Mantel focuses her discussion of organizational culture and its effect on the cognitive psychology of clinical decision-making by a HCO’s physicians, it goes without saying that the same dynamics necessarily affect *all* members of the health care delivery team. To slightly modify another quote from her:

Conceptualizing patient care as provided at the level of the individual physician [*team member*], however, is a serious mistake because it fails to recognize the link between an HCO’s organizational culture and its affiliated physicians’ [*team members*] clinical decisions. . . . [I]t is imperative that we abandon the myth of the independent physician and recognize that patient care increasingly is a product of an organizational system.<sup>304</sup>

We have already discussed at length the team-delivery of health care services by today’s institutional providers and what it implies for needed medical tort reform. Nonetheless, it is worth here emphasizing the particular contribution that we, like Professor Mantel, believe that adoption of enterprise liability would make to a more equitable system of medical tort liability *and* a more virtuous corporate culture:

Although proposals for enterprise medical liability are not new, recognition of the close link between organizational culture and patient-care decisions provides a new justification for such proposals. Specifically, enterprise liability would recognize that organizational norms and values may contribute to errors in physicians’ professional judgments, such as incorrect diagnoses or selecting deficient plans of treatment. *By imposing sole legal responsibility for medical errors on HCOs, enterprise liability would motivate HCOs to pay closer attention to how their organizational culture may contribute to poor medical decision[-]making by their affiliated physicians.*<sup>305</sup>

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301. *Id.* at 477.

302. *Id.* at 484.

303. *Id.*

304. *Id.* at 505 (emphasis added).

305. *Id.* at 516–17 (emphasis added).

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Again, it goes without saying that such proposition applies to *all* members of the health care team involved in the delivery of medical and supportive health care services.

*B. The Critical Importance of a Commitment to “Mission Primacy”*

A new legal paradigm is needed which would allow a conceptualization of the corporation not as a person, but as an organizational actor. *By emphasizing the organizational character of the corporation, this new legal framework brings into view the corporation’s status as a moral world.* Through its acknowledgment of the corporation’s existence as a moral world, *the legal theory of the corporation can be reintegrated with practical approaches to the corporate entity necessary to confront the ethical concerns of corporate life which press upon us.*<sup>306</sup>

We see the HCBC as offering such a “new legal framework” – encompassing a renewed “moral world” . . .

- that is committed to the “primacy” of a “dual organizational mission” – *i.e., both* the ongoing and consistent provision of affordable, high-quality, high-value, and readily accessible health care services *and* targeted profit seeking and distribution . . . ; and
- that formally recognizes and accepts its “institutional fiduciary responsibilities” (and corresponding liability) *both* for the professional provision of competent health care *and* for the general accomplishment of its organizationally-mandated dual missions.<sup>307</sup>

As we explained in our 2019 article:

[U]nlike Professors Greaney and Boozang – *who advocate only a ‘doctrinal recognition’ of mission primacy – we advocate that mission primacy be made an explicit and fully-enforceable legal requirement under the constitutive structure of the HCBC’s legal form itself.* Such requirement would limit wayward application of what has been called the ‘best judgment rule’ – the ‘nonprofit equivalent of the business judgment rule that allows corporate directors space in which to exercise their discretion’ – that has too-often enabled inappropriate nonprofit emulation of for-profit conduct. As noted by Professor

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306. Nesteruk, *supra* note 295, at 97 (emphasis added).

307. *See supra* Part I.

Henry B. Hansmann: ‘In the case of the nonprofit corporation, . . . the purpose of the charter is primarily to protect the interests of the organization’s *patrons* from those who control the corporation.’<sup>308</sup>

Simply put, we believe that something more than a “doctrinal recognition” is necessary for the primacy of the HCBC’s “dual mission” to be sustained. The fundamental point of the HCBC’s legally-recognized dual mission is to ensure that the entire organization becomes and remains truly committed to the idea of a private (*i.e.*, non-governmental), “not-only-for-profit”<sup>309</sup> health care delivery system that consistently provides affordable, high-quality, high-value, and readily accessible health care services at the lowest possible cost, while remaining committed to “*the excellence of its product and the excellence in its treatment of its various constituencies.*”<sup>310</sup> Such commitment requires “an organization with the right kind of culture” – one that “cultivates not simply virtuous behavior . . . but actual virtue. Its citizens behave virtuously not because they are rewarded for so doing and punished if they do not, but because *they value so doing* and have *second-order desires* accordingly.”<sup>311</sup>

308. Corbett, *supra* note 17, at 289–90 (emphasis in original).

309. As we noted in our 2013 article:

The recognition that mission objectives other than pursuit of profit are sufficiently important in health care to justify giving them more formalized legal status finds support in Robert G. Evans’ concept of a “*not-only-for-profit*” sector” – a designation referring to “firms ‘in which a legal claimant to profits is well-defined, but profits represent only one among several competing objectives of the firm’s ownership and management.’

Corbett, *supra* note 3, at 167 (citing Theodore R. Marmor *et al.*, *A New Look at Nonprofits: Health Care Policy in a Competitive Age*, 3 YALE J. ON REG. 313, 319 (1986) (emphasis added)).

310. See *supra* Part V.

311. Metzger & Dalton, *supra* note 288, at 541 n.331 (emphasis added) (quoting Edwin M. Hartman, *The Commons and the Moral Organization*, 4 BUS. ETHICS Q. 253, 258 (1994)). Professor Susanna K. Ripken further elaborates on the concept of *second order desires*:

In organizations with strong corporate cultures, the culture is integrated into the lives of the members and it becomes difficult to see oneself apart from it. There are psychological and sociological dimensions to this integration: ‘[G]roups are not only external features of the world that people encounter and interact with, . . . they are also *internalized* so that they contribute to a person’s *sense of self*. Groups define who we are, what we see, what we think and what we do.’ People naturally develop a sense of loyalty to groups, identifying with the goals and values of the group and making them their own. Strong cultures can actually help determine what makes one happy and what kind of person one wants to be, in part, by defining for the person what counts as success. In Frankfurtian terms, cultures can affect one’s *second-order desires*, causing one not only to want certain things, but also to want to want them, *i.e.*, to desire to be the type of person who values these things. . . .

Susanna K. Ripken, *Corporations Are People Too: A Multi-Dimensional Approach to the Corporate Personhood Puzzle*, 15 FORDHAM J. CORP. & FIN. L. 97, 134–35 (2009) (emphasis in original and added). She goes on to note: “Harry Frankfurt’s well-known philosophical theory of the concept of the person posits that having freedom of will is essential to being a person, and that one has this freedom of will only when one can have the will one wants to have, *i.e.*, the capacity for *second-order desires*.” *Id.* at 135 n.139 (emphasis added) (citing Harry G. Frankfurt, *Freedom of the Will and the Concept of a Person*, 68 J. PHIL. 5, 5–20 (1971)).

## VI. SUMMARY AND CONCLUSION

‘The failure of most [integrated delivery systems] to provide greater value over the past 15 years has been due to their over-emphasis on achieving functional and economic integration to the neglect of the clinical integration process. . . . [T]hese new organizations ‘*failed to fulfill their potential because the main driver was to create a structure rather than to develop objectives or the desired outcome of integration.*’ . . .’<sup>312</sup>

. . .

[T]he push toward vertically integrated systems in the 1990s ‘*did not create the desired social-psychological change: Despite being nominally part of the same organization, physicians and hospitals continued to see themselves as separate groups with divergent interests, values, and worldviews;*’ . . . research from the 1990s . . . found that ‘*membership in PHOs and IPAs had little effect on physicians’ identification or commitment’ to integrated delivery networks.*<sup>313</sup>

We will end where we began – with our five objectives for operationalizing the HCBC. *The first objective* was the HCBC’s adoption of an integrated systems approach to facilitate care coordination and the development and appropriate use of evidence-based clinical practice guidelines. Enough has already been said about the implications of today’s team-provided health care and the importance of HIT and data analytics in improving communication and care coordination. As to evidence-based medicine, we have directly stated that “the HCBC is well structured to develop its own CPGs, to indemnify its physicians and staff for following them, and to assume legal accountability for outcomes through acceptance of enterprise liability.”<sup>314</sup> Such CPGs would be developed under the auspices of the HCBC by the very health care teams who would be responsible for implementing and following them, reflecting their consensus view of the clinically-best and most cost-effective practices available. As such, these CPGs should not be met by the kind of professional resistance that historically has confronted many third-party- and even government-developed guidelines. The CPGs themselves will not be deemed to establish the definitive “standard of care” in any legal proceeding, but rather only to be relevant evidence of such standard<sup>315</sup> – reflecting the HCBC’s best judgment of best practices. Accordingly, those health team members following the CPGs will

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312. Mantel, *supra* note 87, at 465 n.31 (internal cites omitted, emphasis added).

313. *Id.* at 466 n.34 (internal cites omitted, emphasis added).

314. *See supra* Part III Section A.1.a.

315. As currently remains the case in most jurisdictions. *See supra* Part III Section A.1.a.

in all cases be “immunized” or “indemnified” by the HCBC against any finding of individual liability (except for demonstrated instances of willful misconduct or gross negligence) through the HCBC’s adoption of exclusive medical enterprise liability as herein discussed.<sup>316</sup> Should any care or treatment consistent with any such CPG be found negligent in any proceeding (*i.e.*, violative of the applicable standard of care), then liability for such negligence shall reside solely with the HCBC itself. Similarly, should any act or omission not covered by a CPG be alleged to violate the standard of care – and result in harm – then any claim resulting from such occurrence will be treated as an exclusive enterprise medical liability claim against the HCBC (with the same, hopefully rare, exceptions for individual liability). In sum, the HCBC shall assume the risk that its CPGs meet the applicable standard of care for medical malpractice; if no CPG covers the situation, the HCBC shall indemnify its health team members in all cases excepting willful misconduct or gross negligence.

*The second objective* was to enhance fairness and equity for victims of “iatrogenic injury” by adopting an alternative theory of tort liability to govern the medical and fiduciary duties and liabilities of integrated system providers. To this end, we have now explained the rationale for the HCBC to operate under a construct of exclusive enterprise medical liability that encompasses a broader range of fiduciary obligations owed by all organizational participants in the direct provision of health care services.<sup>317</sup> We have described in some detail how the EML construct here proposed: differs from others’ understandings of the “tort theory of enterprise liability” in different contexts; builds upon a policy proposal first advanced in the late 1980s by two prominent academics; and, continues to garner considerable support among health law scholars.<sup>318</sup> In contrast to prevailing tort reform efforts to date – which almost universally limit plaintiffs’ damages and/or erect further barriers to claim adjudication – the EML construct here proposed for the HCBC directly addresses the thorny issues of “defendant indeterminacy” and “proximate causation” that have too often thwarted meritorious plaintiff claims, particularly in today’s team-delivered health care environment.<sup>319</sup> While critics may protest that such an approach may well result

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316. See *supra* notes 264–267 and accompanying text. Should there be a case, however, in which an individual team member willfully failed to follow an applicable HCBC-CPG, or was otherwise grossly negligent in relation thereto, and harm resulted – then the HCBC’s indemnification would not apply and that individual would be subject to an individual finding of negligence for which they would be individually liable. See Kinney, *supra* note 264, at 502–03 (discussing the problems for meaningful health care reform created by NPDB reporting requirements and questioning the continuing value of such reporting). It is only in such instances that the HCBC would report that individual to the National Practitioner Data Bank. *Id.* at 503.

317. See *supra* Part III.

318. See *supra* note 261 and accompanying text.

319. To again quote Professor Furrow:

Complexity in medicine – the combination of medical progress and industrialization – *is producing more medical adverse events and errors than ever before.* Mark Chassin and Jerod

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in more malpractice litigation, we would respond: (1) historically (and still), the incidence rate of medical injury far exceeds the number of malpractice claims filed, which in turn far exceeds the percentage of claims receiving compensation;<sup>320</sup> (2) the HCBC is committed to the primacy of a dual organizational mission which includes “the ongoing and consistent provision of affordable, high-quality, high-value, and readily accessible health care services,” together with *limited* profit seeking<sup>321</sup> – *not* the minimization of costs associated with compensating those whom it wrongfully injures; (3) the HCBC’s adoption of enterprise medical liability, together with development and use of its own professionally-acceptable CPGs, should go a long way toward improving its quality assurance and risk management efforts and corresponding liability claims experience; and (4) (as will be discussed next), the HCBC will make significant reductions in the overhead cost of its liability coverage and payouts by self-insuring via its own captive.

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Loeb observe: ‘Hospitals house patients who are increasingly vulnerable to harm due to error, and the complexity of the care hospitals now provide increases the likelihood of those errors.’ A study of a large Chicago-area hospital concluded that the Harvard study, the bedrock for the data projections in *To Err Is Human*, *underestimated the incidence of injuries by a significant percentage*. Drugs continue to be a source of patient harm. Furthermore, *studies of medical practice variation conclude that many physicians practice in ways that endanger patients, in spite of clear practice guidelines to the contrary*. This complexity – the combination of medical progress and industrialization – is producing more medical adverse events and errors, with new studies concluding that the frequency of patient injury continues to grow. In spite of this growing evidence of patient injury, *in no other area of civil law has reform pushed so aggressively against the tool of litigation on behalf of injured plaintiffs, even with evidence of substantial underclaiming by patients who suffer adverse events*.

Barry R. Furrow, *The Patient Injury Epidemic: Medical Malpractice Litigation as a Curative Tool*, 4 DREXEL L. REV. 41, 46–47 (2011) (emphasis added) (citing Lori B. Andrews *et al.*, *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349 LANCET 309, (1997) (“Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1.2% of the 1047 patients made claims for compensation.”)).

320. As Jane Elaine Ballerini has observed:

Every year, ‘about 15 malpractice claims are filed for every 100 physicians, and about 30 percent of those claims result in an insurance payment.’ Of over 35 million annual hospitalizations across the country, there are 350,000 medical injuries, of which 10,000 are serious and permanent disabilities and another 75,000 are fatal. Only about 55,000 lawsuits result from these injuries, with an even smaller amount, 15,000, producing any payments through settlements or jury awards.

...

While there is conflicting data about the types and causes of medical errors, the medical malpractice litigation system consistently fails to compensate the majority of patients who are injured in the course of receiving medical care. *For decades, the number of lawsuits filed has not come fractionally close to the number of injuries sustained from medical errors*.

Ballerini, *supra* note 211 at 364–65 (emphasis added) (citing Catherine T. Struve, *Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation*, 72 FORDHAM L. REV. 943, 976 (2004) (“[T]he Harvard Medical Practice Study estimated that some 27,000 hospital patients in New York State in 1984 were injured as a result of negligent medical care, but that fewer than 3,800 patients asserted malpractice claims – a substantial ‘gap’ between potential and actual claims.”)).

321. *See supra* Part I.

*The third objective* was to significantly reduce the overhead costs of insurance coverage for the HCBC's prospective medical and fiduciary liabilities. This will be directly accomplished by eliminating use of profit-making, third-party, commercial liability insurance in favor of self-insurance through the HCBC's own "captive" operating on a nonprofit basis.<sup>322</sup> Combined with the acceptance of enterprise medical liability, such step will have several cost-saving consequences: the cost of coverage to the HCBC will be significantly reduced by eliminating the profit overhead necessarily imbedded in the premium pricing of third-party commercial carriers; self-insurance will eliminate the price vicissitudes of the commercial market's "insurance cycle," which often result in premium increases totally unrelated to any individual insured's claims experience; and, since the HCBC will be the only entity insured by its captive, it will be "able to direct all underwriting, claims, and investment decisions" free "of a commercial carrier's competing interests in serving shareholders or other insureds."<sup>323</sup> Finally, the HCBC will be able to direct the policies of its captive in ways that will facilitate risk management activities and possible settlement programs that could identify and resolve prospective claims before they are brought.<sup>324</sup>

*The fourth objective* was for the HCBC to essentially become a payer to itself by offering a more cost-efficient, market-competitive private insurance option to interested enrollees. It would do this by "by becoming a state-licensed and regulated health insurance provider of its own non-HMO, non-capitated, indemnity plan – operating essentially as a *nonprofit* Preferred Provider Organization ("PPO")."<sup>325</sup> Just as we believe that becoming its own liability insurer would enhance the HCBC's risk management and quality assurance activities while simultaneously reducing costs, so we believe that offering a lower-cost indemnity plan alternative would redound to the HCBC's benefit by attracting new patients through its provision of a more affordable "private" (*i.e.*,

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322. "Captives are of interest to all industries because they allow corporate control over the captive; reduce premiums that do not [sic] reflect profits for commercial insurers or expenses related to any other non-associated risk; and, for for-profit corporations, permit tax deductions for premiums paid to the captive." See Kinney, *supra* note 264, at 497. Note that there appears to be a typographical or "double negative" error in the text: it would seem that the language should read something like "reduce premiums such that they *not* reflect profits for commercial insurers or expenses related to any other non-associated risk . . ." *Id.*

323. See *supra* Part IV Section A.1.

324. What Professor Hermer notes about ACOs is equally true for the HCBC:

Insuring via a captive or via self-insurance permits a parent to direct the policies of the captive. This is particularly relevant for ACOs in the context of medical malpractice insurance. If an ACO wanted to employ a disclosure and offer program, . . . it could direct its captive to do so. It could additionally coordinate research on medical errors and quality improvement programs. Captives that do such things and more already exist. . . .

Hermer, *supra* note 95, at 298.

325. See *supra* Part IV. Section B.

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non-governmental) health insurance option. That is, since such option could be “priced” by the HCBC “at cost” to the enrollee without the additional “profit” requirements of a commercial carrier, it might well offer quality competition to employer-sponsored plans with all of their attendant ERISA complications and potential problems.<sup>326</sup>

*The fifth and final objective* was to restore patient trust in institutional health care providers by creating and sustaining an organizational “culture of virtue.” This can be accomplished in two basic ways: first, by consciously focusing on, shaping, and promoting a “formal” and “informal” organizational culture within the HCBC that values – *above all else* – “medicine’s professional norms and commitment to excellence, while reinforcing and sustaining a recognition of the broad scope of fiduciary responsibility necessarily attendant to the team-delivery of health care services;”<sup>327</sup> second, by legally-mandating adherence to the primacy of the HCBC’s dual organizational mission, with its *principal emphasis* on “the ongoing and consistent provision of affordable, high-quality, high-value, and readily accessible health care services.”<sup>328</sup> As we have previously noted, in 2009 Pope Benedict XVI called for “*a broad new composite reality embracing the public and private spheres, one which does not exclude profit, but instead considers it a means for achieving human and social ends*”<sup>329</sup> – perhaps, with the “right kind of culture,” the HCBC will bring it about in today’s institutional health care delivery system.

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326. See *supra* Part IV. Section B.2.

327. See *supra* Part V.

328. That is to say, a dual mission where “[p]ursuit of ‘profit’ – in the sense of residual revenue over expenses necessary to meet ongoing capital needs for replacement and growth – would necessarily remain, but as a secondary rather than sole or even primary objective.” Corbett, *supra* note 17, at 288.

329. *Id.* at 207.