Feature

Fiduciary Engagement in Artificial Intelligence Innovation: A Governance Imperative

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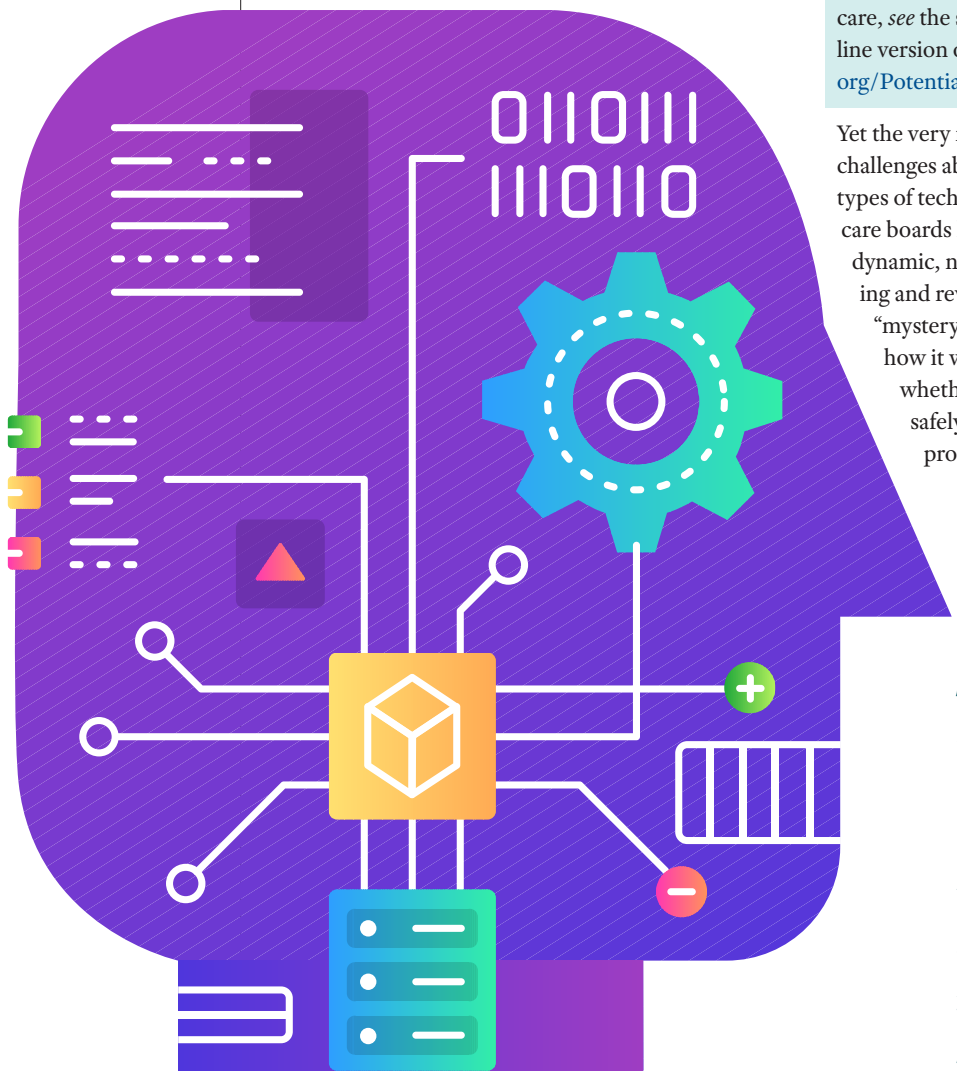
Positioning boards to effectively exercise their fiduciary responsibilities for Artificial Intelligence (AI) innovation is a major governance imperative that demands the immediate and ongoing attention of boards and their executive teams. As the primary advisor to the board and its committees on legal and governance matters, the chief legal officer (CLO) is well-suited to guide the leadership team in this effort.

The Emerging Presence of AI

The pace and proliferation of AI discovery, investment, and deployment in health care and the life sciences has accelerated well beyond expectations. Prior expressions of skepticism and resistance are giving way to a sense of cautious excitement about its potential for overwhelmingly positive implications. This extends across a wide spectrum of applications in diagnosis and treatment, drug development, clinical workload reduction and other operational efficiencies, and patient engagement and satisfaction enhancements.

For an overview of potential applications of AI in health care, *see* the supplemental materials posted with the online version of this article at http://americanhealthlaw.org/PotentialAIApplications.

Yet the very nature of AI technology presents fiduciary challenges above and beyond those associated with the types of technology innovation with which many health care boards have become familiar. AI technology is dynamic, not static, and requires ongoing monitoring and revalidation of its safety and efficacy. The "mystery" and confusion over what AI really is and how it works raises a fundamental question as to whether and how AI can and should be used safely in medical decision making, research, and product development.



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AI technology's breadth, complexities, and barriers present unique governance challenges for health care company boards that require a well-integrated, comprehensive enterprise risk approach.

Health care AI applications, particularly in clinical care, are still largely "emerging" and without a meaningful performance track record. A lack of trust and confidence among providers, patients, and the public presents a significant barrier to the adoption of AI solutions.[1] A sufficient pool of personnel with "AI literacy" (which encompasses more than information technology and data science) is absent. Resistance to AI adoption exists among personnel who may fear AI will replace them. Data availability and integrity challenges, as well as data privacy and security concerns, exist on a much wider and deeper scale than with other innovative technology. Novel ethical and discrimination considerations that are difficult to detect, quantify, and resolve arise from potential misapplication of AI and the data supporting it. A return on investment in AI takes more time and is more difficult to measure than for other digital health technology solutions.

The Governance Connection and Challenge

There should be no doubt as to the board's right and responsibility to meaningfully engage in AI matters, despite the complexity of AI technology and associated barriers to board literacy. "AI is more than an issue for the technology team"; and it "is not a single thing" nor solely a concept of technology, but rather is an operational system that extends itself across the organization and its hierarchies.[2] As such, AI technology's breadth, complexities, and barriers present unique governance challenges for health care company boards that require a well-integrated, comprehensive enterprise risk approach.

Indeed, active board engagement in AI implementation is supported by leading statements of governance principles and practices. For example, the National Association of Corporate Directors (NACD) in its recent Blue Ribbon Commission report, *Fit for the Future: An Urgent Imperative for Board Leadership,* challenges boards to respond to and focus on the transformative opportunities presented by AI innovation as a "new driver of growth and risk."[3]

Board responsibility for AI innovation decision making and oversight is firmly grounded in the following traditional governance functions:

- *Strategic Planning*: The relationship of AI to the long-range mission of the organization is a fundamental board responsibility and properly the province of the board's strategic planning committee. "True . . . value only emerges when AI implementation has been tightly linked to . . . strategy . . . and when AI-powered output has progressed into normal business as usual operations far enough to yield substantive value."[4] "It's not just about installing AI technologies. It's about using AI as a strategic lever to transform the business . . ."[5]
- *Clinical Quality and Risk*: The introduction of AI into clinical operations presents certain unique strategic, operational, and patient care and safety risks to the health system. This relates directly to the board's responsibility for establishing and communicating the organization's AI risk profile to guide management's implementation of the plan for identifying and managing the major risks of the organization.
- *Legal/Compliance*: An organizational commitment to AI implicates traditional legal and compliance regimes in somewhat less familiar ways than do other forms of technology and solutions. To fulfill its compliance oversight obligations, the board must appreciate the current legal and regulatory framework for AI innovation in health care and the life sciences, monitor related changes, and empower compliance staff accordingly.
- *Social Responsibility*: AI innovation also implicates board oversight of organizational, environmental, and social-related commitments. The use of intelligent systems such as AI technology in the delivery of health care must be monitored with a spotlight on the ethical, social, cultural, and economic considerations that impact the interests of all health system stakeholders (e.g., fairness, equity, inclusivity, privacy, bias, discrimination, mental and physical harm).[6]

Beginning the governance development process *now* will position boards and executive leadership, clinicians, researchers, and other key constituencies to make decisions, manage the risk, and harness the value of AI in the near term and to continue to do so when AI becomes a pervasive technology in health care.

The health system's CLO can play a significant role in supporting AI governance by helping establish a framework for identifying specific AI-related governance needs and allocating specific governance responsibilities as appropriate.

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Confronting the AI Governance Challenge

Meeting the Fiduciary Standard of Care in the AI Context. The complexity and range of AI technology uses and risks demands an unusually close level of engagement by boards, particularly at the formative stages of developing the oversight and decision-making framework. Boards should resist the understandable temptation to defer extensively to management and, as the NACD Blue Ribbon Report recommends, to prepare themselves to "engage more proactively, deeply and frequently" and in greater depth than on more traditional board agenda items. For many boards, this will be inescapably challenging, as it will require venturing into uncharted territory, making significant changes to traditional governance mechanisms, risk appetites and risk tolerances, enduring more trial and error, and making a greater time commitment than in other board oversight contexts.

Framework for Decision Making and Oversight of AI Innovation. The board's primary task in charting a safe course through this promising but seemingly treacherous frontier is to establish a framework from which the board can effectively address AI strategy and risk management. Engendering trust in the AI technology must be at the core of that framework. "To do that, [the board] must ensure the integrity, fairness, 'explainability', and resilience of [the] AI models,"[7] not only when first implemented but throughout their entire life cycle.

Building the Board's AI Governance Framework. As to its oversight obligations, the board will be expected to make a significant effort to develop a framework from which it can monitor and hold management accountable for AI strategy, integration, and risk. For many health systems, this framework will be different and more involved than those applied for oversight of traditional operational matters. For companies that have implemented an overall innovation oversight function, the framework for AI governance oversight should be aligned and integrated with that function.

As to its decision-making obligations, the board will be expected to maintain an awareness of the types of decisions it will be called upon to make; the cadence with which those decisions will present themselves to the board or key committees; the advantages and disadvantages presented by individual decisions; and the need to retain outside advisors to support the deliberations of the board or committee.

As to its loyalty obligations, the board will be expected to address the intersection of the organizational use of AI with existing policies and procedures, including those relating to conflict of interest, confidentiality, and appropriation of corporate opportunity.

"Soft Law"*—An Important Tool for Constructing an AI Governance Oversight Framework.* The current "Hard Law" framework for regulating the quality, safety, and efficacy of health care delivery and medical products was not developed with AI innovation in mind. While the need for regulation has been widely acknowledged and supported in the private sector,[8] progress toward that end has been slow. Given the pace and complexity of AI innovation, it is unlikely any Hard Law scheme alone will provide all that will be needed to develop and support a responsible AI innovation governance framework.[9] Therefore, while a board's existing corporate compliance program will provide a base, it will not be enough and boards and their executive teams must turn to other resources for constructing a framework that will promote trust in AI technology, harness the many benefits of AI, and manage its novel and complex enterprise risks.[10]

"Soft Law" is a construct that has been applied in the past for managing the risk of other sophisticated, emerging technology in the absence of a fully developed legal and regulatory scheme for doing so.[11] Soft law is typically comprised of policies, procedures, codes of ethics, guidelines, etc. that are derived from a combination of non-binding pronouncements of governmental agencies, private sector organizations, and public-private partnerships and that establish requirements and standards that go beyond the minimum requirements of Hard Law. While it may lack the force of Hard Law, Soft Law can be more easily adapted to the dynamic nature of AI innovation. A board-constructed AI governance framework derived from such Soft Law itself is a form of Soft Law.

Fortunately, health and life sciences industry boards can draw on Soft Law resources available in practical guidance from the various public Soft Law initiatives of the Office of the President,[12] Office of Management and Budget,[13] the Department of Health and Human Services (HHS),[14] and the Food and Drug Administration (FDA).[15] Private sector counterparts include those of professional societies, industry trade organizations[16] and standard setting organizations,[17] industry "watchdogs," private sector collaborations,[18] as well as voluntary certification and accreditation organizations that are likely to appear on the scene.[19]

The FDA's proposed approach, which is particularly instructive for the health and life sciences contexts, essen-

tially aligns the nature and rigor of its oversight in close parallel with the spectrum of AI technology sophistication and the associated risks. More specifically, for AI at the lower end of the spectrum of sophistication that applies rules-based algorithms to well-curated, structured data to solve a narrow and clearly defined problem, the FDA takes a more flexible approach using elements of FDA pre-certification and "self-regulation."[20] For AI technology at the highest end of the sophistication spectrum, which autonomously applies data algorithms that can be as difficult to understand as those of the human brain to solve a broad range of problems, the FDA oversight and approval framework would mirror its current, more prescribed and rigorous pre-market approval framework for high-risk medical products.[21] In short, the closer the AI is to making decisions in a "black box" that are not explainable and understandable to an independent clinician and that are relied on as the primary basis for clinical decisions, the more rigorous and prescriptive will be the FDA's requirements. Of course, while AI technology may begin at the low end of the sophistication spectrum, it will likely evolve over time toward the other end of that spectrum, and the governance framework should anticipate such changes and build in flexibility to adapt along the life cycle of the technology.

Application of AI Soft Law to Board's AI Governance Framework. From these AI Soft Law initiatives emerge a series of key considerations for a board to address in its own Soft Law governance framework for generating and sustaining trust in AI innovation. These include: (a) the purpose of the AI (patient care v. non-patient care, clinical v. administrative, etc.); (b) sophistication of the AI (e.g., rules based v. autonomous); (c) data accessibility, quality, and integrity; (d) data privacy and security protections; (e) explainability and understandability of the AI's results; (f) degree of regulatory oversight/approval required for marketing and use of the AI; (g) compliance with applicable laws and industry standards; (h) transparency (with providers, patients, employees, and the public) concerning whether and how the technology will be used and associated risks; (i) user experience; (j) agility, adaptability, and resiliency; (k) real-world performance monitoring and change management over the AI's entire life cycle; (l) social responsibility with regard to other human dimensions of AI use (e.g., ethics, fairness and non-discrimination in availability and use); (m) partnering and collaborating to obtain expertise and other resources needed to support the trustworthiness of the AI; and (n) accountability with regard to the foregoing.

With these in mind, a board should consider the following as important components of its own AI governance framework for AI investment, development, and deployment:

- A responsible decision-making philosophy and approach that clearly articulates the lines of accountability between the board/board committees and management for managing AI's novel and complex enterprise risks while providing sufficient flexibility for the organization to adapt and respond quickly to the speed and dynamic nature of AI innovation, discovery, and deployment;
- Clear board delegation of primary responsibility for supporting the board in its AI decision making and oversight to the appropriate board committee (e.g., a new standing committee on innovation, including AI innovation) composed of members with specialized expertise and staffed by executives with specific organizational responsibility for AI, and mechanisms for coordination of that committee with other relevant board committees on a regular basis;
- Criteria for identifying, assessing, and selecting AI innovation opportunities that align closely with the priorities encompassed in the organization's AI innovation strategy and enterprise-wide strategic plan, as well with the organization's mission, values, and ethical standards;
- Principles, guidelines, and criteria for evaluating the potential uses and associated risks that parallel the spectrum of AI technology complexity and sophistication (i.e., its degree of autonomy, and its understandability and explainability to the users);
- Ongoing monitoring of the safety and effectiveness of existing AI technology development and deployment initiatives as they evolve and over their entire life cycle;
- Data governance and stewardship principles that address data availability, quality, and integrity (i.e., accuracy, completeness, risk of bias, and discrimination) as well as data privacy and security;
- Ongoing education of the board and executive leadership concerning new developments in AI technology generally, changes in the evolving legal and regulatory framework, and changes in the organization's own AI oversight framework;[22]
- A plan for "reskilling" the workforce at every level of the organization that has a role in fostering AI innovation. "It's not just about

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installing AI technologies. It's about using AI as a strategic lever to transform the business. And that requires building deep AI capabilities across the organization—both from the bottom up and the top down—across technology, people, data and process";[23]

- Principles and guidelines for communication and educational programs that will promote transparency with patients and providers on matters such as when it will be used, how it will be used in making diagnostic and treatment decisions, and what role the provider will play in reviewing and making use of the AI solutions findings and recommendations;
- Principles and criteria for selecting partners and forming partnerships that align with the organization's strategy, mission, values, culture, and risk tolerance and maintain a philosophy of shared accountability, responsibility, and risk among the participants;
- Criteria and mechanisms for measurement of both quantitative and qualitative "Return on Investment" and related benefits to organizational mission and purpose;
- Integrating AI innovation-related policies and policy considerations with other governance and operating procedures (including but not limited to policies for managing board and management conflicts of interest and dualities, and board and management confidentiality policies); and
- Establishing and maintaining an inventory of AI-related corporate opportunities for purposes of stimulating board discourse; informing officers, directors, and other executives; and reducing misappropriation risks.

Building a Board and Committee Structure for Governance Oversight of AI Innovation. The health system's CLO can play a significant role in supporting AI governance by helping establish a framework for identifying specific AI-related governance needs and allocating specific governance responsibilities as appropriate. The World Economic Forum's new monograph, *Governance: Empowering AI Leadership*, may be helpful in this regard.[24] The monograph identifies four specific steps that can be used to pursue such an evaluation: (1) decide which [organizational AI] activities require governance oversight; (2) decide whether to keep, reassign, or set up new governance responsibilities; (3) establish a governance structure for AI (as part of this exercise decide how best to address AI ethical concerns—e.g., create a new board committee, add to/recalibrate the tasks of an existing committee, or use the board as a whole); and (4) clearly allocate and articulate the relative, ultimate AI decision-making and oversight authority and responsibility of the board, board committees, and management.[25]

Critical to the board's ability to provide effective oversight of AI may be the establishment of a standing board committee with dedicated responsibility to monitor management's implementation of board-approved AI strategies, the inclusion within the committee of members with specialized expertise,[26] staffing the committee with management with specific organizational responsibility for AI, an established process for reporting to the full board on a regular basis, and a clear articulation of the need for this AI standing committee to consult and coordinate with other key board committees whose responsibilities are implicated by AI innovation, such as Innovation, Audit & Compliance, and Strategic Planning.

Despite the "Soft Law" approach recently articulated by various governmental oversight bodies, health care and life sciences boards should anticipate the potential for closer monitoring and tightening of the regulatory framework as such governmental bodies learn more about the associated risks of AI through their current, softer oversight approach.[27] Thus, as part of its responsibility for comprehensive legal and regulatory compliance risk management, an important role of the Audit & Compliance committee will be ongoing monitoring and board/committee education of the evolving legal and regulatory framework.

Conclusion

For most health care and life sciences companies, investment in and deployment of AI technology is expected to be a critical strategic component for the foreseeable future. While the goals and objectives for AI implementation are normally straightforward, the actual implementation of AI will be challenging and fraught with uncertainty and complexity. For these and similar reasons, effective, ongoing governance oversight of AI will be a critical organizational concern. There will be no "one-size-fits-all" approach, and the governance framework itself must reflect and be able to accommodate the highly dynamic nature of AI.

The CLO, as the board's primary governance advisor, is the logical corporate executive to provide leadership team support in this regard. The CLO can assist the board in understanding the application of its fiduciary duties to the organization's AI strategies, provide recommendations on AI-specific governance structures and policies, integrate thought leaders and managers across the many functional areas implicated by AI, and coordinate management-to-board information and reporting systems on AI matters.

As discussed above, the complexity and mystery of AI will undoubtedly require a greater commitment from directors and management. Therefore, establishing a framework for board decision making and oversight at the earliest possible stage of an organization's development and implementation of its AI strategy will

contribute significantly to the board's ability to fulfill its fiduciary responsibilities and thereby enhance the AI initiatives' trustworthiness and prospects for success.

1 *See, e.g.,* Optum, Inc., 3rd Annual Optum Survey on AI in Health Care (2020), https://www.optum.com/business/resources/ai-in-healthcare/2020-ai-survey.html.

2 Karen Silverman, *Why Your Board Needs a Plan for AI Oversight,* MITSloan Mgmt. Rev. (Winter 2021), https://sloanreview.mit.edu/article/why-your-board-needs-a-plan-for-ai-oversight/.

3 Nat'l Ass'n of Corp. Dirs. (NACD), *Fit for the Future: An Urgent Imperative for Board Leadership* (Sept. 23, 2019), https://www.nacdonline.org/insights/publications.cfm?ItemNumber=66271 (hereinafter NACD Blue Ribbon Report). *See also* World Economic Forum monograph, *Governance: Empowering AI Leadership*, https://wef-ai.s3.amazonaws.com/WEF_Empowering-AI-Leadership_Governance.pdf [hereinafter World Economic Forum monograph].

4 KPMG, *Living in an AI World—achievements and challenges in artificial intelligence across five industries,* at 1 (Jan. 2020), https://advisory.kpmg.us/content/dam/advisory/en/pdfs/2020/living-in-ai-world.pdf (hereinafter KPMG 2020 Survey).

5 *Id. at* 9.

6 *See* Reid Blackman, *If Your Company Uses AI, It Needs an Institutional Review Board*, Harv. Bus. Rev. (Apr. 1, 2021), https://hbr.org/2021/04/if-your-company-uses-ai-it-needs-an-institutional-review-board; Adam Hadhaz, *Debiasing artificial intelligence: Stanford researchers call for efforts to ensure that AI technologies do not exacerbate health care disparities,* Stanford News (May 14, 2021), https://news.stanford.edu/2021/05/14/researchers-call-bias-free-artificial-intelligence/.

7 KPMG 2020 Survey, *supra* note 4, quote of Traci Gusher, Principal, Innovation and Enterprise Solutions, KPMG U.S. Lead, Artificial Intelligence, cover page.

8 *Id.* at 14. For recent AI-focused legislative and regulatory initiatives in the European Union, *see* Avi Gesser, et al., *The Future of AI Regulation: Draft Legislation from the European Commission Shows the Coming AL Legal Landscape*, https://wp.nyu.edu/compliance_enforcement/2021/05/05/the-future-of-ai-regulation-draft-legislation-from-the-european-commission-shows-the-coming-ai-legal-landscape-2/; Avi Gesser, et al., *The Future of AI Regulation: Draft Legislation from the European Commission Shows the Coming AL Legal Landscape (Part 2)* (Apr. 24, 2021), https://www.debevoisedatablog.com/2021/04/24/part-2-on-the-future-of-ai-regulation-draft-legislation-from-the-european-commission-shows-the-coming-ai-legal-landscape/; and *Europe fit for the Digital Age: Commission proposes new rules and actions for excellence and trust in Artificial Intelligence* (Apr. 21, 2021), https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1682.

9 *See* Gary Marchant, "*Soft Law" Governance of Artificial Intelligence*, AI Pulse (Jan. 25, 2019), https://aipulse.org/soft-law-governance-of-artificial-intelligence/; John Villasenor, *Soft law as a complement to AI regulation*, Brookings (July 31, 2020), https://www.brookings.edu/research/soft-law-as-a-complement-to-ai-regulation/.

10 The Department of Health and Human Services' (HHS') stated goal for its own oversight of AI initiatives reflects this balancing of risks and benefits. HHS, *Artificial Intelligence (AI) Strategy* (Jan. 23, 2021), https://www.hhs.gov/sites/default/files/final-hhs-ai-strategy.pdf (hereinafter HHS 2021 AI Strategy).

11 *See* Marchant, *supra* note 9 and Villasenor, *supra* note 9.

12 Executive Order 13,960, *Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government* (Dec. 8, 2020), https://www.federalregister.gov/documents/2020/12/08/2020-27065/promoting-the-use-of-trustworthy-artificial-intelligence-in-the-federal-government; Executive Order 13,859, *Maintaining American Leadership in Artificial Intelligence* (Feb. 14, 2019), https://www.federalregister.gov/documents/2020/12/08/2020-27065/promoting-the-use-of-trustworthy-artificial-intelligence-in-the-federal-government.

13 *Guidance for Regulation of Artificial Intelligence Applications* (Draft Memo), 85 Fed. Reg. 1731, 1825 (Jan. 13, 2020), https://www.whitehouse.gov/wp-content/uploads/2020/01/Draft-OMB-Memo-on-Regulation-of-AI-1-7-19.pdf.

14 HHS 2021 AI Strategy, *supra* note 10.

15 *See, e.g.,* FDA, *Digital Health Innovation Action Plan*, https://www.fda.gov/media/106331/download; FDA, *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* (Jan. 12, 2021), https://www.fda.gov/media/145022/download. Also noteworthy are the private sector collaborations the FDA has already formed to achieve a consensus on "good machine learning practices" with organizations known for leadership in development of governance processes and standards for complex and emerging technology. *Id.*

16 *See, e.g., ANSI/CTA-2090 The use of Artificial intelligence in Health Care: Trustworthiness*, Consumer Technology Association (CTA) R13 Artificial Intelligence and R13 WG 1 Artificial Intelligence in Healthcare (Feb. 2021), https://shop.cta.tech/collections/standards/products/the-use-of-artificial-intelligence-in-healthcare-trustworthiness-cta-2090.

17 For example, The Institute of Electric and Electronic Engineers (IEEE), one of the world's largest standard-setting organizations, launched its major effort in 2016, *The IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems*, https://standards.ieee.org/industry-connections/ec/autonomous-systems.html.

18 For example, the Partnership on AI was originally formed by several large technology and ecommerce players but expanded to include think tanks, academic organizations, provisional societies, and charitable groups. *See* https://www.partnershiponai.org/about; https://www.partnershiponai.org/partners; https://www.partnershiponai.org/tenets.

19 Marchant, *supra* note 9 and Villasenor, *supra* note 9.

20 FDA, *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)—Discussion Paper and Request for Feedback* (Apr. 2, 2019), https://www.fda.gov/media/122535/download (proposing a basis for AI/ML-based Software as a Medical Device that would rely on a predetermined change control plan submitted for FDA premarket review that would identify anticipated modifications and the associated methodology the applicant would apply to changes in a measured way so as minimize patient risk. FDA pre-approval of the methodology would depend on many factors (e.g., changes in intended use) and associated potential patient risk.).

21 *Id.*

22 Silverman, *supra* note 2.

23 KPMG 2020 Survey, *supra* note 4, at 9.

24 World Economic Forum monograph, *supra* note 3.

25 *Id.* at 10-12.

26 This may be aided if the relevant state corporation law allows individuals who are not members of the governing board to serve as voting members of the committee.

27 Noteworthy in this regard is the increased interest in the use of AI by the Federal Reserve Board and several other financial services regulators as evidenced by their recent joint *Request for Information and Comment on Financial Institutions' Use of Artificial Intelligence* and the related governance, risk management and controls, https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20210329a1.pdf.