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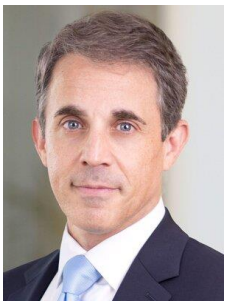
Liability Risk For AI In Medical Devices Demands Greater Care

By **Andrew Kaplan and Lucia Pallier** (January 14, 2025, 6:58 PM EST)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After more than a decade of anticipation, machine learning and artificial intelligence are finally starting to make a meaningful impact in clinical practice.[1]

Between 2017 and 2019, the U.S. Food and Drug Administration approved more than 40 medical devices using AI for clinical application.[2]

Despite their potential, however, AI algorithms in medical devices are facing scrutiny, especially regarding potential liability in cases of patient injury. To date, much of this concern has centered on physician malpractice.[3]

That said, physicians are only one part of a complex ecosystem that includes health systems and device manufacturers, and liability for each is closely intertwined.[4] Regulators have been watching applications of AI in the healthcare sphere and its implementation in medical products in particular.

In December 2024, the FDA issued a guidance document setting forth marketing submission recommendations for artificial intelligence-enabled devices "to promote the development of safe and effective AI-enabled devices."[5]

The same month, the new EU Directive 2024/2853 reforming product liability in light of challenges posed by new technologies, such as AI, came into effect to ensure "that claimants enjoy the same level of protection irrespective of the technology involved and that all businesses benefit from more legal certainty and a level playing field."[6]

As regulators push for legal reform and cases implicating product liability for AI in medical technology are on the rise, manufacturers must think about strategies addressing liability risks.

Potential liability for AI in medical devices can have far-reaching implications, including whether promising algorithms reach clinical practice. In other words, heightened liability risks for the use or development of AI in biomedical technology could discourage both developers and healthcare leaders from integrating these innovations into clinical care.

Different Types of Medical Devices Using AI

In the past decade, a multitude of AI applications to aid clinical practice and patient treatment have

been integrated into medical devices entering the market.

These range from AI diagnostic technologies to AI-assisted medical treatment and AI-based implants. While the core liability issues for these technologies are similar, nuances in the implementation of the products may impact liability outcomes in specific cases.

The evolving landscape of AI innovation includes the following.

Diagnostic AI Technologies

AI tools used to assist with medical diagnosis include various products such as systems scanning imaging, making diagnostic suggestions based on symptom input, or risk screening.

Using advanced algorithms to analyze data and recognize patterns, these systems are transforming healthcare and enhancing the accuracy, speed and accessibility of diagnoses.

For instance, risk screening algorithms such as the AI system developed by Zebra Medical Vision[7] analyze X-rays, mammograms and CT scans to identify individuals at high risk for diseases including fractures, brain bleeds, coronary artery disease and breast cancer, enabling earlier intervention and potentially preventing serious complications.

In a similar application, PathAI has created algorithms — including one called TumorDetect — that assist in cancer diagnosis by evaluating biopsy samples.[8] Another AI-driven tool, Google's DeepMind, can detect eye disease by analyzing retinal scans.[9] Such tools provide input to specialists, enhancing diagnostic quality and reducing human error.

AI-Assisted Medical Treatment

Tools using AI for medical treatment can encompass different applications, such as algorithms suggesting medication dosage or devices using AI-guidance during surgery, which allow for more precise, personalized and effective interventions.

One example is the AI-based drug discovery platform developed by Insilico Medicine that uses AI to identify new molecular agents and targets for drug treatments, potentially accelerating the development and personalization of medications.[10]

In the U.K., Oxford University researchers are working on an AI-assisted program called DrugGPT, aimed at aiding physicians with medication prescription and management.[11]

For surgery, AI-powered systems like the Da Vinci Surgical System offer robotic assistance with minimally invasive procedures, enhancing surgeons' precision through real-time guidance and feedback.[12]

These innovations hold promise for increasing treatment effectiveness and reducing complications, though they also raise questions about oversight and accountability in AI-guided medical decisions.

AI-Based Implants

Implantable medical devices integrating AI are another novel way to improve patient care by

continuously monitoring and adjusting treatments for the device while implanted.

For example, insulin pumps, like the Medtronic MiniMed 780G, use AI algorithms to measure blood glucose levels and automatically adjust insulin delivery, helping people with diabetes maintain optimal glucose control with minimal manual intervention.[13]

In cardiology, AI-powered cardiac implanted electronic devices — monitoring heart rhythms and adjusting pacing to prevent arrhythmias — are being investigated.[14]

And in the somewhat more distant future, brain-computer interfaces currently being developed by Neuralink Corp. may help quadriplegics operate robotic limbs.[15] These AI-based implants increase treatment precision and patient quality of life by enabling responsive, personalized care.

Current AI-MedTech Caselaw — A Blurred Boundary Between Professional and Product Liability

Despite their innovative character and contribution to new clinical care models, AI applications in medical products can expose manufacturers to certain liability risks because of the newness of the technology and the potentially unpredictable nature of generative AI. Recent case law discussing professional and product liability in the context of AI tools used in medical products, highlights these potential risks.

Lowe v. Cerner

In the product liability suit Lowe v. Cerner Health Services Inc. in 2020, the plaintiff, Michael Taylor, sued Cerner in the U.S. District Court for the Eastern District of Virginia for its allegedly faulty development of a software system used to enter medical orders for patient care.

Cerner sold the system to various hospitals, including the Virginia Hospital Center, where the plaintiff had undergone surgery.

Because of alleged design defects in the system related to the start time of physicians' orders, the plaintiff argued that his blood oxygen measurements — pulse oximetry — were started too late, causing a drop in blood oxygen levels to go undetected, which resulted in brain damage and physical impairments.

An initial and separate action the plaintiff had brought against the hospital and physician settled. The plaintiff subsequently asserted negligence claims against Cerner under Virginia law, alleging that the software was negligently designed, and that Cerner negligently failed to warn system users of those design defects, which in turn caused the lack of monitoring of his oxygen level.

The district court awarded summary judgment to Cerner because the plaintiff failed to identify industry standards that Cerner needed to meet, and because Cerner was not on notice of the software's alleged dangerous feature.

However, on Nov. 29, 2022, the U.S. Court of Appeals for the Fourth Circuit vacated and remanded the grant of summary judgment. The court held that a jury reasonably could conclude that Cerner's software contained design defects not complying with industry standards, that Cerner was on notice, and that Cerner failed to warn users about these defects.

The court held that under Virginia law, the plaintiff was not required to eliminate other proximate causes of the injury, i.e., the hospital's and the physician's actions.

While no final judgment has been entered in this action, the Fourth Circuit decision shows that courts may impose liability for AI-aided systems in a healthcare setting, and that liability allocation can extend to encompass both professional and product liability in certain matters.

Sampson v. Heartwise Health Systems

In Sampson v. HeartWise Health Systems Corp. in 2023, Alicia Sampson filed a wrongful death action against HeartWise, the developer of a cardiovascular disease prevention program, as well as Isaac Health, a clinic operating under a licensing agreement with HeartWise, Isaac Health's owners, and two physicians.

The cardiovascular disease prevention program in question consisted of a battery of up to 31 physical tests[16] intended to assist in the detection of vascular and cardiac abnormalities.

The data points collected from the tests were then processed by HeartWise's proprietary software program using screening principles and protocols to generate a report based on the test results, including a readout as to whether a patient's results for each test were normal.

The decedent had sought a HeartWise medical evaluation at the Issac Health clinic due to his family history of congenital heart defects. According to the report generated for decedent, the data from the left ventricular echocardiogram and EKG was within the normal range.

However, the decedent passed away several days later because of a congenital heart defect, giving rise to the plaintiff's wrongful death action. The trial court granted summary judgment to defendants, which the Supreme Court of Alabama affirmed in part and reverse in part.

The Supreme Court affirmed the circuit court's award of summary judgment on HeartWise's negligence claim, holding that under the licensing agreement between HeartWise and Isaac Health, the physicians retained clinical judgment and final decision-making responsibility about diagnosis and treatment plan.[17]

This case is noteworthy because it underlines the importance of clear agreements between the parties in establishing protocols for the use and management of AI systems in clinical practice.

Strategies for Medical Device Manufacturers to Avoid Liability Risk

Besides well-thought-out strategies in the FDA review process, manufacturers of medical devices using AI algorithms should also make sure that they limit their liability through thorough product design, comprehensive warnings and post-market research and surveillance.

Thorough Risk Assessment During Product Design

As the cases discussed above highlight, at the inception of any new medical technology — and especially one using AI — the product design should thoroughly analyze, identify and document the risks and how to mitigate those risks.

Medical device manufacturers using AI in their products should be able to demonstrate that neither the algorithm itself nor the algorithm combined with other components of the product could have feasibly been designed in a different way to avoid or reduce harm to consumers, without introducing other risks.[18]

For AI, this may include expert analysis of possible autonomous developments of the algorithm, to identify potential changes that could occur once the device is on the market. In addition, a review of the current market landscape may also help to ascertain technologically feasible safety precautions employed by competitors.

Comprehensive Warnings

Additionally, when designing appropriate warnings for medical products using AI, it is important to carefully consider issues such as the evolving nature of algorithms or unforeseen use by consumers.

In particular, manufacturers should evaluate all potential uses of the device by a reasonable consumer, including reasonably foreseeable issues the consumer may encounter.

For instance, in the context of insulin pump litigation, courts have held that a medical device manufacturer must consider the users' potential cognitively impaired state when using the pump while under the influence of an acute hypoglycemic event, as the U.S. District Court for the Western District of Kentucky did in Dalton v. Animas Corp. in 2012.[19]

That is, warnings for AI-powered products should be drafted to account for the consumer's physical condition when using the product, which may lead to actual uses of the product not strictly compliant with its intended use.

Post-Market Research and Surveillance

Post-market research and surveillance[20] are especially critical for AI-powered medical devices, because of the constantly evolving nature of AI algorithms. This includes an ongoing analysis of whether new developments in the product's technology may have materially altered the product's risk profile.

How FDA Review Process Affects Potential Liability

The 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetics Act includes an express preemption provision that preempts most state law liability on the basis that the FDA, through its comprehensive approval process, is wholly responsible for ensuring the safety and efficacy of medical devices.[21]

Preemption assumes that the safety and efficacy of medical products is fully evaluated by the FDA review and approval process.

Under established U.S. Supreme Court precedent, MDA preemption applies to product approved through the FDA's robust premarket approval process, which is typically used for Class III medical devices.[22]

Such preemption usually does not apply to devices cleared by the FDA through its premarket notification process. To the extent medical technology using AI consists of multiple components with some

components having undergone the premarket approval process, while others have not, it may be argued that preemption should apply only to those that did obtain premarket approval.[23]

Contract Carefully to Mitigate Risks

Often AI technologies are developed by specialized product developers that either license or sell the technology to medical device manufacturers for use in their products.

If such technology is licensed or sold by a third party to a finished product manufacturer, the agreement should be clear to delineate which party has responsibility for any liabilities resulting from claims made regarding alleged defects in the technology.

Conclusion

AI-driven medical devices often operate in ways that exceed traditional definitions of human control, making it challenging to assign fault when issues arise.

Therefore, traditional liability frameworks, focused primarily on physician malpractice and product liability, may not fully accommodate the complexities of AI-assisted treatment, where responsibility is shared among developers, health systems, and device manufacturers.

Despite the uncertainties, however, it is possible to navigate the medtech AI market safely and to minimize liability risks attendant to such cutting-edge technologies.

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[1] Maliha G, Gerke S, Cohen IG, Parikh RB. Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation. Milbank Q. 2021;99(3):629-647, accessible at https://www.milbank.org/quarterly/articles/artificial-intelligence-and-liability-in-medicine-balancing-safety-and-innovation/.

[2] Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nat Med. 2019; 25(1): 44-56.

[3] Price WN, Gerke S, Cohen IG. Potential liability for physicians using artificial intelligence. JAMA. 2019; 322(18):1765.

[4] Mello MM, Guha N. Policy Brief: Understanding Liability Risk from Healthcare AI. Stanford University Human-Centered Artificial Intelligence (HAI). 2024; accessible at: https://hai.stanford.edu/policy-brief-understanding-liability-risk-healthcare-ai; Parasidis E. Clinical decision support: elements of a sensible legal framework. J Health Care Law Pol. 2018; 20(2):183.

[5] Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions - Guidance for Industry and Food and Drug

Administration Staff, December 2024, FDA-2022-D-2628, accessible at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.

[6] EU Directive 2024/2853 signed into law by the European Parliament and the Council of Europe on 10/23/2024, accessible at Directive - 2024/2853 - EN - EUR-Lex.

[7] See https://d3.harvard.edu/platform-digit/submission/zebra-medical-vision-transforming-patient-care-through-ai/.

[8] See https://www.pathai.com/resources/pathai-introduces-tumordetect-an-ai-solution-to-automate-tumor-assessment-and-case-prioritization-for-anatomic-pathology-laboratories/.

[9] See https://deepmind.google/discover/blog/using-ai-to-predict-retinal-disease-progression/.

[10] See https://www.nature.com/articles/d43747-021-00039-5.

[11] See https://www.theguardian.com/science/2024/mar/31/druggpt-new-ai-tool-could-help-doctors-prescribe-medicine-in-england.

[12] See https://www.intuitive.com/en-us/products-and-services/da-vinci.

[13] See https://www.fda.gov/medical-devices/recently-approved-devices/minimed-780g-system-p160017s091.

[14] Krittanawong, C., Rogers, A.J., Johnson, K.W. et al. Integration of novel monitoring devices with machine learning technology for scalable cardiovascular management. Nat Rev Cardiol 18, 75–91 (2021); Bisignani G, Cheung JW, Rordorf R, Kutyifa V, Hofer D, Berti D, Di Biase L, Martens E, Russo V, Vitillo P, Zoutendijk M, Deneke T, Köhler I, Schrader J and Upadhyay G (2024) Implantable cardiac monitors: artificial intelligence and signal processing reduce remote ECG review workload and preserve arrhythmia detection sensitivity. Front. Cardiovasc. Med.11:1343424.

[15] See https://neuralink.com.

[16] These tests including certain labs, an EKG, a limited left ventricular ultrasound with a three-minute stress test, an ultrasound of the carotid arteries, aorta, and thyroid, and a pulmonary function test.

[17] However, the court reversed and remanded the summary judgment that had been entered for Heartwise with respect to plaintiff's fraud allegations.

[18] Fearrington v. Boston Sci. Corp., 410 F. Supp. 3d 794, 803-804 (S.D. Tex. 2019); see also Restatement (Third) of Torts: Prod. Liab. § 2 (1998), according to which a manufacturer must be able to show that the "foreseeable risks of harm posed by the product could [not] have been reduced or avoided by the adoption of a reasonable alternative design."

[19] Dalton v. Animas Corp., 913 F. Supp. 2d 370, 376 (W.D. Ky. 2012).

[20] The FDA has certain postmarketing surveillance programs in place, mostly for drugs, see https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs. In addition, the FDA

recently announced its development of a postmarketing surveillance system for medical devices. See https://www.gao.gov/products/gao-24-106699.

[21] Medical Device Amendments of 1976, Pub. L. No. 94 295, 90 Stat. 539 (codified at 21 U.S.C. § 360c). According to the MDA, plaintiffs were barred from recovering for injuries that resulted from a "requirement … which is different from, or in addition to, any requirement applicable under [the MDA], and … which relates to the safety or effectiveness of the device."

[22] Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

[23] See, e.g., Shuker v. Smith & Nephew, PLC, 885 F.3d 760 (3rd Cir. 2018).