Session 401 | Gamechangers and Tightrope Walkers: How Digital Health Companies Can Balance Innovation and Government Compliance with Data Use, Artificial Intelligence and Virtual Health

The digital health revolution presents the promise of radically transforming the way we diagnose diseases, manage our health and live in society. Without a doubt, the technology that populates the digital health landscape was made possible by innovations in science and medicine. These new technologies raise complex questions about government compliance, privacy, ethics and social norms that lead us to ponder how to remain human as we observe artificial intelligence being incorporated into precision medicine, image analytics, genomics and population health.

This panel will draw on the growing Austin health care innovation ecosystem to highlight the intersection between digital health innovators, government regulators, and legal experts. Speakers will share thoughts on how to balance the desire to elevate health outcomes, improve the experiences of patients and clinicians, and reduce the costs of healthcare against regulatory requirements, ethical and social concerns. Discussion topics will address a variety of issues, including (i) The legal challenges and complexities facing digital health innovators as they move forward; (ii) Ways to mitigate the risk that health data could be used for untoward purposes; and (iii) the ethical concerns raised by the use of electronic health records and the integrity of health data.
**Moderator:**

Sabrina M. Punia-Ly, Arent Fox LLP

Sabrina is an experienced health care litigator and advisor. She regularly represents hospitals, medical staffs, and health systems in matters relating to peer review, residency program dismissals, Anti-SLAPP suits, and retaliation claims. Sabrina also counsels clients on NPDB and Business and Professions Code 805 Reports, physician credentialing, peer review hearing procedures, state licensing, Medicare certification, EMTALA (the federal law prohibiting “patient-dumping”), government investigations as it pertains to the state and federal False Claims Act, and Stark Laws.

**Speakers:**

Dr. Elizabeth Truong, Licensed Psychiatrist and Austin-based Digital Health Startup Entrepreneur.

Dr. Truong is a licensed psychiatrist and Austin-based digital health startup entrepreneur. She has built mobile software products and led implementations that help traditionally underserved patients improve access to health care and better outcomes while reducing health care costs. She leverages her clinical skills as a leader and speaker to advocate for mental health awareness and education. She is actively involved with the Texas Medical Association, helping to shape state policies for patients, physicians, and public health.

Phil L. Kim, Associate at Haynes and Boone, LLP

Phil Kim has extensive experience in healthcare law and focuses his practice on transactional and regulatory healthcare matters for clients seeking to navigate one of the most heavily regulated industries. He represents various types of providers, ranging from healthcare systems, hospitals, ambulatory surgery centers, physician groups (including non-profit health organizations, or NPHOs), home health providers, and other healthcare professionals in mergers and acquisitions, joint ventures, and operational matters, which include licensure, contractual, and administrative issues.

Phil regularly advises clients on healthcare compliance issues involving liability exposure, the Stark law, anti-kickback statutes, and HIPAA/HITECH privacy issues. He has also counseled clients in a broad spectrum of matters involving state and federal healthcare laws, complex business issues, employment issues, and various government agencies, including different state Medicaid agencies, the Texas Medical Board, and Medicare Administrative Contractors.

Jessika Tuazon, Associate at Epstein, Becker & Green, P.C.

Jessika Tuazon is an associate in Epstein, Becker & Green, P.C.’s Health Care and Life Sciences practice. Her practice focuses primarily on advising pharmaceutical, medical device, regenerative medicine, digital health and food companies on business, regulatory and enforcement issues related to their operations. She counsels clients on various matters related to premarket clearance and approval and works closely with them to develop effective legal and regulatory solutions, ensuring compliance through all stages of the product life cycle. She also assists companies in developing good promotional practices and other policies and strategies related to pharmaceutical, device and medical development and marketing activities. Jessika also conducts health regulatory due diligence for transactions in the life sciences industry and has extensive experience in licensing and regulatory issues in the health care and life sciences industries. Through EBG, she also provides legal counsel to the Combination Products Coalition. She is recognized as a *Southern California Rising Star* for Food and Drug Law by Super Lawyers magazine. She earned her B.A. from the University of Southern California and her J.D. from the University of Miami School of Law, and is admitted to practice law in California and Florida.
Tahir Amin, Co-Executive Director at I-Mak

Tahir Amin is an attorney with 25 years of experience in IP. He practiced as a solicitor of the Senior Courts of England and Wales with two leading IP firms in the United Kingdom, and as in-house global IP counsel for a multinational company. In 2004, Amin moved to India, where he was instrumental to the passage of a health-friendly patent law. That process led him to co-found the Initiative for Medicines, Access and Knowledge (I-MAK), with the express purpose of re-shaping patent law to better serve the public.

Amin’s pioneering work challenging patents on behalf of patients and the public has established a new model for treatment access, one that restores balance to the system by upending the structural power dynamics that allow inequities to persist. I-MAK’s legal challenges have enabled $52 billion in savings for health programs and increased access to medicines for millions of patients worldwide. I-MAK’s 2018 investigation Overpatented, Overpriced has been cited repeatedly in Congressional testimony as America grapples with its prescription drug pricing crisis, and was recently featured in the NYT, NBC and Bloomberg.

Tahir has served as legal advisor to the European Patent Office, United Nations Environment Programme and World Health Organisation. He is a former Harvard Medical School Fellow in the Department of Global Health & Social Medicine and a 2009 TED Fellow. Amin is a frequent speaker on patent policy and rising drug prices, and has been featured in CNBC, The New York Times, Bloomberg, The Wall Street Journal, and Reuters.

Course Materials / Bibliography. The course materials are tailored for attorneys, and many of them provide practical considerations for attorneys assisting clients in navigating various legal challenges associated with adopting different types of novel medical technologies in health care, including AI and machine learning.


Relevance: this article provides an introduction to the use of artificial intelligence in precision medicine technologies and provides a discussion on the ethical and legal challenges that are created.


Relevance: this article discusses how federal agencies released guidebooks to educate and guide mobile health app developers create and maintain compliant apps.


Relevance: this article discusses how federal agencies have cracked down on mobile health app developers due to their apps misleading marketing claims and irresponsible privacy practices.

Relevance: this short and accessible article defines fundamental terms like AI and machine learning for a legal audience, and gives an introductory overview of key legal and policy challenges to the adoption of AI in medical produce development and clinical medicine.


Relevance: this article by one of our panelists, a member of the firm at Epstein Becker Green, describes how the increases uptake of AI applications in consumer health care products may increase cyber security and privacy risks.


Relevance: This legal article by one of our panelists describes current efforts by mobile health companies to develop applications for use in health care, and analyzes significant legal barriers to their uptake. The author concludes that “while mobile health holds out tantalizing potential to improve upon the cost and accessibility of healthcare, there will be significant resistance to licensing and scope of practice reforms until broader political economy questions concerning the long-term viability of the medical profession are answered.”


Relevance: This legal article by one of our panelists describes how the use of AI in healthcare will exposed providers and facilities to increased risk of medical malpractice liability. It prescribes a collaboration between all industry sectors to ensure that such technologies are employed in a safe way that would reduce liability risks.


Relevance: This article explores issues of legal liability in the context of the use of novel medical technology in clinical practice. It considers the accuracy of machine vision systems to help address challenging malpractice concerns. Additionally, it looks at how legal liability is affected in other industries where use of machine learning is growing.


Relevance: this article written for a policy maker audience gives recommendations for how to best promote the uptake of AI in clinical settings. The articles gives valuable insights to attorneys helping clients navigate such an uptake.


Relevance: This article presents five key questions that legal compliance officers should consider and address when implementing AI technology in clinical settings, including the purpose of the data being collected and whether doing so would change terms of employment.


Relevance: This white paper by the FDA describes the FDA’s foundation for a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications.


Relevance: This publication describes issues with electronic transfer of protected health information, which has become one of the largest exposures to an individual’s personal sensitive information, in a digital world where this information is being increasing used for analytics, personalized medicine, and more.


Relevance: This is an article by one of our panelists, Alaap Shah, member of the firm Epstein Becker Green, which provides an in-depth summary of the recent updates the SEC had related to cybersecurity disclosures which would also affect digital health.


Relevance: This toolkit developed by America’s largest professional organization representing the hospital industry will assist attorneys working in digital health to understand how to help their clients navigate telehealth programs. It gives market data on the current uptake of telehealth and explains characteristics of successful programs.

Gamechangers and Tightrope Walkers:

How Digital Health Companies Can Balance Innovation and Government Compliance with Data Use, Artificial Intelligence and Virtual Health

NAPABA
Health Law Section
November 9, 2019
Overview: Health Care and the Digital World

Health care is changing in a big way. As technology advances, its impact on health care has resulted in advances in the treatment and quality of medicine, medical devices, and more. As innovations in artificial intelligence (AI), digital tools, and machine learning emerge, so have novel legal risks.

Key questions

• How have digital health companies disrupted our conventional view on medicine to promote and deliver better health outcomes and reduce healthcare costs?
• How are digital health companies addressing ethical and legal concerns? (e.g. use of AI, EHR, or telemedicine)
• How will policymakers, health care providers, and other stakeholders balance the interests of innovation while protecting and preserving, among other things, patient privacy or safety?
• What laws and regulations will be called upon to keep patients, populations, and data safe without compromising growth of digital health?
Stakeholders / Potential Clients for Attorneys Working on These Issues

- Health Care Providers (e.g., Hospitals/Physicians/Clincs)
- Federal, State, Local Government
- Technology Industry
- Health Insurance Industry
- Patients and Consumers
- Pharmaceutical and Medical Device Industry
- Telemedicine Industry
Stakeholders (cont.)

**THE US DIGITAL HEALTH ECOSYSTEM 2019**

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Key Terms - Definitions

**Artificial Intelligence**: The study and design of “intelligent agents,” or computer systems that perceive their environment in some manner and respond with actions to maximize their chance of success – activities generally associated with intelligent beings.

**“Big Data”**: Data that is often characterized in terms of the “three Vs” of volume (large quantities of data), variety (heterogeneity in the data), and velocity (fast access to the data). In medicine, the data come from many sources: electronic health records, medical literature, clinical trials, insurance claims data, pharmacy records, and patients.

**Cybersecurity**: The practice of defending computers, servers, mobile devices, electronic systems, networks, and data from malicious attacks.

**“Internet of Things (IoT)”**: The IoT, as applied to health care, seeks to leverage convenient, efficient, and automated devices and software applications to connect to health care information technology (IT) systems through computing networks.

Sources: ScienceDaily; Kaspersky Lab; Shah, Alaap B.; Price, W. Nicholson. See “Resources List” for sources further defining and discussing these terms.
Key Terms – Definitions (cont.)

Electronic Health Record (EHR): A digital version of a patient’s paper chart. EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users. While an EHR does contain the medical and treatment histories of patients, an EHR system is built to go beyond standard clinical data collected in a provider’s office and can be inclusive of a broader view of a patient’s care.

Evidence Based Medicine (EBM): The process of basing clinical decision-making on the best available objective and unbiased medical research.

Mobile health ("mHealth"): The provision of health services and information via mobile technologies such as mobile phones and Personal Digital Assistants (PDAs)

Telehealth: The use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration

Sources: HHS Office of the National Coordinator for Health IT (ONC); Khan, Fazal; World Health Organization (WHO); US Health Resources and Services Administration (HRSA); See “Resources List” for sources further defining and discussing these terms.
Speakers

• **Sabrina M. Ly (Moderator)**
  - Health Care Associate – Arent Fox LLP

• **Elizabeth Truong, M.D.**
  - Former Co-Founder and Chief Clinical Officer, digital health startup

• **Phil Kim**
  - Associate – Haynes and Boone, LLP

• **Jessika Tuazon**
  - Associate – Epstein Becker Green
Resource List


Resource List (cont.)

https://www.fda.gov/media/122535/download


REALIZING THE POTENTIAL FOR AI IN PRECISION HEALTH

BY TOM LAWRY, STEVE MUTKOSKI, AND NATHAN LEONG
Artificial intelligence (AI)—intelligent technology capable of analyzing, learning, and drawing predictive insights from data—is transforming many sectors of the global economy; whether AI also will transform health care is no longer a matter for significant debate. Immensely powerful AI capabilities have driven major advances in “precision health” technologies—personalized and predictive health solutions that help to both prevent and treat disease and also promote wellness—by enabling the analysis of and extraction of insight from increasingly large amounts of health data. But with the advent of these solutions, the question has become: How do we respond to the ethical and legal challenges they can create?

The Promise of Precision Health Today

Precision medicine technologies, which consider an individual’s genetic makeup and potentially other unique factors, such as lifestyle and environment, have been used in medical practice to determine the appropriate medical treatment for some time. But the real public health opportunity lies in precision health. Precision health involves not just identifying the right treatment for a particular patient—but also individualizing all aspects of health care for that patient, including disease risk and prognosis prediction, leading to better disease detection and prevention. Rather than the right treatment at the right time for the right patient, precision health looks to ensure the right medical decision for each individual patient.

AI-driven precision health technologies hold great promise, including in improving quality of care and patient outcomes. While we might be years or decades away from realizing the full potential of precision health, early efforts are already solving important challenges today and demonstrate the critical role of AI technology and advances in computing capabilities.

For example, Microsoft partnered with St. Jude Children’s Research Hospital and DNAnexus to develop a genomics platform that provides a database to enable researchers to identify how genomes differ. Researchers can inspect the data by disease, publication, and gene mutation and also upload and test their own data using the bioinformatics tools. Because the data and analysis run in the cloud, powered by rapid computing capabilities that don’t require downloading, researchers can progress their projects much faster and more cost-efficiently.

In another example, Adaptive Technologies partnered with Microsoft to build AI technology to map and decode the immune system, similar to the way the human genome has been decoded, to reveal what diseases the body currently is fighting or has ever fought and enable earlier and more accurate diagnosis of disease and a better understanding of overall human health.

Microsoft also is collaborating with researchers to use machine learning and natural language processing to convert text (e.g., journal publications) into structured databases to help identify the most effective, individualized cancer treatment for patients. Without this type of technology, it takes hours for a molecular tumor board of many specialists to review one patient’s genomics and other data to make treatment decisions.

While there is great promise in AI-driven precision health systems, there also are many challenges to the successful development and adoption of these systems, including technological and economic challenges. For example, as medicine becomes more personalized, the market for any particular therapeutic product becomes smaller, potentially leading to higher-priced diagnostic tests and “personalized” medicines—potentially disadvantaging economically less well-off patients. Likewise, payers may be reluctant to pay for early risk prediction technologies when it is not clear which of those tests actually improve outcomes or reduce costs in the long term. These issues and others raise particularly thorny legal and ethical challenges to use of AI for precision health.

Principles for Responsible Development

Society only will achieve the public health promise of AI-driven precision health if these systems are developed and deployed responsibly. In the book *The Future Computed*, with a forward co-authored by Brad Smith and Harry Shum, Microsoft has proposed a series of principles to guide the responsible creation and deployment of AI and the development of best practices and regulatory frameworks for the use of AI that merit consideration in the precision health context.

Many of the guiding principles identified by Smith and Shum are not new to the health care sector, and reliability and safety, “representativeness,” and lack of bias, as well as privacy, have long been principles of medical ethics. Therefore, in some ways, the medical community may be better prepared to implement these principles for the use of AI than other sectors. But at this point in time, the medical community has by no means solved the challenges addressed by these principles even for traditional medical technologies, and the rise of AI-driven precision health systems raises new and different dimensions to these challenges.

Reliability and Safety

Precision health technologies must perform accurately, reliably, and safely. While medical technologies long have been required to demonstrate safety and effectiveness pursuant to regulation by regulators such as the U.S. Food and Drug Administration (FDA), AI-driven systems challenge the traditional models for demonstrating reliability.

One particular challenge for precision health technologies is
“Self-improving” or “continuous learning” AI is one example of promising AI-driven precision health technology that puts in sharp relief the challenge of ensuring reliability and safety within the existing regulatory models. As many have observed, our current regulatory regime assumes that “any product may be clinically tested, produced, marketed, and used in a defined, unchanging form.” That is clearly in some tension with the concept of a tool that will continually learn by analyzing new data—which supposes constant resubmission for regulatory review, whether that learning is supervised by a human or not.

The dynamic nature of continuous learning AI means we will need to develop new ways to ensure the safety and reliability of such systems. We will need to develop a regulatory regime that ensures that the continuous learning system makes to itself, ostensibly improvements, do not instead introduce errors into the model that could injure subsequent patients. But at the same time that new regime must be more nimble, so as to not require nearly constant revalidation of the device or its model. A regime to ensure the reliability of AI systems should involve the following: systematic evaluation of the quality and suitability of the data and models used to train AI-driven systems; adequate explanation of the system operation including disclosure of potential limitations or inadequacies in the training data; medical specialist involvement in the design and operation process; evaluation of the role of medical professional input and control in the deployment of the systems; and a robust feedback mechanism from users to developers.

**Fairness, Inclusiveness, and Bias**

Precision health systems should treat everyone in a fair and balanced manner. In theory, AI-driven systems make objective decisions and do not have the same subjective biases that influence human decision making. But, in practice, AI systems are subject to many of the same biases.

Because AI-driven systems are trained using data that reflect our imperfect world, without proper awareness and control those systems can amplify biases and unfairness that already exist within datasets—or can “learn” biases through their processing. “Under-representation” in datasets may hide population differences in disease risk or treatment efficacy. For example, researchers recently found that cardiomyopathy genetic tests were better able to identify pathogenic variants in white patients than patients of other ethnicities, the latter of which had higher rates of inconclusive results or variants of uncertain significance. Even data that are representative can still include bias because they reflect the discrepancies and biases of our society, such as racial, geographic, or economic disparities in access to health care.

Nonrepresentative collection of data also can produce bias. For example, reliance on data collected through user-facing apps and wearables may skew toward socioeconomic advantages and populations with greater access to connected devices and cloud services. Similarly, genetic testing remains cost-prohibitive for many consumers, so AI systems that leverage such genetic datasets may be skewed toward more economically advanced consumers. And data obtained from electronic health records (EHRs) will reflect disparities in the patient populations treated by health systems implementing EHR systems; the uninsured or underinsured and those without consistent access to quality health care (such as some patients in rural areas) often will be underrepresented in EHR datasets. EHR data themselves may introduce bias because they were collected for clinical, administrative, and financial purposes (patient care and billing) rather than for research and, therefore, may be missing critical clinical contextual information.

We also must ensure fairness in application. Precision health technologies that are designed to predict health outcomes to improve
quality of care could be unfairly implemented to make decisions about who receives care in an effort to reduce costs. For example, researchers developed a machine learning system to help predict six- to twelve-month mortality risks. The system was designed to improve upon current prognostic efforts by physicians when making determinations about whether a patient is eligible for hospice care and to improve end-of-life care. But such a system could be unfair if deployed to withhold treatment from patients with a higher mortality risk.

AI systems also may reflect the biases of those developing the systems and the clinicians implementing and interpreting the AI systems. This makes it particularly important that precision health technologies are developed by diverse groups of individuals and teams, and that they include appropriate medical experts. In addition, the health care professionals that implement precision health technologies in their practice must continue to exercise their own professional judgment in making patient care and treatment decisions. Finally, data scientists and AI developers must continue to develop analytical techniques to detect and address unfairness in AI-driven technologies.

Transparency and Accountability
Underlying the principles of reliability, fairness, and security are two fundamental principles: transparency and accountability. Because decisions made by precision health systems will impact patients’ health and care, it is particularly important that everyone relying on these systems (health care professionals, patients, managed care organizations, regulators) understand how the systems make decisions. Equally important, as precision health systems play a greater role in both diagnosis and selection of treatment options by health care professionals, we will need to work through existing rules around accountability, including liability.

As a threshold matter, these systems should provide “holistic” explanations that include contextual information about how the system works and interacts with data to enable the medical community to identify and raise awareness of potential bias, errors, and other unintended outcomes. Precision health systems may create unfairness if health care professionals do not understand the limitations (including accuracy) of a system or misunderstand the role of the precision health system’s output.

Even if it is difficult for users to understand all the nuances of how a particular algorithm functions, health care professionals must be able to understand the clinical basis for recommendations generated by AI systems. As discussed above, even where the results of AI systems may be technically reliable, they may not always be clinically relevant to a particular patient, and health care professionals will need to continue to exercise their judgment between the two. Transparency is not just how the AI system explains its results, but also teaching health care providers and users how to interrogate the results—ensuring doctors and others relying on precision health systems understand the limitations of the systems and do not put undue reliance on them. Recent court cases involving use of algorithms by state officials to assess and revise benefits for citizens with developmental and intellectual disabilities under a state Medicaid program provide a glimpse of how accountability issues will arise and be adjudicated. In these cases, courts required the states to provide patients with information about how the algorithms were created so that patients could challenge their individual benefit allocations.

Beyond transparency, developers of AI-driven precision health systems should have some degree of accountability for how the systems operate, and those that deploy the systems in medical practice should exercise appropriate judgment when integrating them into medical decision making. At this point, there remain more questions about how accountability should be addressed than there are answers. For example, does it make sense simply to extend existing tort liability regimes that are designed to address injuries arising from defective products or negligent medical practice to also include injuries arising from the deployment and use of precision health technologies? And how should the balance of responsibility for use of suggestions provided by AI-driven precision health systems fall between system developers, health care institutions implementing the systems, and health care professionals utilizing the systems in clinical decision making? Are health care institutions required to independently evaluate each system, and if so, how?

Privacy and Security
AI-driven precision health systems should be secure and respect privacy. These systems will require unprecedented access to sensitive personal health data by technology developers and others, including researchers and clinicians. Protection and security of that data are critical to ensuring patients are willing to share their data and permit their use in innovation.

Privacy of health data, in particular, is already the subject of data protection laws. For example, in the United States, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) governs the use and disclosure of personally identifiable health information by health care providers and health plans and their business associates. In addition, many states have implemented genetic privacy laws that govern consent for genetic testing and disclosure of genetic testing results. But these existing frameworks may not adequately address the myriad privacy concerns that come with the explosion of health data and the many ways in which health data are collected, stored, shared, and used in the development of precision health systems.

Equally important is ensuring patients understand both when those protections are in place and the full ramifications of voluntarily sharing data, whether among various formal
research projects or through more “open source” medical, genetic, or genealogical projects such as GEDmatch (a genetic database to which individuals voluntarily contribute their genetic data). News that law enforcement authorities identified and captured the “Golden State Killer” using GEDmatch has shed a bright light on the fact that genetic information is highly identifying. In the weeks since the announcement that such data had been used to identify the Golden State Killer, law enforcement officials around the country have begun using these data to find the perpetrators of many additional unsolved crimes. Not only does a person’s DNA identify him or her, but it facilitates identification of even distantly related individuals, which one commentator said, “read like science fiction, whether you find them hopeful or horrifying.” Concerns regarding confidentiality of genetic databases are not new. In December 2016, Congress required federally funded research involving genetic data to issue “Certificates of Confidentiality” protecting the privacy of research subjects, including from disclosure in court proceedings. However, it remains to be seen whether these Certificates of Confidentiality, or other legislation that might be formulated, will fully shield research data from disclosure or use by law enforcement.

We also must balance privacy protection with facilitating access to the data that AI-driven precision health systems require to operate effectively. This requires the development and implementation of security methods, such as differential privacy, homomorphic encryption, and techniques to separate data from identifying information about individuals (the latter of which is a particular challenge for genetic information). Developers of AI systems must continue to invest in the development of privacy protection and data security technologies that can be deployed with those systems.

**Preparing the Health Care Profession**

The development of AI-driven precision health technologies has given rise to questions about whether these systems will replace doctors. Such fears are likely unfounded. Most, if not all, countries are experiencing severe clinician shortages. And these shortages are only predicted to get worse in the U.S. over the next ten years. For example, a report for the Association of American Medical Colleges predicts a shortage of physicians through 2030 under every combination of scenarios modeled. Rather than being a threat to clinicians, AI-infused precision health tools might well be essential to improving the efficiency of care, thereby mitigating some of the issues resulting from future shortages of trained and experienced clinicians.

The promise of precision health systems to improve care likely will come not from replacing clinicians, but rather in automating repetitive tasks, thereby freeing clinicians time to focus on high-value activities in the patient care and treatment process. In this regard, properly designed systems will focus on augmenting the skills and experience of highly trained clinicians in keeping with the natural workflows of clinical delivery processes.

**Conclusion**

AI-driven precision health technologies hold great promise. We already see applications today that advance our understanding of health and disease, improve patient care and the public health, and reduce health care costs. But these systems must be carefully developed and deployed to ensure they are reliable, fair, transparent, private, and secure. Systems that are not could do more harm than good. Equally critical for precision health is the continued need for clinicians to exercise medical judgment, both in the development and in the application of AI-driven systems that augment health care practice. Only when we realize the importance of, and work together on, all these critical issues will we all truly realize precision health’s potential.

**Endnotes**

2. The 1998 approval of Herceptin to treat HER2-positive metastatic breast cancer with a companion diagnostic to identify HER-2 positive breast cancer patients often is cited as one of the earliest success stories of personalized medicine. See, e.g., Amalia M. Issa, Personalized Medicine and the Practice of Medicine in the 21st Century, 10 McGill J. Med. 53 (2007).
5. AI for Precision Medicine, PROJECT HANOVER, https://hanover.azurewebsites.net/.

9. To date, FDA has authorized marketing of only a few AI-based medical devices and has done so through its traditional approach and without AI-specific guidelines. FDA cleared the first AI-driven medical device in 2017. Letter from Robert Ochs, Dep’t of Health & Human Servs., to Arterys Inc., K163253 510(k) Summary (Jan. 5, 2017), https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163253.pdf. That device applies deep learning to provide “editable, automated contours” of cardiac ventricles from multiple MRI scans of the heart to calculate blood volume. FDA also classified two AI-based
devices earlier this year, including triage software that uses an AI algorithm to analyze CT images and identify a potential stroke and software that uses an AI algorithm to analyze retinal images to detect more than mild diabetic retinopathy during routine eye exams. Letter from Angela C. Krueger, U.S. Food & Drug Admin., to IDx, LLC, DEN180001 Classification Order (Apr. 11, 2018), https://www.accessdata.fda.gov/ cdrh_docs/pdf18/DEN180001.pdf; Letter from Angela C. Krueger, U.S. Food & Drug Admin., to IDx, LLC, DEN170073 Classification Order (Feb. 13, 2018), https://www.accessdata.fda.gov/ cdrh_docs/pdf18/DEN180001.pdf. But FDA has recognized that it lacks strong internal expertise in evaluating AI-based medical technologies and is working with experts to determine how AI-based technologies can be validated and demonstrated to be reliable. Mike Miliard, FDA Chief Sees Big Things for AI in Healthcare, Healthcare IT News (Apr 30, 2018), http://www.healthcareitnews.com/ news/fda-chief-sees-big-things-ai-healthcare. Additionally, not all precision health applications of AI require FDA review.


