A CURRENT REGIME OF UNCERTAINTY:
IMPROVING ASSESSMENTS OF LIABILITY FOR DAMAGES CAUSED
BY ARTIFICIAL INTELLIGENCE

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The use of artificial intelligence (AI) within the healthcare industry, especially within the practice of telehealth or telemedicine, is quickly gaining momentum. Courts, however, face great difficulty in addressing the question of liability as it pertains to such use of AI, specifically due to the inconsistency in the distinction between medical device and medical procedure and the inconsistency in the application of different standards of care and preemption conditions to AI. Courts should adopt a new guiding principle and frame the question of liability as it pertains to the use of AI within the healthcare industry as one of either medical malpractice or product liability, specifically accounting for the extent to which AI dictates the course of the healthcare provided to patients.

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I.   Introduction

Ponder the following: You roll over in your bed, unable to muster the strength to arise and seize the day. Lightheaded, you reach for the tissues on your nightstand. You then rummage around for your iPhone, eventually accessing your home screen and navigating to an application dubbed "Your.MD."[1]

The application greets you with a simple message: "Tell me about the symptoms you have today."[2] Your thumbs go to work. "Fatigue." "Headache." "Runny Nose." Ellipses crop up in the bottom left-hand corner of your screen. "How long have you had these symptoms for?"[3] You continue communicating with that which any rational person would presume is a licensed healthcare practitioner, ultimately being presented with a list of diagnoses, causes, and treatments.

You do not realize that you have been communicating with a chatbot, a form of artificial intelligence (AI) that is increasingly being employed by healthcare providers, enabling users to bypass initial, in-person visits with their healthcare practitioners, prepare

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[1] Your.MD, *Your.MD April 2017 Demo*, YouTube (May 11, 2017), https://www.youtube.com/watch?v=DFzN-3IqPEg [https://perma.cc/9ANA-C7T3].

[2] *Id.*

[3] *Id.*

for follow-up visits and procedures, and maintain observance of their individual care plans.[4]

The use of AI within the healthcare industry is quickly gaining momentum. The federal government, under its Centers for Medicare and Medicaid Services, has actively supported and incentivized the use of AI by awarding grants to healthcare providers seeking to employ the technology.[5] The U.S. Food and Drug Administration (FDA) recently approved the first use of an autonomous AI system by the University of Iowa.[6] Federal government support and advancements in AI render unsurprising the recent finding by the U.S. Department of Health and Human Services that the majority of healthcare providers employ some form of AI.[7]

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[4] Rachel Z. Arndt, *Healthcare Providers are Teaming with Chatbots to Assist Patients*, MODERN HEALTHCARE (Dec. 8, 2018), https://www.modernhealthcare.com/article/20181208/TRANSFORMATION01/181209977/healthcare-providers-are-teaming-with-chatbots-to-assist-patients [https://perma.cc/N78B-Z7RL].

[5] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs., *Artificial Intelligence (AI) Health Outcomes Challenge*, CMS.GOV (last updated Aug. 1, 2019), https://innovation.cms.gov/initiatives/artificial-intelligence-health-outcomes-challenge [https://perma.cc/J3VD-ATE5] (announcing receipt by Centers for Medicare and Medicaid Services of over three hundred applications for grants by innovators seeking to demonstrate how artificial intelligence may be used to predict unplanned hospital and skilled nursing facility admissions and adverse events).

[6] Bill Siwicki, *University of Iowa Healthcare Rolls Out First Autonomous AI Diagnostic System Cleared by the FDA*, HEALTHCAREITNEWS (July 12, 2018), https://www.healthcareitnews.com/news/university-iowa-healthcare-rolls-out-first-autonomous-ai-diagnostic-system-cleared-fda [https://perma.cc/Y9AQ-ZNMG].

[7] *See, e.g.*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., REPORT TO CONGRESS: E-HEALTH AND TELEMEDICINE 3–4 (2016), https://aspe.hhs.gov/system/files/pdf/206751/TelemedicineE-HealthReport.pdf [https://perma.cc/ZH2G-RPHF] ("[I]t is estimated that sixty-one percent of health care institutions currently use some form of telehealth, and between forty and fifty percent of all hospitals in the United States currently employ some form of telehealth." (internal citations omitted) Smartphone applications are included as forms of telehealth identified by the U.S. Department for Health and Human Services).

State and federal courts have rarely been presented with the question of liability as it pertains to the use of AI within the healthcare industry, specifically within the practice of telehealth or telemedicine. The distinction between medical device and medical procedure or service limits the theories of liability upon which the courts currently rely. If an AI platform is deemed by the FDA to constitute a medical device, for instance, the development of the platform by the developer is generally subject to product liability standards. If, on the other hand, an AI platform is deemed by the FDA to constitute a medical procedure or service, the use of the platform by the healthcare practitioner is generally subject to medical malpractice standards. The standards are substantially different. The former provides for strict liability in the absence of fault on the part of such developers and practitioners and the potential imposition of punitive damages and the latter provides for liability only where such developers and practitioners breach their duty to act reasonably. Courts therefore face great difficulty in addressing the question of liability as it pertains to the use of AI within the healthcare industry, particularly given the inconsistency in the distinction between medical device and medical procedure or service and the fact that such a distinction limits the theories upon which courts currently rely.

The courts face further difficulty, given the inconsistency in the application of existing legislation and regulation to AI platforms and, specifically, in the application of different standards of care and preemption conditions for such platforms. Some states, for instance, require that healthcare practitioners exercise a degree of care that the general, nationwide healthcare profession ordinarily exercises under the same or similar conditions and circumstances. Some other states require that practitioners exercise a degree of care that the healthcare profession ordinarily exercises within the same community or locality. Others have adopted a hybrid standard of care that comprises elements of the national standard and the community or locality standard. Such inconsistency is rendered much more drastic depending upon the elected approach of the FDA in characterizing AI platforms. If the FDA approves an AI platform as a medical device subject to its regulations, it partly preempts product liability claims against healthcare developers.

Alternatively, if it refuses to approve an AI platform as a medical device subject to its regulations, the FDA enables individuals to bring any liability claims against healthcare developers and practitioners, including medical malpractice and product liability claims.

The inconsistencies in the distinction between medical device and medical procedure and in the application of different sets of legislation and regulation to AI platforms create uncertainty for courts, developers of AI platforms, and the healthcare providers utilizing such platforms. This uncertainty permeates throughout the potential liability of developers and providers, jeopardizing the health and safety of patients in the process.

Such uncertainty may also be abridged by a more uniform adoption of existing theories of liability and standards of care by courts. With the assistance of federal legislation or administrative regulation, promulgated by the FDA, courts should adopt a new guiding principle and frame the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine as one of either medical malpractice or product liability.

In deciding between the two theories of liability, courts should account for the extent to which AI platforms dictate the course of the healthcare provided to patients. In cases of medical malpractice, in particular, the standard of care to which such platforms will be expected to adhere ought to be that of the reasonably prudent healthcare practitioner whose professional judgement would have governed in the absence of such platforms. Given variation between the different standards of care established by the states, as well as the fact that telehealth or telemedicine applications of AI enable healthcare services to be provided across different states, courts should ultimately assess the standard of care to which such applications will be expected to adhere on a national basis. Such uniform adoption by the courts may ensure that developers and healthcare providers are held more accountable for their negligent development and use of AI and may ensure that patients are safeguarded.

This article will proceed in five parts. Part II will offer a brief discussion of the emerging application of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine. Part III will assess the liability issues raised by such an application. Part IV will offer an analysis of the varying theories of liability that courts currently rely upon when presented with such liability issues. Finally, Part V will offer a recommendation as to how courts should adopt a more uniform approach to such liability issues and address any pertinent considerations and counterarguments.

II.   The Emerging Application of Artificial Intelligence within the Healthcare Industry through the Lens of the Practice of Telehealth and Telemedicine

In a report from its annual meeting held last year, the American Medical Association defined AI as "a host of computational methods that produce systems that perform tasks normally requiring human intelligence. These computational methods include, but are not limited to, machine image recognition, natural language processing, and machine learning."[8]

The use of AI within the healthcare industry is quickly gaining momentum. Healthcare insurance providers, for instance, have employed claims review processes that utilize AI to review the medical records of individuals and identify those at risk of incurring the most substantial costs for healthcare services.[9] Healthcare practitioners have similarly employed clinical decision

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[8] Iliana Peters et al., *Insight: AI in Health Care – A Look at Critical Data Regulations*, Big L. Bus. (Aug. 23, 2019), https://www.bloomberglaw.com/document/X4I35I1G000000?bna_news_filter=health-law-and-business&jcsearch=BNA%2520000016c4e33dcb4a17f5fff34220001#jcite [https://perma.cc/5PWJ-J58G].

[9] *See, e.g.*, Susan Morse, *How Health Insurance Companies Use AI to Make Consumers Healthier*, Healthcare Finance (Nov. 9, 2018), https://www.healthcarefinancenews.com/news/how-health-insurance-companies-use-ai-make-consumers-healthier [https://perma.cc/Q2YJ-8XZX] (Prognos, for instance, "uses a lab registry of 18 billion clinical records to stratify risk for a group of beneficiaries who have just enrolled.").

support systems that utilize AI to align observations of patients with their individualized genetics, medical histories, and symptoms as well as generalized population-based healthcare knowledge and, thereby, assist the practitioners in improving their decision-making at the point of care.[10] As an example, Saint Luke's Health System in Kansas City, Missouri, identified that a number of its patients transferred from community-based and rural hospitals passed away due to not being diagnosed with sepsis early enough.[11] Saint Luke's Health System began employing a clinical decision support system that assesses the lab work and vital signs records of transfer patients pursuant to an algorithm, enabling the transfer team to identify transfer patients with sepsis and administer treatment thereto, decreasing the mortality rate thereof by thirty percent.[12] In other contexts, healthcare practitioners have also employed software that utilizes AI to recognize their individualized speech and vocabulary and automatically create transcriptions of their speech, enabling them to more accurately document their sessions with patients without expending as much time.[13]

Specifically, the use of AI is proliferating within the practice of telehealth or telemedicine, as the amount of AI and healthcare practitioners consulting with patients via telecommunications is increasing.[14] The majority of AI uses within the practice comprise

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[10] *See, e.g.*, Bill Siwicki, *New Study Identifies Top 11 Clinical Decision Support Vendors*, HEALTHCAREITNEWS (Oct. 9, 2018), https://www.healthcareitnews.com/news/new-study-identifies-top-11-clinical-decision-support-vendors [https://perma.cc/9RHD-NJ2W] ("Seventy-four percent of healthcare provider organizations use clinical decision support technology, according to a new study from Reaction Data relying on CDS to make more informed medication orders (30%), lab orders (24%), medical imaging orders (20%), choosing wisely (13%) and other (13%).").

[11] *Id.*

[12] *Id.*

[13] *See, e.g.*, Benjamin Harris, *Using Artificial Intelligence, Speech Recognition to Optimize Note Taking*, HEALTHCAREITNEWS (June 11, 2019), https://www.healthcareitnews.com/news/using-artificial-intelligence-speech-recognition-optimize-note-taking [https://perma.cc/JY3M-Z9Q7].

[14] *See, e.g.*, Kumba Sennaar, *Artificial Intelligence in Telemedicine and Telehealth – 4 Current Applications*, EMERJ (Feb. 16, 2019), https://emerj.com/ai-sector-overviews/artificial-intelligence-in-telemedicine-and-telehealth [https://perma.cc/6MUB-KJG7] ("In an effort to increase clinical

either diagnostic support or virtual consultation platforms.[15] Diagnostic support is the use of AI to operate chatbots, such as those employed by the Your.MD application, that utilize machine learning algorithms to recommend a diagnosis to patients based upon their individualized genetics, medical histories, and symptoms.[16] Virtual consultation platforms, on the other hand, employ clinical decision support systems, providing for remote consultations between healthcare practitioners and their patients and utilizing AI to align observations therefrom with the individualized genetics, medical histories, and symptoms of the patients as well as generalized population-based healthcare knowledge.[17] The AI utilized by the virtual consultation platform analyzes such data and provides recommendations to the practitioners, assisting them in improving their decision-making at the point of care.[18]

HealthTap is one example of a diagnostic support platform that, akin to Your.MD, employs chatbots to recommend a diagnosis to patients based upon their individualized genetics, medical histories, and symptoms.[19] The machine learning algorithms utilized by the chatbots were developed over a six-year period, based upon thousands of questions by patients and answers by healthcare practitioners that span 141 medical specialties.[20] The HealthTap platform has been downloaded over one million times.[21] Remarkably, its chatbots have answered over 2.6 million

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and administrative capacity through telehealth, researchers are developing AI-driven technology for healthcare professionals and consumers.").

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.* (Lemonaid Health, a virtual consultation platform, requires patients to complete an online health questionnaire, including information on their allergies, medications, medical history, and symptoms, and then uses such information to match the patient with a healthcare practitioner within two minutes.).

[19] *Id.*

[20] *Id.*

[21] *Id.*

questions.[22] AdaHealth, another example of a diagnostic support platform, has been downloaded over four million times.[23]

InfiniteMD, conversely, is one example of a virtual consultation platform that specifically provides for second-opinion remote consultations between healthcare practitioners and cancer patients. The platform further utilizes AI to align observations therefrom with the individualized medical histories of the patients as well as generalized clinical trial data and data from other consultations conducted through the platform. In doing so, it assists the practitioners in recommending particular clinical trials for which the patients may be eligible.[24] InfiniteMD claims that twenty-eight percent of its consultations resulted in a change or correction in diagnosis, and that over seventy-two percent of its consultations resulted in a revised treatment plan.[25] Lemonaid Health, another example of a virtual consultation platform, has processed over 48,000 consultations across fourteen states in just over two years.[26]

The use of AI within the practice of telehealth or telemedicine is accompanied by reductions in healthcare expenditures by healthcare insurers and providers as well as patients.[27] One review

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[22] *See   HealthTap*,   GOOGLE   PLAY   (Jan.   30,   2020), https://play.google.com/store/apps/details?id=com.healthtap.userhtexpress&hl=e nUS [https://perma.cc/79WJ-T5C2] ("Search content from over 2.6 million doctor-answered questions and 700,000 topics and articles across over 850 conditions.").

[23] *See* Sennaar, *supra* note 14.

[24] *Id.*

[25] Justine Hofherr, *The Doctor is in: How InfiniteMD Plans on Using AI to Give Patients Second Opinions*, BUILTINBOSTON (Feb. 9, 2018), https://www.builtinboston.com/2018/02/09/how-infinitemd-using-ai-give-patients-second-opinions [https://perma.cc/94KM-LZK6].

[26] Antoinette Siu, *John Muir Expands Care With $25 Telemedicine Visits*, S.F. BUS. TIMES (Aug. 14, 2017), https://www.johnmuirhealth.com/about-john-muir-health/press-room/Press-releases/2017-8-14-john-muir-health-expands-care-with-telemedicine.html [https://perma.cc/YET4-USCS].

[27] *See, e.g.*, Am. Telemedicine Ass'n., *Examples of Research Outcomes: Telemedicine's Impact on Healthcare Cost and Quality* 1, AM. TELEMEDICINE ASS'N   (Apr.   2013),   https://www.amdtelemedicine.com/telemedicine-resources/documents/ATATelemedicineResearchPaper_impact-on-healthcare-cost-and-quality_April2013.pdf [https://perma.cc/4BNV-9Y5B] ("[S]tudies are

of twenty-three different telehealth or telemedicine applications of AI between 1997 and 2007, for instance, demonstrated reductions in total cost, cost per patient, and cost per visit.[28] Additionally, the American Telemedicine Association notes that "for most telemedicine applications, studies have shown that there is no difference in the ability of the provider to obtain clinical information, make an accurate diagnosis, and develop a treatment plan that produces the same desired clinical outcomes as compared to in-person care when used appropriately."[29] One review of twenty-nine different telehealth or telemedicine applications of AI between 2001 and 2007 demonstrated a moderate, positive, and significant effect on clinical outcomes, particularly for cardiovascular and psychiatric conditions.[30] Indeed, "using mobile health to eliminate preventable human errors and promote evidence-based decision-making would seem to increase the quality of healthcare."[31] Furthermore, patient satisfaction with the use of AI in the practice of telehealth or telemedicine has consistently been very high.[32] One examination that accounted for differences in patient age, education, gender, income, insurance, and race unearthed an overall patient satisfaction of 98.3%.[33] In strong contrast, one examination of patient satisfaction with their human healthcare providers, particularly among cardiovascular patients, unearthed an overall patient satisfaction of 76.5%.[34]

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consistent in finding that telemedicine saves the patients, providers and payers money when compared with traditional approaches to providing care.").

[28] *Id.* at 3.

[29] *Id.* at 4.

[30] *Id.* at 5.

[31] Fazal Khan, *The "Uberization" of Healthcare: The Forthcoming Legal Storm Over Mobile Health Technology's Impact on the Medical Profession*, 26 Health Matrix 123, 129 (2016).

[32] Am. Telemedicine Ass'n., *supra* note 27, at 6.

[33] *Id.* (stating the examination in question, while reported by the American Telemedicine Association, was conducted independently, by Susan S. Gustke, David C. Balch, Vivian L. West, and Lance O. Rogers).

[34] Mohd Noor Norhayati et al., *Patient Satisfaction with Doctor-Patient Interaction and its Association with Modifiable Cardiovascular Risk Factors Among Moderately-High Risk Patients in Primary Healthcare*, 5 PeerJ (2017).

Nonetheless, the expanding use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine is also accompanied by surprisingly under-analyzed issues of fraud and abuse, insurance coverage and reimbursement, information privacy and security, licensure, and liability.[35] For instance, federal legislation on such use has predominately addressed insurance coverage and reimbursement.[36] The Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2017, for instance, expanded Medicare coverage and reimbursement to some telehealth or telemedicine applications of AI.[37] State legislation on such use has predominately addressed insurance coverage and reimbursement.[38] In 2017, for instance, sixty-two pieces of state legislation were introduced in the legislatures of thirty-four states, most of which predominately addressed insurance coverage and reimbursement.[39] Liability, in particular, has not been thoroughly addressed, leaving unanswered questions regarding the attribution and evaluation of responsibility for any injuries suffered by patients as a result of the use of AI.

III.   LIABILITY ISSUES RAISED BY THE EMERGING APPLICATION OF ARTIFICIAL INTELLIGENCE WITHIN TELEHEALTH AND TELEMEDICINE

The use of novel medical technologies within the healthcare industry often brings about a reconceptualization of medical liability, raising questions as to the applicability of various standards of care and the identification of the responsible party for negligence or wrongdoing. Artificial intelligence is no different. It

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[35] *See generally* Mei Kwong, *Special Issue: What will 2018 Bring for Telehealth Policy?*, CTR. FOR CONNECTED HEALTH POL'Y (Jan. 2, 2017), https://mailchi.mp/cchpca/special-issue-what-will-2018-bring-for-telehealth-policy [https://perma.cc/89FK-QJHZ].

[36] *Id.*

[37] *See generally* Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017, S.870, 115th Cong. (2017).

[38] *See* Kwong, *supra* note 35. ("The most frequently addressed issues in state legislation were public and private payer reimbursement.").

[39] *See id.*

is unique, however, in the issues it raises in the attribution and evaluation of responsibility for any injuries suffered by patients as a result of its use, particularly within the practice of telehealth or telemedicine. For the first time, the observations and recommendations of AI could depose the professional judgements of rigorously trained healthcare practitioners.[40]

Researchers at Stanford University recently developed an AI platform that analyzed more than 100,000 chest X-rays made publicly available by the National Institutes of Health, compared the X-rays to those of HIV-positive patients in South Africa, and demonstrated an ability to correctly diagnose tuberculosis among such patients at a rate thirteen percent higher than healthcare practitioners therein.[41] Researchers at Google similarly developed an AI platform that analyzed a small subset of images of diabetic retinopathy adjudicated by ophthalmologists that specialize in retinal diseases and demonstrated an ability to adjudicate the images of moderate or significant diabetic retinopathy on its own at an accuracy of ninety-seven percent as compared to the accuracy of eighty-four percent at which the ophthalmologists adjudicated the images.[42] Researchers at Google and Stanford have thus developed AI platforms that have accurately and constructively deposed the professional judgements of healthcare practitioners.

Nonetheless, AI platforms are predisposed to certain biases that healthcare practitioners may be better equipped to manage. For instance, one hospital system used an AI platform to determine whether its pneumonia patients would respond better to in-home treatment than to treatment at the hospital system. In doing so, the hospital system subjected itself to the biases inherent to the

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[40] *See* Gary E. Marchant & Lucille M. Tournas, *AI Health Care Liability: From Research Trials to Court Trials*, J. HEALTH & LIFE SCI. L. 23, 26 (2019).

[41] Richard Harris, *How Can Doctors be Sure a Self-Taught Computer is Making the Right Diagnosis?*, NAT'L PUB. RADIO (Apr. 1, 2019), https://www.npr.org/sections/health-shots/2019/04/01/708085617/how-can-doctors-be-sure-a-self-taught-computer-is-making-the-right-diagnosis [https://perma.cc/XXP2-XHWJ].

[42] Laura Lovett, *Google Researchers Find Trained AI Detects Diabetic Retinopathy on Par with Experts*, MOBI HEALTH NEWS (Mar. 14, 2018), https://www.mobihealthnews.com/content/google-researchers-find-trained-ai-detects-diabetic-retinopathy-par-experts [https://perma.cc/XU9H-MZ7C].

underlying data and reasoning mechanisms employed by the AI.[43] The platform determined that asthmatic pneumonia patients would respond better to in-home treatment based upon data demonstrating that such patients achieved better outcomes than non-asthmatic pneumonia patients when admitted to, and treated at, the hospital system.[44] However, such data was indicative of asthmatic pneumonia patients normally being admitted to acute care units, where they receive immediate and focused treatment, due to their being at a greater risk than non-asthmatic pneumonia patients.[45]

Similarly, the AI platform developed by the researchers at Stanford University was also subject to biases, recognizing in its analysis and comparison of X-rays information around the edge of the images that demonstrated the type of X-ray machine through which the images were transmitted.[46] After detecting that a portable X-ray machine had been used, the platform was more likely to diagnose the HIV-positive patients with tuberculosis, since such machines are more frequently used in hospitals and pneumonia is more common amongst hospitalized patients than amongst those who opt for office visits with their healthcare practitioners, demonstrating that AI platforms are predisposed to certain biases that healthcare practitioners may be better able to account for.[47] "It was being a good machine-learning model and it was aggressively using all available information baked into the image to make its recommendations," said one of the researchers who developed the platform.[48] Even that, however, was not enough.

Artificial intelligence, as employed within the practice of telehealth or telemedicine, is no less predisposed to such biases. For instance, Doctor Hazel, a virtual consultation platform, utilizes

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[43] Rich Caruana et al., *Intelligible Models for HealthCare: Predicting Pneumonia Risk and Hospital 30-Day Readmission*, KD'15 PROCEEDINGS OF THE 21ST ACM SIGKDD INTERNATIONAL CONFERENCE ON KNOWLEDGE DISCOVERY AND DATA MINING 1721 (2015).

[44] *Id.*

[45] *Id.*

[46] Harris, *supra* note 41.

[47] *Id.*

[48] *Id.*

AI to determine whether photographs of moles uploaded by its users are benign or potentially cancerous.[49] Doctor Hazel, however, is predisposed to a sampling bias due to the minute amount of data being analyzed and compared by the AI it utilizes.[50] The platform reports its having correctly determined moles to be potentially cancerous at a rate of eighty-five percent, demonstrating that there exists substantial potential for its reporting of false negatives, where users are told that their moles are benign when, in fact, they are potentially cancerous.[51]

A healthcare practitioner may better account for such biases, demonstrating that the observations and recommendations of AI perhaps ought not to so readily depose the professional judgments of such practitioners. An overreliance on AI and its inherent biases may nonetheless pose significant risks, particularly of misdiagnoses, especially to those patients who seek to bypass in-person visits with their healthcare practitioners, prepare for follow-up visits and procedures, and maintain observance of their individual care plans by means of applications of telehealth or telemedicine. Accordingly, there exists, note researchers, "a significant and growing liability exposure for health care providers, product manufacturers, and health care institutions, given the uncertainties created about whether, how, and when AI should be measured, if at all, by traditional notions of the standard of care."[52]

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[49] Dave Muoio, *Doctor Hazel, an AI Aimed at Skin Cancer Detection, is Latest in a Long Line*, Mobi Health News (Sept. 18, 2017), https://www.mobihealthnews.com/content/doctor-hazel-ai-aimed-skin-cancer-detection-latest-long-line [https://perma.cc/U4SQ-VZCM].

[50] Sarah Buhr, *Doctor Hazel Uses AI to Try to Determine if you Have Skin Cancer*, Tech Crunch (Sept. 17, 2017), https://techcrunch.com/2017/09/17/doctor-hazel-uses-ai-to-try-to-determine-if-you-have-skin-cancer/ [https://perma.cc/6MVX-4X8S] ("The main hurdle right now is getting the data needed to help Doctor Hazel predict skin cancer with at least a ninety percent accuracy. 'There's a huge problem in getting AI data for medicine. It's painful to get the data, even from large institutions. No one wants to share . . . [b]ut amazing results are possible. The more people share, the more accurate the system becomes.'").

[51] Muoio, *supra* note 49.

[52] Marchant & Tournas, *supra* note 40, at 23.

Furthermore, the rapid emergence of the application of AI within the healthcare industry, particularly within the practice of telehealth or telemedicine, may result in some applications beyond the comprehension of some healthcare practitioners as well as an inability of clinical guidelines and clinical support systems to keep pace.[53] "As technologies change so rapidly," explain Marchant and Tournas, "what might be malpractice if relied on today may be negligent to not use tomorrow."[54] Despite its quickly gaining momentum, state and federal courts have rarely been presented with the question of liability as it pertains to the use of AI within the healthcare industry, specifically within the practice of telehealth or telemedicine.[55]

IV.   APPROACHES COURTS MAY TAKE WHEN FACED WITH TELEHEALTH AND TELEMEDICINE LIABILITY ISSUES

When presented with the question of liability as it pertains to the use of AI within the healthcare industry, the courts may theoretically rely upon such varying theories of liability as medical malpractice and product liability and, in cases of medical malpractice, different standards of care. In doing so, the courts create uncertainty for the developers of AI platforms and the healthcare providers utilizing such platforms as to their potential liability, jeopardizing the health and safety of patients in the process. Indeed, "[n]o courts have yet had the opportunity to address" the question of liability as it pertains to the use of AI within the healthcare industry.[56]

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[53] *Id.* at 34.

[54] *Id.*

[55] *Id.* at 33.

[56] *Id.* at 40; *see also* W. Nicholson Price II et al., *Potential Liability for Physicians Using Artificial Intelligence*, J. AM. MED. ASS'N (Oct. 4, 2019), https://jamanetwork.com/journals/jama/article-abstract/2752750 [https://perma.cc/45K2-BFAJ] ("In part because AI is so new to clinical practice, there is essentially no case law on liability involving medical AI.").

A. *The Inconsistency in the Distinction Between Medical Device and Medical Procedure or Service and the Effect of Such Distinction Upon Theories of Liability*

Courts face great difficulty in addressing the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine. This difficulty is made more drastic as administrative, legislative, and judicial bodies have yet to address whether AI constitutes a medical device or, rather, a medical procedure or service.[57] The distinction between medical device and medical procedure or service limits the theories upon which the courts currently rely when presented with questions of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine. Liability for uses of AI within the healthcare industry may be evaluated under either the traditional product liability standards for manufactured products or under the commonplace medical malpractice liability standards for healthcare practitioners.[58] The medical malpractice liability standards for healthcare practitioners and the product liability standards for manufactured products are substantially different.

In alleging product liability, the plaintiff must demonstrate that (1) his or her injury resulted from a product defect that rendered the product unreasonably dangerous, and (2) the defect existed at the time the product left the developer.[59] Product liability relies

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[57] Marchant & Tournas, *supra* note 40, at 32.

[58] *Id.* at 26.

[59] *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. LAW INST. 1998); *see also* Jessica S. Allain, Comment, *From Jeopardy! to Jaundice: The Medical Liability Implications of Dr. Watson and Other Artificial Intelligence Systems,* 73 LA. L. REV. 1049, 1067 (2013). The requirement that the plaintiff demonstrate the existence of a defect at the time the product left the developer raises interesting questions for developers of artificial intelligence platforms and the healthcare practitioners utilizing such platforms. Because artificial intelligence platforms sometimes utilize machine learning, whereby the platforms automatically learn and improve from experience, defects may arise that did not exist at the time the platform left the developer. The question remains as to whether such defects may expose developers and practitioners to liability. Similarly, the question remains as to whether biases in the platform's

upon a more plaintiff-friendly, strict liability standard for design defects, manufacturing defects, and warning defects in manufactured products, enabling plaintiffs to prevail even in the absence of fault or intent on the part of the defendant.[60] Further, product liability doctrine provides for punitive damages.[61]

On the other hand, in alleging medical malpractice, the plaintiff must demonstrate that (1) the defendant healthcare practitioner owed a duty to the plaintiff, (2) the defendant breached such duty, and (3) the breach of such duty proximately caused injury to the plaintiff.[62] Medical malpractice relies upon a more defendant-friendly, negligence standard, enabling plaintiffs to prevail only if they demonstrate that defendants breached their duty to act as reasonably prudent healthcare practitioners, often by means of the expert testimony of other similarly situated practitioners.[63] Medical malpractice doctrine, in contrast to product liability doctrine, provides for a statutorily defined amount of damages.[64]

If an AI platform is deemed by the FDA to constitute a medical device, the development of the platform by the developer is generally subject to product liability standards.[65] If the FDA deems an AI platform to constitute a medical device, the availability of product liability as a claim may be limited. Traditionally, for instance, hospitals and healthcare practitioners have been rendered immune from product liability actions arising out of the use of medical devices because courts have held the primary function of hospitals and practitioners to be the provision of medical procedures or services rather than medical devices.[66] Further, the learned intermediary doctrine may prevent the plaintiff from bringing such a product liability action against the developer of the

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decision-making that result from its learning of data constitute defects that may expose developers and practitioners to liability.

[60] Marchant & Tournas, *supra* note 40, at 26.

[61] *Id.*

[62] *See* 6 MED. MALPRAC. CHKLSTS. & DISC. § 47:15 (2019); *see also* Laura E.A. Wibberley, *Telemedicine in Illinois: Untangling the Complex Legal Threads*, 50 JOHN MARSHALL L. REV. 885, 895–96 (2017).

[63] Marchant & Tournas, *supra* note 40, at 26.

[64] *Id.*

[65] *Id.* at 33.

[66] Allain, *supra* note 59, at 1067.

product if the developer satisfied his duty to warn users of the potential dangers inherent in the use of the product.[67] On the other hand, if an AI platform is deemed by the FDA to constitute a medical procedure or service, the use of the platform by the healthcare practitioner is generally subject to medical malpractice standards.[68]

The FDA has approved some AI platforms as medical devices while refusing to approve other platforms as such, instead apparently accepting them as medical procedures or services.[69] For example, the FDA approved the AI platform developed and utilized by researchers at Google to detect diabetic retinopathy as a medical device.[70] A similar platform developed and utilized by researchers at IBM, however, is accepted as a medical procedure or service, utilized by healthcare practitioners without having undergone approval or oversight by the FDA.[71] In approving some AI platforms as medical devices while refusing to approve other platforms as such, the FDA subjects the developers of similar platforms and the healthcare practitioners utilizing such platforms to substantially different standards, one that provides for strict liability in the absence of fault on the part of such developers and practitioners and the potential imposition of punitive damages, and another that provides for liability only if such developers and practitioners breach their duty to act reasonably.

The consequences of developers of AI platforms or the healthcare practitioners utilizing such platforms being subjected to different standards of product liability or medical malpractice may be demonstrated by a hypothetical application of medical malpractice standards to the factual scenario presented in *Taylor v.*

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[67] *Id.*

[68] Marchant & Tournas, *supra* note 40, at 33.

[69] *Id.* at 32.

[70] U.S. Food & Drug Admin., *FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems*, FDA.GOV (Apr. 11, 2018), https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye [https://perma.cc/PAS4-EU7B].

[71] Marchant & Tournas, *supra* note 40, at 32.

Intuitive Surgical.[72] The factual scenario in *Taylor* demonstrated an ambiguity as to whether an AI platform or the healthcare practitioner operating such a platform was culpable for the harm suffered by the plaintiff.[73]

In *Taylor*, the plaintiff brought a product liability claim against the manufacturer of a robotic surgical system that utilized AI for injuries sustained by a patient who had been operated upon by the system, even when the surgeon operating the system may have been more responsible for the errors that caused the injuries than the manufacturer.[74] The surgeon was trained and credentialed to operate the system.[75] As part of his training, the surgeon received a manual that recommended that the maximum body mass index for candidates eligible for operation be set at thirty.[76] Nonetheless, the patient who had been operated upon presented to the surgeon with a body mass index of thirty-nine.[77] The patient suffered from severe complications throughout the surgery and thereafter required assistance with ambulating and breathing, eventually passing away within four years after his having been operated on.[78] The Washington Court of Appeals affirmed the jury's decision finding for the manufacturer, holding that the manufacturer provided adequate warning to the surgeon and, thereby, satisfied its duty to provide a warning regarding the nature of the system it had developed.[79]

Alternatively, had the plaintiff brought a medical malpractice claim against the surgeon operating the system, the jury may have decided for the plaintiff, especially since the decision by the surgeon to operate on a patient who presented with a body mass index of thirty-nine, in contravention of the recommendation that the maximum body mass index for candidates eligible for

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[72] Taylor v. Intuitive Surgical, Inc., 355 P.3d 309 (Wash. Ct. App. 2015), *aff'g* Case No. 09-2-03136-5 (Wash. Superior Ct. 2013).

[73] *Id.*

[74] *Id.* at 312.

[75] *Id.* at 311.

[76] *Id.*

[77] *Id.*

[78] *Id.* at 312.

[79] *Id.*

operation be set at thirty, may constitute a breach of the duty of the surgeon to exercise reasonable care. Thus, the potential determination by the FDA that the system either constitutes a medical device or a medical procedure or service may have foreclosed the plaintiff from bringing particular claims or relying upon particular standards, each of which provide for different assessments of fault and damages. Accordingly, the inconsistency in the distinction between medical device and medical procedure or service creates uncertainty not only for courts but, also, for the developers of AI platforms and the healthcare providers utilizing such platforms as to the potential liability of developers and providers, jeopardizing the health and safety of patients in the process.

B. *The Inconsistency in the Application of Different Sets of Legislation and Regulation and the Effect of Such Application Upon Applicable Standards of Care and Preemption Conditions*

The courts face further difficulty in addressing the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine, because medical devices and medical procedures or services are subject to different sets of legislation and regulation. The federal government is tasked with legislating, and the FDA is tasked with regulating, medical products.[80] State governments, on the other hand, are tasked with legislating and regulating the practice of medicine, including medical procedures or services.[81]

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[80] *See* Bill Sutton, *Overview of Regulatory Requirements: Medical Devices – Transcript*, FDA.GOV (Nov. 2011), https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medical-devices-transcript [https://perma.cc/KQ2R-JDBY] ("The US Food and Drug Administration (FDA) is responsible for regulating and supervising the safety of foods, dietary supplements, drugs, vaccine, biological medical products, blood products, medical devices, radiation-emitting products, veterinary products, and cosmetics.").

[81] *See generally* Richard Epstein, *Government Regulation of the Practice of Medicine: How the FDA Overreaches the Regulation of Medical Practice*, HARV. L. SCH.: BILL OF HEALTH (Sept. 30, 2013), http://blog.petrieflom.law.harvard.edu/2013/09/30/government-regulation-of-

Such legislation and regulation render more difficult analyses of questions of liability raised by applications of AI within the healthcare industry, especially considering that such legislation and regulation establish different standards of care to which healthcare developers and practitioners are expected to adhere. Twenty-nine states, for instance, require the same standard of care for telehealth or telemedicine applications of AI as is required for traditional, in-person visits with healthcare practitioners.[82] "The issue is that the standards of care for traditional in-person encounters vary by state."[83]

In Georgia, for instance, healthcare practitioners must exercise a reasonable degree of care, interpreted to encompass the degree of care that the general, nationwide healthcare profession ordinarily exercises under the same or similar conditions and circumstances, attested to by an expert witness.[84] Other states, such as Idaho and Washington, require the degree of care ordinarily exercised under the same or similar conditions to account for care ordinarily exercised within the same community or locality.[85] A standard of care that accounts for community or locality generally requires that the expert witness attesting to the standard hail from the same community or locality as the defendant and compare the care provided by the defendant to the applicable standard in the community or locality within which the care was provided.[86] Standards of care, however, are still subject to state-by-state variations in the geographic scope of the applicable community or locality. Idaho, for instance, limits the applicable community or

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the-practice-of-medicine-how-the-fda-overreaches-the-regulation-of-medical-practice-2/ [https://perma.cc/4M7X-XJB5].

[82] Adelyn B. Boleman, Comment, *Georgia's Telemedicine Laws and Regulations: Protecting Against Health Care Access*, 68 MERCER L. REV. 489, 507 (2017) (stating the standard of care established within the states wherein the patient is seen governs).

[83] *Id.* at 508.

[84] *See* Smith v. Finch, 681 S.E.2d 147, 149 (Ga. 2009); *see also* Kapsch v. Stowers, 434 S.E.2d 539, 540 (Ga. 1993) (holding Georgia has already embraced the national standard of care to good effect).

[85] *See, e.g.*, Idaho Code Ann. § 6-1012 (1976); *see also* Wash. Rev. Code Ann. § 7.70.040(1) (2011).

[86] *See, e.g.*, Sheeley v. Mem'l Hosp., 710 A.2d 161, 165–66 (R.I. 1998).

locality to the geographic area typically served by the hospital, but if no such hospital exists, a geographic area similar to that within which the care was provided may constitute the applicable locality.[87] Washington, on the other hand, expands the applicable community or locality to the entire state of Washington.[88] Other states, such as Louisiana, have adopted a hybrid standard of care, which comprises elements of the national standard adopted by Georgia and the community or locality standards adopted by Idaho and Washington.[89] Specifically, hybrid states require that specialists abide by the national standard and that general practitioners abide by the community or locality standard.[90]

Such inconsistent legislation and regulation render analyses of liability raised by applications of AI within the healthcare industry more complex, especially considering that this legislation and regulation subject applications of AI to different preemption conditions.[91] Indeed, when the FDA approves an AI platform as a medical device subject to FDA regulations, the FDA partly preempts product liability claims against healthcare developers.[92] Alternatively, when the FDA refuses to approve an AI platform as a medical device subject to FDA regulations because use of the platform constitutes the practice of medicine, individuals may bring liability claims against healthcare developers and practitioners, including medical malpractice and product liability claims.[93] Such inconsistency in the application of different sets of legislation and regulation—and, specifically, in the application of different standards of care and preemption conditions—may

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[87] Idaho Code Ann. § 6-1012.

[88] Wash. Rev. Code Ann. § 7.70.040(1).

[89] *See, e.g.*, Ray v. Ameri-Care Hosp., 400 So. 2d 1127, 1137–38 (La. Ct. App. 1981), *writ denied*, 404 So. 2d 277 (La. 1981) (Specialists are "subject to the higher standard of care ordinarily practiced by physicians within that particular specialty rather than the standard of care exercised by generalist physicians practicing in the same community. The locality factor is no longer involved in determining the standard of care required of specialists in malpractice suits.").

[90] *Id.*

[91] Marchant & Tournas, *supra* note 40, at 33.

[92] *Id.*

[93] *Id.*

further create additional uncertainty for courts, developers of AI platforms, and healthcare providers utilizing such platforms as to the potential liability of developers and providers. In doing so, this inconsistency may further jeopardize the health and safety of patients.

Indeed, because of the inconsistency in the establishment of different standards of care, "the 'safest' way to use medical [artificial intelligence] from a liability perspective is as a confirmatory tool to support existing decision-making processes rather than as a source of ways to improve care."[94] Even where AI platforms provide for more accurate assessments of patient conditions, such as the platform developed by Stanford researchers which correctly diagnosed tuberculosis among patients at a higher rate than healthcare practitioners, the inconsistency in the establishment of different standards of care incentivizes practitioners to reject such assessments out of fear that their accepting may fall short of the degree of care exercised by practitioners nationally or those within the same community or locality.[95] "Without legislation enacted specifically to accommodate this new technology or sufficient case law to establish precedent on the legal issues raised, courts are forced to analogize new technologies to previous ones for which laws exist."[96]

Thus, when faced with the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practices of telehealth or telemedicine, courts ought to reestablish the demarcation between medical malpractice liability and product liability, clarifying for healthcare developers and practitioners the standards to which they will be expected to adhere and safeguarding patients in the process. The predicament at hand has been summarized as follows:

> If the machine is evaluated under a different standard than the human
> doctor who it replaces in performing a specific task, this discrepancy

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[94] Price II et al., *supra* note 56.

[95] *See id.*

[96] Amanda Swanson & Fazal Khan, *The Legal Challenge of Incorporating Artificial Intelligence into Medical Practice*, 6 J. HEALTH & LIFE SCI. L. 90, 116 (2012).

may bias the outcome of a head-to-head competition between human and machine. Imposing a higher standard on the AI machine may deprive patients of better care and could deprive the health system of potential cost savings provided by an AI system. On the other hand, imposing a lower standard of care on the AI machine may encourage the offering of substandard care.[97]

In other words, the ambiguity in the standards to which healthcare developers and practitioners are expected to adhere jeopardizes the health and safety of patients, rendering a clarification by the courts much more necessary.

V.   A RECOMMENDATION AS TO HOW THE COURTS OUGHT TO MODIFY THEIR APPROACH WHEN FACED WITH SUCH LIABILITY ISSUES

Such a predicament may be abridged by a more uniform adoption of existing theories of liability and standards of care by the courts. With the assistance of federal legislation or administrative regulation, perhaps promulgated by the FDA, courts could and ought to adopt a new guiding principle. Further, courts should frame the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine as one of either medical malpractice or product liability. In deciding between the two theories of liability, the courts should account for the extent to which AI platforms dictate the course of the healthcare provided to patients.[98]

For instance, if AI platforms completely depose the professional judgment of healthcare practitioners and if they err in their observations or recommendations based upon their internal machine learning mechanisms, they should be held to malpractice liability standards.[99] The standard of care to which such platforms will be expected to adhere ought to be that of the reasonably prudent healthcare practitioner whose professional judgment would have governed in the absence of such platforms. Some states, including Colorado and Mississippi, have established the standard

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[97] Marchant & Tournas, *supra* note 40, at 38–39.
[98] *Id.* at 39.
[99] *Id.*

of care to which such platforms will be expected to adhere as that of the reasonably prudent healthcare practitioner whose professional judgment would have governed in the absence of such platforms.[100] Twenty-nine medical boards, including that of Georgia, have also established a similar standard of care.[101] Given variation between the different standards of care established by the states, as well as the fact that telehealth or telemedicine applications of AI enable healthcare services to be provided across different states, courts should hold the standard of care to which such applications will be expected to adhere on a national basis. The standard of care should be that of the general, reasonably prudent healthcare practitioner whose professional judgment would have governed in the absence of such platforms, without accounting for community or local variation.[102] Such applications would, therefore, be held to the same standard, regardless of the physical location of either the healthcare practitioner or his or her patient.[103]

Undeniably, some cases may arise in which AI platforms err in their observations or recommendations based upon their internal learning mechanisms as well as defects in their design, manufacture, or warnings. In such cases, the decision between the two theories of liability ought to be dependent upon whether internal learning mechanisms or defects in design, manufacture, or warning are more responsible for the harm suffered by the patient. Where the AI platforms err in their observations or recommendations based upon defects in their design, manufacture, or warnings, they ought to be held to product liability standards.

In modifying their approach to the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine, the

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[100] *See, e.g.*, Colo. Rev. Stat. Ann. § 10-16-123(2) (2016) ("Any health benefits provided through telemedicine shall meet the same standard of care as for in-person care."); Miss. Code Ann. § 83-9-353(2) (2014) ("Treatment recommendations made via electronic means shall be held to the same standards of appropriate practice as those in traditional provider-patient setting.").

[101] Boleman, *supra* note 82, at 507.

[102] *Id.* at 517.

[103] *Id.*

courts may address the very issues arising from the inconsistency in the distinction between medical device and medical procedure or service and the fact that such a distinction limits the theories upon which the courts currently rely. By accounting for the extent to which AI platforms dictate the course of the healthcare provided to patients, rather than whether the platforms are deemed to be medical devices or medical procedures or services, courts may subject developers of similar AI platforms and healthcare practitioners utilizing such platforms to the same standards. In doing so, courts may provide clarity for developers and practitioners as to their potential liability and safeguard the health and safety of patients in the process.

In modifying their approach, courts may also address the very issues arising from the inconsistency in the application of different sets of legislation and regulation to AI platforms and, specifically, in the application of different standards of care and preemption conditions for such platforms. By assessing the standard of care to which these platforms will be expected to adhere on a national basis—as that of the general, reasonably prudent healthcare practitioner whose professional judgment would have governed in the absence of such platforms, without account for community or local variation—courts may subject the developers of AI platforms and the healthcare practitioners utilizing such platforms to the same, singular standard of care, despite community or local variation in the development, marketing, sale, and utilization of these platforms. In doing so, the courts may ensure fairness for the various developers, healthcare practitioners, and the patients that are developing, utilizing, and being subjected to such platforms. The courts may, further, provide clarity for developers and practitioners as to their potential liability, regardless of whether an AI platform or a practitioner erred in the healthcare provided to the patient, and safeguard the health and safety of patients in the process.

Again, the use of AI within the practice of telehealth or telemedicine has demonstrated significant benefits. For example, use of AI technology has been accompanied by reductions in healthcare expenditures by healthcare insurers and providers. Additionally, patients have seen positive effects on clinical

outcomes, and AI technology has increased patient satisfaction, despite differences in patient age, education, gender, income, insurance, and race.[104] Thus, in modifying their approach to the question of liability as it pertains to the use of AI within the healthcare industry and, specifically, within the practice of telehealth or telemedicine, courts should remain cognizant of such benefits, careful not to deter developers from developing innovative AI platforms. Indeed, "the pharmaceutical and medical device industries often rail against the obstructionism of the federal government towards new medical technologies."[105] This modified approach, however, remains sensitive to such concerns, allowing for safeguards that aim to ensure that developers are not deterred from developing innovative AI platforms.

For instance, one safeguard may be the introduction of a legislative or regulatory requirement that healthcare practitioners *meaningfully* review the observations or recommendations of AI platforms, thereby reducing liability exposure where such platforms err in their observations or recommendations based upon their internal machine learning mechanisms or defects in their design, manufacture, or warnings.[106] "Freezing the standard of care to require meaningful human participation would head off [the] consequences [of liability]," notes Froomkin.[107]

Nonetheless, any legislative or regulatory requirement that healthcare practitioners "meaningfully" review the observations or recommendations of AI platforms may be difficult to implement. For instance, the determination of the extent to which practitioners are required to review the observations or recommendations of AI platforms, may be complicated by the fact that the capabilities of AI platforms are continually being enhanced.[108] "In the abstract,

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[104] Am. Telemedicine Ass'n., *supra* note 27, at 1–6.

[105] Khan, *supra* note 31, at 142.

[106] 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, 97 (2019).

[107] *Id.*

[108] *See id.*

however, it is very hard to define the appropriate level of review with any precision."[109]

Accordingly, the extent to which practitioners will be required to review the observations or recommendations of AI platforms may need to be determined on a case-by-case basis rather than subjected to a firm standard.[110] Any legislative or regulatory requirement that healthcare practitioners meaningfully review the observations or recommendations of AI platforms may invite more inefficiency in healthcare decision-making.[111] Moreover, and relatedly, any legislative or regulatory requirement that healthcare practitioners meaningfully review observations or recommendations of AI platforms, may be incredibly costly to healthcare practitioners and their patients.[112] Indeed, such a requirement may risk "forgoing a larger number of beneficial outcomes that will not happen because the [artificial intelligence] plus physician is too expensive. The risk here is that some people may not be able to afford the care that they otherwise might have had."[113]

Another safeguard that aims to ensure that developers are not deterred from developing innovative AI platforms may be the introduction of some arrangement of "enterprise liability" in which developers of AI platforms, healthcare practitioners, or hospitals utilizing such platforms pay the federal government an excise tax for their development or utilization of such platforms.[114] This enables the federal government to establish a compensation program for patients injured as a result of such development or utilization.[115] The healthcare industry is well-suited for the theory of enterprise liability because (1) the industry can reasonably expect and insure against the potential injuries that may be caused by AI platforms after consideration of its past experiences with such platforms and resulting clinical outcomes; (2) the industry is

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[109] *Id.*

[110] *See id.*

[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] Swanson & Khan, *supra* note 96, at. 135–36.

[115] *Id.*

well-equipped to develop and implement quality assurance programs that can mitigate the potential for injuries that may be caused by such platforms; and (3) the industry stands in the best financial position to distribute and sustain the losses that may be caused by such platforms.[116]

One arrangement of enterprise liability that may serve as a model is the Vaccine Compensation Program, established by the National Childhood Vaccine Injury Act.[117] The Act enabled prompt and adequate "compensation to be paid for vaccine-related injury or death" while maintaining the "nation's supply of vaccines by insulating manufacturers from liability."[118] The Program requires that an excise tax be placed on every vaccine dose administered and that patients injured by vaccines "bring their claims in the U.S. Court of Federal Claims before seeking other remedies against" developers of vaccines or healthcare practitioners administering such vaccines.[119] An arrangement similar to the Vaccine Compensation Program may "[impose] the burdens ensuring the safety of [AI] technologies on the healthcare industry as a whole, thereby relieving individual physicians [and developers] from liability for technology's few but inevitable failures."[120]

VI.   CONCLUSION

The use of AI within the healthcare industry is quickly gaining momentum. The state and federal effort to contain the spread of the novel Coronavirus, for instance, has resulted in an increase in the use of AI within the healthcare industry, especially within the practice of telehealth or telemedicine, as state and federal governments have relaxed regulations governing the use thereof.[121]

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[116] *Id.* at 136–37.

[117] *Id*. at 143.

[118] *Id.*

[119] *Id.*

[120] *Id.* at 135.

[121] *See* Jennifer Kay, *Florida Providing Free Telehealth, Flu Shots for State Employees*, BLOOMBERG L. (Mar. 26, 2020), https://news.bloomberglaw.com/health-law-and-business/florida-providing-free-telehealth-flu-shots-for-state-employees [https://perma.cc/92FT-LQYX] (state government response); *see also* Anjali N.C. Downs et al., *Insights: Waived Medicare Telehealth*

On March 26, 2020, Florida Governor Ron DeSantis signed an executive order requiring the State Group Insurance Program, which provides coverage to state employees and their dependents, to include within its coverage telehealth or telemedicine services at no additional cost to beneficiaries.[122] Similarly, on March 6, 2020, President Donald Trump signed into law the Coronavirus Preparedness and Response Supplemental Appropriations Act, enabling the Centers for Medicare and Medicaid Services to expand coverage of telehealth or telemedicine services to all Medicare beneficiaries, regardless of their location.[123]

State and federal courts, however, have rarely been presented with the question of liability as it pertains to the use of AI within the healthcare industry, specifically within the practice of telehealth or telemedicine. The courts face great difficulty in addressing such a question of liability, particularly given the inconsistencies in the distinction between medical device and medical procedure or service and in the application of different sets of legislation and regulation to AI platforms.

Such inconsistencies create uncertainty not only for the courts but, also, for the developers of AI platforms and the healthcare providers utilizing such platforms as to the potential liability of developers and providers, jeopardizing the health and safety of patients in the process. This uncertainty may be abridged by a more uniform adoption of existing theories of liability and standards of care by the courts. With the assistance of federal legislation or administrative regulation, perhaps promulgated by the FDA, courts ought to adopt a new guiding principle and frame the question of liability as one of either medical malpractice or

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Copayments Leave Unanswered Questions, BLOOMBERG L. (March 27, 2020), https://news.bloomberglaw.com/health-law-and-business/insights-waived-medicare-telehealth-copayments-leave-unanswered-questions [https://perma.cc/9WFW-QWEG] (federal government response).

[122] *See* Kay, *supra* note 121.

[123] *See* Anjali N.C. Downs et al., *Insight: Key Medicare Telehealth, HIPAA Changes During Coronavirus Pandemic*, BLOOMBERG L. (March 26, 2020), https://news.bloomberglaw.com/health-law-and-business/insight-key-medicare-telehealth-hipaa-changes-during-coronavirus-pandemic [https://perma.cc/83U3-3XEX].

product liability. In deciding between the two theories of liability, courts should account for the extent to which AI platforms dictate the course of the healthcare provided to patients. Courts ought to assess the standard of care to which such applications will be expected to adhere on a national basis.

A more uniform adoption of existing theories of liability and standards of care by the courts may ensure that developers and healthcare providers are held more accountable for their negligent development and use of AI and that patients are safeguarded in the process. In modifying their approach to the question of liability, courts should remain careful not to deter developers from developing innovative AI platforms. The modified approach, however, remains sensitive to such concerns, allowing for safeguards that may ensure that developers are not so deterred.