Say 'Goodbye' to Medical Negligence Cases as We Know Them

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Whether you know it or not, some form of artificial intelligence (AI) is likely involved in your current health care. AI use in health care will continue to grow exponentially in ways unimaginable just a few years ago. As AI use increases, medicine will improve, which will likely mean less errors and, therefore, less claims. For claims that do arise in the new era of AI use, we can anticipate they will be more complex, cost more to litigate and impact a larger class of patients.

As health care technology grows, two recent cases of interest, *Lowe v. Cerner*, 2022 WL 17269066 (6th Cir., Nov. 29, 2022) and *In re Acclarent*, 2024 WL 2873617 (Tex. App. 2024), foreshadow the future of claims associated with electronic medical record (EMR) systems enhanced by AI. Very soon, expect cases involving health care errors to be based on both negligence and products liability principles with reliance on academically trained EMR clinical informatics as experts—which will change the way cases are raised and defended.

Until the mid-2000s, medical records were one-dimensional, pen-to-paper physical documents stored in folders and maintained on shelves, and access to the information contained therein was limited. Decades of well-established legal precedent pertaining to discovery, preservation and production were easy to apply to paper medical records. The advent of EMRs changed that, and with the new integration of AI in health care, the chart is now three-dimensional, interactive and, in some instances, even make suggestions to health care providers. Twentieth century legal standards simply cannot apply to the 21st century AI-enhanced EMR. It is akin to applying horseback riding rules to interstellar travel.

In addition to changes in how the medical record is documented, procured and preserved, products liability doctrines may now apply to cases involving EMR errors. The trial court in *Lowe v. Cerner* held that an EMR system vendor can be sued after a patient was injured due to a charting error by the physician who admitted confusion in how to document the timing of an order. Given that EMRs are used almost universally with every patient, as opposed to the narrow use of traditional medical devices like defibrillators and orthopedic devices, the *Lowe* decision has set the precedent for a whole host of new medical device cases based upon medical provider user error due

to a confusing EMR system. As the EMR becomes more complex and boosted by AI chatbots, clinical decision support (CDS) and computer assisted diagnosis (CAD), it should be anticipated that health care providers and EMR/AI vendors will be sued together more regularly.

A recent decision from the Texas appellate courts, *In re Acclarent*, demonstrates this point. In this case, the prospective plaintiff sought pre-complaint depositions of physicians and a medical device manufacturer surrounding an event involving a sinus surgery. The prospective plaintiff's intention was to learn more about an AI-enhanced feature of the product that was used during the surgical procedure at issue, which allegedly may have malfunctioned, causing injuries.

Among other things, the prospective plaintiff sought to learn the identity of the AI provider; how the device engineers interacted with the AI provider in enhancing the medical device; communications with and submissions by the device manufacturer, if any, to the Federal Drug Administration (FDA) about the AI enhancement; any product recalls due to faulty AI; all communications between the potential physician defendant and the product manufacturer on the use of the AI-enhanced device; and reports of other patient injuries due to errors by the AI-enhanced medical device.

Another reason for the prospective plaintiff's request to access the pre-complaint depositions was to vet whether she had a product liability case, a straightforward medical malpractice case, or a hybrid case involving the physicians and the medical device manufacturer. Her attorney argued that a product liability component could impact many aspects of the anticipated lawsuit, including the venue, jurisdiction, application of a preemptive defense by the device manufacturer, and timing of the filing of her case based on the applicable statute of limitations.

The Texas court of appeals ultimately denied the request for pre-complaint depositions of the device manufacturer, but the case illustrates the new issues to consider as AI becomes more integrated into health care decision making, diagnosis and treatment.

A hybrid medical malpractice/products liability claim can lead to more cases being filed in plaintiff-friendly venues, similar to mass tort cases, given that EMR systems are used almost universally and in every state. Jurisdiction may also be in play, particularly if the medical device was FDA-approved and eligible for a preemption defense.

Applicable statutes of limitations will also be of even greater importance moving forward. If a product liability case has a longer statute of limitations than a medical negligence case, there may be situations where the plaintiffs seek a "second bite at the apple" and file a products liability case after the completion of the medical negligence case. However, a general release in the medical malpractice case may preclude recovery in a subsequent products liability case. Where plaintiffs choose not to file against the EMR/AI vendor and pursue a malpractice case only, the medical defendants may decide to join the EMR/AI vendor in their cases to attempt to reduce their comparative negligence. However, with joinder comes additional legal burdens and costs for the defendants. They, too, will

have to consider venue and jurisdictional consequences in bringing an EMR/AI vendor into a case.

The last and most important change to medical error cases in the age of AI-enhanced EMR systems is the importance of having a qualified medical informatics expert to support the prosecution or defense of the case. They are just as important as medical standard of care and causation experts. EMR systems, which were already complicated before AI-enhancement, have and will continue to become more complex and evolve at a faster rate than ever before. If there truly is an EMR error associated with an injury, no party benefits from expert guidance that is misguided and ill-informed. For these reasons, both plaintiffs and defendants are encouraged to retain "medical informatics professionals" to guide them in their cases, rather than rely on persons whose only forensic experience with these systems is from litigation.

The American Medical Informatics Association (AMIA) has recently published guidance for the retention of qualified experts on EMR issues in litigation, and there is an ample supply of these specialists. In short, these guidelines suggest the retention of a specialist academically trained in clinical informatics with experience in EMR design, development, implementation and use, with robust involvement in promoting the profession and its issues. Essentially, these specialists are "chart physicians" who will guide the parties through litigation using scientifically-supported techniques to verify or refute information within a patient's record; efficiently assist with investigations into whether the AI-enhanced EMR caused or contributed to a plaintiff's injury; and serve as a conduit between the parties and EMR/AI vendors in locating specific relevant information. Because the chart is no longer a repository for patient information but, rather, a tool to assist health care providers in caring for their patients, it makes sense that true scientists, not litigation specialists, provide direction to the parties, courts and juries as to how these complicated systems work.

AI-enhanced health care may finally fulfill the promise that EMR adoption would reduce errors, improve care, make health care more affordable and reduce claims. We are already seeing progress in this regard, but make no mistake about it, errors will continue and cases will be harder to explain given the complexity of the EMR. These will not be the cases we are accustomed to litigating. It's time to say farewell to simple negligence and "hello" to the use of "chart physicians" and products liability concepts. ◘

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