

No. 26-388

IN THE
Shawnee Supreme Court

October Term 2026

METROPOLITAN HEALTH SYSTEM, INC., ET AL.,

Petitioners,

v.

EVELYN MILLER, INDIVIDUALLY AND AS SPECIAL ADMINISTRATOR FOR THE STATE

OF ELIAS MILLER, DECEASED,

Respondent.

On Writ of Certiorari to the
Shawnee Court of Appeals
for the Second District

BRIEF FOR PETITIONERS

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QUESTIONS PRESENTED FOR REVIEW

- I. Whether the diagnostic error of an AI software tool integrated into a healthcare system's branded telehealth platform can lead to that healthcare system being held vicariously liable under the doctrine of apparent agency.
- II. Whether Shawnee's four-year statutes of repose bars Respondent's claims or whether the periods were tolled/extended by:
 - (a) The annual diagnostic evaluations by Cyber MD constitute a "continuous course of treatment" per Shawnee Revised Statute § 12-404; or
 - (b) The algorithmic flaw's latent and un-discoverable nature and later retraining under exceptions listed in Shawnee Revised Statute § 12-410.

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OPINIONS BELOW

The unreported opinion of the Circuit Court of Simmons County, *Miller v. Metropolitan Health System, Inc.*, No. 25-L-24601 (Mar. 6, 2025) is contained in the Record of Appeal at pages 2–13, where the Circuit Court GRANTED the Defendant’s motion for summary judgement. The unreported Opinion of the Shawnee Court of Appeals for the Second District, *Miller v. Metropolitan Health System, Inc.*, Dkt. No. 25-123 (Feb. 24, 2026), is contained in the Record of Appeal at pages 16–28. The Court of Appeals REVERSED and REMANDED the Circuit Court’s decision in its entirety.

STATUTORY PROVISIONS INVOLVED

This case involves three provisions of the Shawnee Revised Statutes: Sn. Rev. Stat. §§ 12-402, 12-404, and 12-410. These provisions are reproduced in Appendix A.

The following provision of the Shawnee Rules of Civil Procedure is relevant to this case: Sn. R. Civ. P. 56.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case arises after an economic downturn and health care shortage in Simmon County. The closure of two local hospitals due to bankruptcy in 2015 contributed to a subsequent loss of over 75% healthcare professionals from 2016 to 2025 in Simmons County; only three primary care practices remained and there was no operating urgent care facility. (*Id.* at 3–4.) Shawnee state officials and federal authorities declared Simmons County a Health Professional Shortage Area and a Medically Underserved Area. (*Id.* at 4.)

Cartersville, in Simmons County, had been home to the Shawnee Steel Company's primary steel mill. (*Id.* at 3.) The steel mill opened in 1950 and contained machinery heavily insulated with asbestos until its closure in 2016 (*Id.*) Despite Occupational Safety and Health Administration's 1970s standards to cease such asbestos use, facilities such as the Cartersville steel mill retained their asbestos insulated machinery. (*Id.*) The facility loosely enforced safety protocols, with workers frequently working without protective respiratory equipment. (*Id.*)

Harmed by the economic downturns and lack of resources, the local population's healthcare resources were limited. Appellants are healthcare network Metropolitan Health Systems, Inc. and healthcare technology company Cyber-Care Solutions, LLC which still service the region. Respondent represents the interest of decedent, a steel worker who developed an adenocarcinoma subsequent to occupational asbestos exposure.

Metropolitan Health Systems, Inc. ("MHS") is a large regional healthcare network with its flagship hospital in Goshen, Shawnee. (*Id.* at 4.) After 2015, MHS's Goshen location was the nearest healthcare facility providing radiology consultations and CT scans in person to Cartersville, Shawnee. (*Id.*)

Cyber-Care Solutions, LLC ("CCS") is a provider of digital health infrastructure with a proprietary remote telehealth platform. (*Id.*) CCS developed Cyber MD, an AI diagnostic software system. (*Id.* at 5.) They sent verification studies and data to the FDA for Cyber MD. (*Id.*) The FDA granted clearance for Cyber MD in February 2017. (*Id.*) This interactive and conversational system allows

patients to “input symptoms via text or voice, asks follow-up questions, compiles clinical history, generates differential diagnoses, and orders/interprets diagnostic tests.” (*Id.*) Prior to initiating a chat session, the user is presented a mandatory pop-up they must accept to proceed. (*Id.*) In red, 16-point font the box states:

Cyber MD is not a licensed health care professional. It is an artificial intelligence software.

(*Id.*)

Cyber MD was trained on a dataset of 40,000 images from three hospital systems; the initial accuracy rate in classifying lung lesions was 97%. (*Id.*) This accuracy dipped to 85% when the images were of patients with occupational asbestos exposure. (*Id.*) CCS discovered this lowered accuracy in October 2022 and subsequently retrained Cyber MD with an additional image set of 10,000 asbestos-exposed images, restoring the high accuracy. (*Id.* at 5–6.) CCS rectified the accuracy discrepancy and deployed the updated algorithm on December 13, 2023. (*Id.*)

Telehealth Platform Deployment and Cyber MD Integration. In 2012, CCS contracted with MHS to provide their telehealth platform. (*Id.* at 4.) CCS hosts the platform, and the patient-facing interface is controlled by MHS. (*Id.*) The telehealth platform is accessed through MHS’s domain and contains branding for MHS but not CCS. (*Id.*) Next to the user login, the webpage states: “By entering the portal, I accept the MHS Terms and Conditions.” (*Id.*) Those terms and conditions are blue, underlined, and hyperlinked with the linked page containing the following disclosure amongst unified text:

All clinical evaluations, imaging reviews, and diagnostic interpretations provided through this digital portal are performed by independent

contractor physicians or automated software applications developed by another company. The physicians and software are not employees or agents of Metropolitan Health System. MHS exercises no operational control over the clinical judgment or diagnostic methods used by the independent contractor physicians or any automated software applications.

(*Id.* at 4–5.) On March 1, 2017, MHS integrated Cyber MD into the telehealth portal. (*Id.* at 5.)

Elias Miller, the decedent, began working at Shawnee Steel Company’s primary steel mill at 20 years old in 1970 until he retired in 2016. (*Id.* at 3.) At the steel mill he was exposed to asbestos and often worked without protective respiratory equipment. (*Id.* 3.) Upon retirement in 2016, the same year the steel mill closed, his most recent chest screening—performed in 2012—was “unremarkable.” (*Id.* at 3–4.)

Mr. Miller experienced shortness of breath on April 9, 2018. (*Id.* at 6.) He subsequently accessed MHS’s telehealth portal, viewed MHS’s “Terms and Conditions” webpage, initiated a Cyber MD virtual intake session, and accepted the required terms. (*Id.* at 5–6.) Mr. Miller provided his history—including occupational asbestos exposure at the steel mill—and Cyber MD ordered diagnostic imaging from a mobile radiology service. (*Id.* at 6.) The mobile unit uploaded the images to the platform two weeks later; Cyber MD reported the X-ray and CT scans displayed no evidence of malignancy. (*Id.*) Cyber MD referred Mr. Miller to a local practitioner for inhaler management and recommended annual follow-up imaging. (*Id.*)

Mr. Miller had annual follow up visits with Cyber MD in May 2019, May 2020, and June 2021. (*Id.*) New imaging was taken in conjunction with the annual

visits; each time Cyber MD stated there was no evidence of a disease and didn't prescribe any treatment. (*Id.*) After the 2021 scan, Cyber MD advised there was no need for continued annual imaging. (*Id.*)

On October 30, 2023—over six years after Cyber MD received FDA clearance and over five years after Mr. Miller's initial intake with Cyber MD—Mr. Miller suffered a spontaneous pneumothorax and was subsequently transported to MHS's Goshen hospital. (*Id.*) A malignant mass was discovered in his lung, and a retrospective review found a visible—but partially obscured—lesion in the original scans taken of Mr. Miller. (*Id.*) The lesion was 7 mm in 2018, grew to 47 mm in 2021, and became a 64 mm mass in October 2023. (*Id.*) Mr. Miller died later on April 14, 2024 at 74 years old from stage IV lung adenocarcinoma. (*Id.* at 2, 7.)

II. NATURE OF THE PROCEEDINGS

The Circuit Court of Simmons County. Respondent Evelyn Miller, decedent's wife, filed this action—individually and as a special Administrator of the estate of Elias Miller—in July 2024 asserting malpractice and product liability claims. (R. at 2, 7.) Respondent asserted that MHS be held vicariously liable under the doctrine of apparent agency for Cyber MD's missed diagnosis. (*Id.* at 2.) Respondent also asserted a strict liability claim due to design defect and failure to warn in the Cyber MD software. (*Id.*)

The Circuit Court of Simmons County evaluated a combined motion for summary judgment by Respondents after the close of discovery. (*Id.*) MHS asserted that they could not be held vicariously liable under apparent agency. (*Id.*) MHS also

asserted the health care malpractice repose period in Sn. Rev. Stat. § 12-04, foreclosed Respondent's claim as a matter of law. (*Id.*) CCS asserted the product liability repose period in Sn. Rev. Stat. § 12-410 foreclosed the product liability claim as a matter of law. (*Id.*) The court found no issue of material fact and the apparent agency relationship to not exist for MHS. (*Id.* at 2.) Additionally, the court found the relevant statutes of repose barred the malpractice and product liability claims. (*Id.* at 2–3.) Accordingly, the Circuit Court of Simmons County GRANTED the Petitioners' combined motion for summary judgement on March 6, 2025. (*Id.* at 3.)

The Shawnee Court of Appeals for the Second District. On appeal, the Shawnee Court of Appeals for the Second District reviewed these claims. (*Id.* at 16.) Upon review, the Court of Appeals REVERSED and REMANDED the Circuit Court's ruling. (*Id.* at 26–27.) Under their de novo review, they found that there were questions of fact. (*Id.* at 16, 21.) Namely, the unconscionability in the underlying agreement and if the decedent, Elias Miller, assented to the denial of an agency relationship. (*Id.* at 16–17.) Furthermore, they found that the statutes of repose did not preclude the health care malpractice or strict product liability claims. (*Id.* at 16–17.)

SUMMARY OF THE ARGUMENT

This case tests whether liability for health care organizations will be greatly expanded throughout the State of Shawnee. The root cause of decedent's adenocarcinoma was occupational exposure from asbestos at the Shawnee Steel Company's mill in Cartersville. The Shawnee Steel Company has since closed the

steel mill. Several local hospitals have also closed with a reduction of healthcare professionals in Simmons County by 75%. MHS's flagship hospital remains open to enable in-person care in the region, and they have also offered care—in partnership with CCS and their FDA-approved Cyber MD product—to keep care available for a resource constrained area.

Before this Court are two questions for review: First, whether through vicariously liability under the doctrine of apparent agency, a healthcare system can be liable for diagnostic errors of an integrated software tool in its branded telehealth platform. Second, whether Shawnee's four-year statutes of repose bars Respondent's claims or if the repose period for the health care malpractice claim is tolled due to a continuous course of treatment and if the product liability repose period is tolled due to statutory exceptions. These questions have important implications for the degree of liability healthcare providers will be exposed to across Shawnee.

I.

First, an autonomous artificial intelligence software tool cannot be an agent under established legal principles. Under the Restatement (Third) of Agency, an agent is explicitly defined as a person, and in clarifying what constitutes legal personhood, the American Law Institute specifically excluded computer software from that categorical definition. *See* Restatement (Third) Of Agency § 1.01 (A.L.I. 2006); Restatement (Third) Of Agency § 1.04 (A.L.I. 2006). Several jurisdictions and agencies have abided by the American Law Institute's categorization of computer

software in refusing to extend legal personhood to artificial intelligence. *See Thaler v. Vidal*, 43 F.4th 1207, 1212 (Fed. Cir. 2022); *United States v. Heppner*, 820 F. Supp. 3d 292, 299 (S.D.N.Y. 2026); 21 U.S.C.A. § 321(h)(1)(B).

Even assuming *arguendo* that an autonomous artificial intelligence software tool can be an agent, Respondents claim of vicarious liability under the doctrine of apparent agency fails due to decedent's assent to the agency disclaimer provided by Petitioner. Both the Circuit Court of Simmons County and Shawnee Court of Appeals for the Second District have adopted the rule for apparent agency as set out in *Gilbert v. Sycamore Mun. Hosp.*, (R. at 8, 21.) *Gilbert's* progeny establish that a clear notice of agency disclaimer by a healthcare provider defeats a claim of vicarious liability as a matter of law. *See James by James v. Ingalls Mem'l Hosp.*, 701 N.E.2d 207, 210 (Ill. App. Ct. 1998). Several states similarly restrict claims of apparent agency in this manner. *See Baptist Mem'l Hosp. Sys. v. Sampson*, 969 S.W.2d 945, 950 (Tex. 1998); *Sword v. NKC Hosps., Inc.*, 714 N.E.2d 142, 152 (Ind. 1999); *Burless v. W. Virginia Univ. Hosps., Inc.*, 601 S.E.2d 85, 96 (W. Va. 2004). Additionally, federal policy regarding the use of artificial intelligence in healthcare heavily disfavors imposing liability. *See* Exec. Order No. 14179, 90 Fed. Reg. 8741 (Jan. 23, 2025).

II.

Second, Respondents claims are statutorily barred by Shawnee's repose periods for health care malpractice and predict liability. Statutory repose periods

reflect the legislature's decision to temporally bar defendants from liability. *See CTS Corp. v. Waldburger*, 573 U.S. 1, 9–10 (2014).

Both the Circuit Court of Simmons County and Shawnee Court of Appeals for the Second District appropriately find Sn. Rev. Stat. § 12-404 contains a repose period for health care malpractice and a tolling provision based on the continuous course of treatment doctrine. (R. at 10, 24.) Looking to New York's analogous statutory structure, similar claims for routine annual visits with no treatment for a diagnosed condition under this doctrine have been denied. *See Shiffman v. Harris*, 720 N.Y.S.2d 262, 262–63 (N.Y. App. Div. 2001). There is no care being interrupted and no ongoing patient-doctor relationship. *See Ulrich v. Veterans Admin. Hosp.*, 853 F.2d 1078, 1081–82 (2d Cir. 1988). In the alternative, the malpractice claim is also barred under Sn. Rev. Stat. § 12-404(a); had the decedent been reasonably diligent and evaluated his medical records or sought a second opinion—rather than rely on a software program with repeated warning it was not a health care professional—he could have discovered the illness.

Both courts also recognized that Sn. Rev. Stat. § 12-410 applies a repose period to product liability claims. (R. at 10, 11, 26.) When other courts have made evaluations of potentially overlapping statutes, such as § 12-410 and § 12-402, they find the more specific product liability repose periods govern over general statutes of limitations. *See Ehrenfelt v. Janssen Pharms., Inc.*, 737 F. App'x 262, 264 (6th Cir. 2018). There are three exceptions to the repose period in § 12-410: (1) express warranties beyond the repose period; (2) misrepresentation or fraudulent

concealment; and (3) latent or hidden defects. The first two were not considered by the lower courts because there was no express warranty and the repose period expired in 2021 before CCS discovered the issue in 2022. The primary contention is that the injury-causing aspect of the product was latent. The misdiagnosis, however, was discoverable by an ordinary reasonably prudent person. Analogizing to the medical malpractice context, a reasonably prudent person would have evaluated their medical records and sought a second opinion after repeatedly being warned that a diagnostic software was not a medical professional. *See Awve v. Physicians Ins. Co.*, 512 N.W.2d 216, 217 (Wis. Ct. App. 1994).

The judgement by the Appeals Court of Shawnee for the Second District conflicts with common law principles and national policy, and it greatly expands liability to healthcare organizations expanding care to underserved areas. As a matter of law, MHS cannot be held liable under the doctrine of apparent agency. Additionally, MHS and CCS cannot be held liable for health care malpractice and product liability because Respondents claims are statutorily barred as a matter of law. The Appeals Court of Shawnee's judgement should be reversed, and summary judgement should be granted for Appellants.

ARGUMENT AND AUTHORITIES

STANDARD OF REVIEW. This appeal on summary judgement raises two issues: whether as a matter of law apparent agency existed and whether the claims are statutorily barred. The first issue is whether a healthcare system can be held vicariously liable under the doctrine of apparent agency for the actions of a third-party AI agent that is integrated into its telehealth platform. The second issue

concerns whether the health care malpractice and product liability claims are statutorily barred. Both issues are matters of first impression in Shawnee. (R. at 7.) The appellate courts previously applied the de novo standard. (*Id.* at 21.) As an issue of first impression warranting “unlimited review,” the de novo standard of review is likewise appropriate for this court to adopt on this appeal of summary judgement. *Kuhn v. Sandoz Pharms. Corp.*, 14 P.3d 1170 (2000). Employing a de novo review will “unify precedent and stabilize the law.” *Cooper Indus. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 436 (2001) (citation modified).

A motion for summary judgement in Shawnee may be granted if “there is no genuine dispute as to material fact and the movant is entitled to judgement as a matter of law.” Sn. R. Civ. 56. A genuine dispute of material facts exists “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see Vance v. Oakridge Health Sys., Inc.*, 142 Sn.2d 88, 94 (2018). Facts must be viewed in “the light most favorable to the nonmoving party.” *Scott v. Harris*, 550 U.S. 372, 380. The moving party also bears the burden to demonstrate there is no genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). When this burden has been met, the nonmoving party must show there is a genuine triable issue. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

I. MHS IS NOT VICARIOUSLY LIABLE UNDER THE DOCTRINE OF APPARENT AGENCY

A. Cyber MD Is Not an "Agent" and Therefore Cannot Enter Into an Agency Relationship with MHS

To establish vicarious liability under the doctrine of apparent agency, there must exist a relationship between a principal, an agent, and a third party. *See* Restatement (Second) of Agency § 267 (A.L.I. 1958); Restatement (Second) of Torts § 429 (A.L.I. 1965); *Gilbert v. Sycamore Mun. Hosp.*, 622 N.E.2d 788, 795–96 (Ill. 1993). Because the term “apparent agency” presupposes the existence of an agency relationship, and because Cyber MD is an artificial intelligence software program—an instrumentality rather than an “agent” capable of creating apparent agency—MHS is entitled to summary judgment.

1. Common law agency principles exclude computer programs and software as being categorized as agents

The common law strictly defines agency as the relationship between legal persons. Agency is “the fiduciary relationship that arises when one **person** (a “principal”) manifests assent to another **person** (an “agent”) that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act.” Restatement (Third) Of Agency § 1.01 (A.L.I. 2006) (emphasis added).

The American Law Institute further rejected the notion that computer programs, such as Cyber MD, can serve as agents:

[A] computer program is not capable of acting as a principal or an agent as defined by the common law. At present, computer programs are instrumentalities . . . If a program malfunctions, even in ways unanticipated by its designer or user, the legal consequences for the

person who uses it are no different than the consequences stemming from the malfunction of any other type of instrumentality. ***That a program may malfunction does not create capacity to act as a principal or an agent.***

Restatement (Third) Of Agency § 1.04 (A.L.I. 2006) (emphasis added).

Because Cyber MD is an artificial intelligence software program, it is an instrumentality and not a “person” with the capacity to act as an agent, therefore no agency relationship can exist between MHS and Cyber MD under the doctrine of apparent agency as a matter of law. This Court should continue the common law understanding of agent and not extend it to the Cyber MD software.

2. Judicial precedent rejects AI legal personhood, preventing Cyber MD from being an agent

Respondent’s assertion that Cyber MD may form an agency relationship conflict with settled judicial principles finding artificial intelligence does not constitute legal personhood. In looking at judicial present, Cyber MD lacks legal personhood.

In *Thaler v. Vidal*, the Federal Circuit held that artificial intelligence cannot be an “inventor” under the Patent Act, 35 U.S.C. § 115. *Thaler v. Vidal*, 43 F.4th 1207, 1212 (Fed. Cir. 2022). The court offered a high degree of deference to the legislature to define that inquiry. The court—adopting that framework—analyzed the use of the word “person” and found it “broadly includes (‘unless the context indicates otherwise’) ‘corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.’” *Id.* at 1211 (citing 1 U.S.C. § 1).

This degree of deference and judicial restraint on expanding legal personhood is found in other Circuits, too. In *United States v. Heppner*, the court refused to extend the attorney-client privilege to communications with an artificial intelligence tool, noting that “AI’s novelty does not mean that its use is not subject to longstanding legal principles.” *United States v. Heppner*, 820 F. Supp. 3d 292, 299 (S.D.N.Y. 2026).

Here neither the Shawnee legislature nor Congress has articulated any presumption that it has expanded the longstanding legal definition of person or agent to include an artificial intelligence program like CCS’s Cyber MD program. This Court should decline to extend personhood or agency to Cyber MD, abiding by both established legal doctrine and recent judicial trends.

3. The FDA classifies software such as Cyber MD as medical devices not agents

CCS received FDA clearance for Cyber MD in 2017. (R. at 5.) The FDA treats diagnostic tools, like Cyber MD, as a medical device rather than as a health care practitioner or as a medical agent. 21 U.S.C. § 321(h).

The FDA regulates the production and sale of medical devices in the US through the Food, Drug, and Cosmetic Act (FDCA) and related rules and regulations. *Code of Federal Regulations*, U.S. Food & Drug Admin., (last updated March 22, 2018), <https://www.fda.gov/medical-devices/overview-device-regulation/code-federal-regulations-cfr>. The FDCA defines a medical device as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or related article” that is “intended for use in the diagnosis of disease or

other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.” 21 U.S.C.A. § 321(h)(1)(B).

The FDA has further introduced the concept of Software as a Medical Device (SaMD) to broaden the scope of medical instruments in the constantly evolving modern age to include software, algorithms, artificial intelligence, and machine learning. *Software as a Medical Device (SaMD)*, U.S. Food & Drug Admin., (last updated Dec. 4, 2018), <https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>.

As a result of receiving FDA clearance as well as being squarely within the statutory definition of a medical device, Cyber MD is legally not an agent. Through common law, judicial precedent, and FDA regulation, Cyber MD does not meet the legal expectations of an agent.

B. By Applying the *Gilbert* Analysis, MHS is not Vicariously Liable Under the Doctrine Apparent Agency

Shawnee has recognized and adopted the doctrine of apparent agency as an additional legal mechanism to hold hospitals vicariously liable for the acts of independent contractors. (R. at 21.) Relying on the Illinois Supreme Court’s decision in *Gilbert v. Sycamore Mun. Hosp.*, Shawnee Courts have held that apparent agency exists when:

(1) the hospital, or its agent, acted in a manner that would lead a reasonable person to conclude that the individual who was alleged to be negligent was an employee or agent of the hospital; (2) where the acts of the agent create the appearance of authority, the plaintiff must also prove that the hospital had knowledge of and acquiesced in them; and (3) the plaintiff acted in reliance upon the conduct of the hospital or its agent, consistent with ordinary care and prudence.

(R. at 21 (citing *Gilbert*, 622 N.E.2d 788 at 795–96 (1993).)

The issue before this Court rests on whether MHS’s hyperlinked terms and conditions defeat the “holding out” element of the *Gilbert* test as a matter of law. In finding that they do not, the Shawnee Appellate Court misapplied the “holding out” element through a narrow reading of *Gilbert*. They ignored both the factual context in which *Gilbert* was decided and the subsequent case law clarifying its holding. For three key reasons, the “holding out” element does not apply to MHS and therefore is not satisfied by Respondent as a matter of law: (1) the existence of conspicuous disclaimers; (2) the nature of care rendered being routine nonemergency services rather than emergent care; and (3) the branding of a healthcare provider do not independently defeat written notice.

1. MHS’s terms and conditions defeat “holding out” element in Gilbert

In *Gilbert*, the court denied hospital’s motion for summary judgment where no notice regarding the emergency room physician’s independent contractor status, which created the impression that all emergency room physicians were hospital employees. *Gilbert*, 622 N.E.2d at 795–96. The *Gilbert* court noted “liability attaches to the hospital only where the treating physician is the apparent or ostensible agent of the hospital. *If a patient knows, or should have known, that the treating physician is an independent contractor*, then the hospital will not be liable.” *Id.* at 794 (emphasis added). The court explained that failing to inform “the patient that the care is provided by independent contractors” does not provide the patient with the requisite knowledge to the defeat “holding out” element. *Id.* at 796.

Here, MHS provided Mr. Miller with explicit and conspicuous disclaimers in its terms and conditions, which clearly stated that “[a]ll clinical evaluations, imaging reviews, and diagnostic interpretations provided through this digital portal are performed by independent contractor physicians or automated software applications developed by another company.” (R. at 5.) Mr. Miller was prompted to— and did—assent to these terms and conditions, which clearly disclosed Cyber MD’s independent status at each visit. In total, Mr. Miller received and assented to four explicit disclosures from MHS regarding the agency status of the tool he elected to use. A patient, exercising ordinary care and prudence, who receives four clear disclaimers and repeatedly assents to them “knew or should have known” that Cyber MD was an independent contractor. *Gilbert*, 622 N.E.2d at 798.

In *James by James v. Ingalls Mem’l Hosp.*, the court directly addressed hospital liability when written a disclosures is provided. *James by James v. Ingalls Mem’l Hosp.*, 701 N.E.2d 207, 210 (Ill. App. Ct. 1998). There the court found that clear written agency disclaimers satisfy the “should know” exception from *Gilbert* and defeat “holding out” as a matter of law. *Id.* at 201–11 (“[Physician]’s independent contractor status was clearly set out in the consent to treatment form, which appellant signed. Under *Gilbert*, appellant here either knew [physician] was an independent contractor or should have known.”).

As in *James*, Mr. Miller signed a consent form that clearly indicated that MHS contracted with an independent software vendor to provide diagnostic services to Mr. Miller. MHS’s consent form specifically used the term “independent

contractor" when referring to Cyber MD and stated, "[t]he physicians and software are not employees or agents of Metropolitan Health System." (R. at 5.) Given similar facts, the *James* court found for the hospital and stated "[c]ertainly having the patient sign a consent for treatment form which expressly states that 'the physicians on staff at this hospital are not employees or agents of the hospital' may make the proving of [holding out] extremely difficult" and found that "appellant has failed to meet her burden as to this element." 701 N.E.2d at 211. *See also Wallace v. Alexian Bros. Med. Ctr.*, 907 N.E.2d 490, 497 (Ill. App. Ct. 2009) (in affirming summary judgment for hospital, noted that *Gilbert* "clearly stated that, to defeat such a claim, all that was required was some evidence to show that the plaintiff knew or should have known of the physician's independent contractor status.").

The reasoning used by Illinois courts has been widely adopted in various sister states. The Texas Supreme Court held that there was no genuine issue of material fact on the element of "holding out" where a consent form provided to the plaintiff disclosed the physician's independent contractor status. *Baptist Mem'l Hosp. Sys. v. Sampson*, 969 S.W.2d 945, 950 (Tex. 1998). The Indiana Supreme Court held that a hospital is not liable under apparent agency if it gives "meaningful notice" (express written notice) that the provider is an independent actor. *Sword v. NKC Hosps., Inc.*, 714 N.E.2d 142, 152 (Ind. 1999). The Supreme Court of Appeals of West Virginia held that an unambiguous disclaimer by a hospital explaining the independent contractor status of physicians will generally

suffice to immunize the hospital from being vicariously liable for physician conduct.” *Burless v. W. Virginia Univ. Hosps., Inc.*, 601 S.E.2d 85, 96 (W. Va. 2004).

Here, MHS had provided clear notice to the decedent as to the agency status of Cyber MD, accordingly this Court should abide by the prevailing national consensus of common law and find no genuine issue of material fact on the element of MHS holding out. A holding to the contrary would unnecessarily increase liability exposure to healthcare providers, thereby disincentivizing healthcare expansion in Shawnee.

2. The nonemergent and routine nature of Mr. Miller’s care disfavors a finding that MHS held out Cyber MD as its agent

Cases in which plaintiffs prevail on a claim of apparent agency, typically arise in the context of emergency room care. Decedent, however, was not seeking emergency care.

These cases are decided on the assumption that notice given in an emergency room setting is severely weakened and therefore insufficient to defeat “holding out.” *See Sword v. NKC Hosps., Inc.*, 714 N.E.2d 142, 152 (Ind. 1999) (“[u]nder some circumstances, such as in the case of a medical emergency, however, written notice may not suffice if the patient had an inadequate opportunity to make an informed choice.”); *Popovich v. Allina Health Sys.*, 946 N.W.2d 885, 898 (Minn. 2020) (“most people entering an emergency room do not know which medical professionals will treat them and instead rely on the hospital to select them.”); *Whitlow v. Rideout Memorial Hospital*, 188 Cal. Rptr. 3d 246, 250 (Cal. Ct. App. 2015) (“often the very nature of a medical emergency precludes choice.”).

Unlike the aforementioned emergency room cases, decedent did not visit MHS nor use Cyber MD in a state of emergency, rather decedent voluntarily and repeatedly elected to use Cyber MD on his own volition, over the span of four years, for his nonemergency and routine diagnostic treatment. Decedent was given clear notice during each of his four uses of Cyber MD as to its independent status and willingly continued to proceed with care. (R. at 4–6.)

Respondent’s relationship with MHS and Cyber MD is more in line with nonemergency routine care in which courts consistently maintain that clear notice is sufficient to defeat the “holding out” element of apparent agency. In *Markow v. Rosner*, the court held that “[b]ecause [plaintiff] received actual notice and was treated in a nonemergency context, there was no ostensible agency and [the hospital] was entitled to judgment as a matter of law.” *Markow v. Rosner*, 3 Cal. Rptr. 3d 363, 372 (Cal. Ct. App. 2016). In its analysis, the court highlighted that the patient received continuous care across multiple visits and was given an agency disclaimer at each visit disclosing that *all* physicians and services furnished were from independent contractors. *Id.*

In this case, decedent received notice about Cyber MD’s status from MHS that stated “*all* clinical evaluations, imaging reviews, and diagnostic interpretations provided through this digital portal are performed by independent contractor physicians or automated software applications developed by another company,” across four visits over four years. (R. at 5–6.) (emphasis added). Because decedent was given clear notice about Cyber MD’s agency status repeatedly over his

continuous nonemergency treatment, MHS is entitled to judgment as a matter of law.

3. *MHS's markings and branding on the remote telehealth platform are insufficient to defeat the "holding out" element*

Respondent and the Court of Appeals contend that MHS's public manifestations created a strong, objective appearance of agency. (R. at 22.) The argument that MHS's branding on the remote telehealth platform and the absence of CCS markings on Cyber MD supersedes the disclosures provided and insulates Mr. Miller from the terms he assented to is erroneous and contrary to the weight of authority.

In *Markow v. Rosner*, plaintiff unsuccessfully advanced a similar theory arguing that several visual indications by a medical center trumped any signed notice about the independent contractor status of their treating physician. 208 Cal. Rptr. 3d 363. (Cal. Ct. App. 2016). These included: (1) the medical center's website identifying the physician as the director of its clinic; (2) instructions directing patients to call the medical center's phone number to schedule appointments with the physician; (3) the physician practicing within medical center buildings bearing its name and logo; (4) the physician's authorized use of the medical center's name and logo on business cards and correspondence; (5) the medical center's ownership of the clinic's equipment and supplies; (6) the employment of the clinic's nurses and staff by the medical center; and (7) the physician wearing a medical center badge. *Id.* at 373–74. The court concluded that all these factors, which far exceed MHS's representations in the present case, were “negated by the actual notice [the medical

center] provided [to the plaintiff] that [the physician] was an independent contractor, not [the medical center]’s agent or employee.” *Id.* at 374; *See also Prutton v. Baumgart*, 165 N.E.3d 485, 500 (Ill. App. Ct. 2023) (“although [the hospital]’s advertisements initially could have been seen to create a genuine question of material fact on the issue of whether [the hospital] held [the physician] out as an employee or agent, this question is resolved by the signed consent forms, which clearly and unambiguously informed plaintiff that the physicians at the hospital, which would include [the acting physician], were independent contractors.”).

Here, because MHS provided clear notice about the agency status of Cyber MD to decedent, MHS’s branding on the remote telehealth platform does not create a genuine question of material fact. Decedent therefore cannot satisfy the “holding out” factor of the *Gilbert* test, and MHS is entitled to summary judgment as a matter of law.

C. The Sign-In Wrap Agreement is Enforceable

1. MHS provided reasonably conspicuous notice by its terms and conditions and Mr. Miller affirmatively manifested assented

The enforceability of online sign-in wrap agreements is governed by a two-part test that looks at: (1) reasonably conspicuous notice, whether the website reasonably communicates the terms to which the consumer will be bound; and (2) manifestation of assent, whether the consumer took some action that unambiguously manifests his or her acceptance to those terms. *See Meyer v. Uber Techs., Inc.*, 868 F.3d 66, 75 (2d Cir. 2017); *Cullinane v. Uber Techs., Inc.*, 893 F.3d

53, 62 (1st Cir. 2018); *Berman v. Freedom Fin. Network, LLC*, 30 F.4th 849, 856 (9th Cir. 2022).

In applying this rule, the Court of Appeals erred in relying on *Berman* and *Cullinane* to establish that the mode and manner of MHS's hyperlinked terms and conditions left any genuine material of fact. The facts relied on by the appellate court in both *Cullinane* and *Berman* are materially distinguishable from the present case, and the failure of the appellate court in addressing these material differences misapplies the principle of these holdings.

In *Berman*, the Ninth Circuit refused to enforce a Sign-In Wrap Agreement where both the defendant's website and notice to the plaintiff were substantially dissimilar to MHS's. The text of the hyperlink to terms and conditions in *Berman* were printed in "tiny gray font" which matched the same gray font as the surrounding, non-clickable, text. *Berman*, 30 F.4th at 856; *see also Cullinane*, 893 F.3d at 63) ("Terms of Service & Privacy Policy hyperlink [were] presented in a gray rectangular box in white bold text similar to the rest of the page.") (citation modified).

The court in applying the reasonably conspicuous notice prong of the rule relied on the standard that terms and conditions must be "sufficiently *set apart* from the surrounding text." *Berman*, 30 F.4th at 857 (emphasis added); *see also Cullinane*, 893 F.3d at 63 ("If everything on the screen is written with conspicuous features, then nothing is conspicuous."). Using the "set apart" standard the court found that the defendant did not meet the burden to establish that it provided

reasonably conspicuous notice to the plaintiff stating “[t]he text disclosing the existence of the terms and conditions on these websites is the antithesis of conspicuous. It is printed in a tiny gray font considerably smaller than the font used in the surrounding website elements, and indeed in a font so small that it is barely legible to the naked eye.” *Berman*, 30 F.4th at 856–57.

In providing what is considered sufficient to constitute a hyperlink that is “set apart,” the court explicitly stated that “[c]ustomary design elements denoting the existence of a hyperlink include the use of a contrasting font color (typically blue) ... which can alert a user that the particular text differs from other plain text in that it provides a clickable pathway to another webpage.” *Id.*; see also *Cullinane*, 893 F.3d at 63 (same).

In the present case, MHS used the exact type of hyperlink deemed acceptable to put a user on notice as illustrated in both *Berman* and *Cullinane*. MHS’s hyperlinked terms and conditions were blue and underlined, were contrasted by a white background, and did not use an oppressively small in font. (R. at 4.) As a result, MHS’s hyperlink was sufficiently “set apart” thereby putting decedent on reasonably conspicuous notice that there was a clickable pathway to another page.

The next material difference in *Berman*, is its lack of explicit warning of the legal significance in signing in subject. The court in *Berman* emphasized that “notice must explicitly notify a user of the legal significance of the action she must take to enter into a contractual agreement.” *Berman*, 30 F.4th at 858. In finding that the defendant did not satisfy the manifestation of assent prong, the court noted that

the defendant’s “webpages stated, ‘I understand and agree to the Terms & Conditions,’ but they did not indicate to the user what action would constitute assent to those terms and conditions. Likewise, the text of the button itself gave no indication that it would bind plaintiffs to a set of terms and conditions.” *Id.* The court then went on to clarify that “[t]his notice defect could easily have been remedied by including language such as, ‘By clicking the Continue >> button, you agree to the Terms & Conditions.’” *Id.*

MHS notified Mr. Miller of the legal consequences of logging into MHS’s telehealth portal. In fact, MHS used the exact wording specified by *Berman*, disclosing to Mr. Miller that “[b]y entering the portal, I accept the MHS Terms and Conditions.” (R. at 4.) Not only are the facts in which *Berman* and *Cullinane* were decided materially distinguishable from MHS, the cases themselves affirm that MHS has satisfied both prongs of an enforceable sign-in wrap agreement.

MHS’s website and display of its terms and conditions more align with *Meyer*, where the Second Circuit upheld a sign-in wrap agreement as enforceable as a matter of law. In *Meyer* the Second Circuit—finding reasonably conspicuous notice—emphasized “when considering the perspective of a reasonable smartphone user, we need not presume that the user has never before encountered an app or entered into a contract using a smartphone. Moreover, a reasonably prudent smartphone user knows that text that is highlighted in blue and underlined is hyperlinked to another webpage where additional information will be found.” *Meyer* 868 F.3d at 77–78.

On the issue of manifestation of assent, the court held that where the plaintiff was presented with notice—nearly identical to that of MHS—which stated “[b]y creating an Uber account, you agree to the TERMS OF SERVICE & PRIVACY POLICY,” the defendant had adequately warned of the impending legal consequences of proceeding. *Id.* at 78.

Because MHS’s terms and conditions (1) used blue underlined text that would put a reasonably prudent user on notice, and (2) used language that adequately warned the deceased of the impending legal consequences of signing in, they have met both the reasonably conspicuous notice and mutual assent requirements of *Berman*, *Cullinane*, and *Meyer*. Accordingly, MHS’s sign-in wrap agreement is enforceable as a matter of law.

2. Neither the size of the font or text nor the duration spent reading the terms and condition invalidate the sign-in wrap agreement

Respondent and the Court of Appeals proffer two additional, yet unavailing, arguments that the sign-in wrap agreement is unenforceable. They argue that the font and coloring of the agency disclaimer, as well as the fact that Mr. Miller only accessed the hyperlinked terms and conditions for four seconds, render the sign-in wrap inoperative because they do not establish Mr. Miller’s assent. (R. at 23.)

This interpretation of contract law, however, is sharply in contrast to existing precedent. In *Meyer*, the court addressed facts nearly identical to the present case in which terms were displayed in small black text. In finding that this fact did not void the sign-in wrap agreement the court stated that “[a]lthough the sentence is in a

small font, the dark print contrasts with the bright white background, and the hyperlinks are in blue and underlined.” *Meyer*, 868 F.3d at 78. As to the issue of Mr. Miller only accessing the link for four seconds, “[w]hile it may be the case that many users will not bother reading the additional terms, that is the choice the user makes; the user is still on inquiry notice ... [a] reasonable user would know that by clicking the [login] button, he was agreeing to the terms and conditions accessible via the hyperlink, whether he clicked on the hyperlink or not.” *Meyer*, 868 F.3d at 79-80.

Here, MHS presented the decedent with a clickable hyperlink that was in blue which sharply contrasted the white background it was presented on. (R. at 4.) And while the decedent only viewed the terms and conditions for four seconds, he made that choice independently and was on enough notice to reasonably know he would be bound by them.

D. The Agency Disclaimer Agreement is Not Procedurally Unconscionable

The Court of Appeals erred in deciding that the disparities between Mr. Miller and MHS created questions of fact. (R. at 23.) The court relied on the decedent’s characteristics including his age and socioeconomic status to create an attenuated an image of inequality between decedent and MHS. (R. at 24.)

In addressing procedural unconscionability, the Wisconsin Supreme Court stated that “[d]isparity in bargaining power alone is not necessarily sufficient to establish procedural unconscionability” *Wis. Auto Title Loans, Inc. v. Jones*, 714 N.W.2d 155, 169 n.42 (Wis. 2006). The American Law Institute further confirms

this principle stating “[a] bargain is not unconscionable merely because the parties to it are unequal in bargaining position” rather it is when “gross inequality of bargaining power, *together with terms unreasonably favorable to the stronger party*, may confirm indications that the transaction involved elements of deception or compulsion, or may show that the weaker party had no meaningful choice, no real alternative, or did not in fact assent or appear to assent to the unfair terms.” Restatement (Second) of Contracts § 208 (A.L.I. 1981).

The record in this case does not show any indication that the notice terms were “unreasonable.” The facts in the record point to the contrary, decedent was presented with a standard and routine disclosure and could have just as easily driven to MHS’s flagship hospital for care just as many other rural people do. If this Court were to find MHS’s agency disclaimer procedurally unconscionable, it would upend decades of common law jurisprudence and widen healthcare disparities in Shawnee.

E. Federal AI Regulatory Policy Preempts Holding MHS Liable

The current administration has made it abundantly clear that the use and development of artificial intelligence within the healthcare sector is a matter of great national importance and that states, like Shawnee, should not interfere with this goal by advancing theories of liability that “unduly burden AI innovation.” The White House, *Winning the AI Race: America's AI Action Plan* 3–5 (2025), <https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf>; Exec. Order No. 14179, 90 Fed. Reg. 8741 (Jan. 23, 2025).

MHS, in implementing Cyber MD, was simply abiding by federal guidance to provide healthcare access to underserved medical communities. If the court were to hold MHS vicariously liable it would not only be an encroachment of power by the judiciary, but it would place chilling liability on innocent healthcare providers throughout the state of Shawnee effectively widening the gap in medical coverage.

Courts that have hastily extended the common law to further hold hospitals liable, have done so under split decision and many critics point to the fact that these rushed decisions are outside of the court's authority and fail to factor in the negative implications of their decision. When the Minnesota Supreme Court adopted the doctrine of apparent agency to hold hospitals vicariously liable, Justice Anderson in his dissent showed clear regret and remorse for the majority's decision:

Hospitals are the subject of intense state and federal legislative scrutiny ... Everything from the number of beds in a hospital during a hospital construction moratorium, to the minimum number of onsite providers, and even the food served, is subject to state regulation ... *In light of these extensive regulations and given that the Legislature has not chosen to prohibit the use of independent contractor physicians in hospital emergency rooms, it is hardly self-evident why we should extend the common law here to further expand hospital liability.*

Popovich v. Allina Health Sys., 946 N.W.2d 885, 900 (Minn. 2020) (Anderson, J., dissenting) (emphasis added).

This Court should not hold MHS vicariously liable. Doing so would not only upend the justified expectations of healthcare providers through this state but also contravene the carefully calibrated goals of state and federal legislatures, the Executive Branch, and federal agencies in ensuring adequate healthcare to meet the demands of an evolving society.

II. THE RESPONDENT'S CLAIMS ARE STATUTORILY BARRED

This court should affirm the Circuit Court of Simmons County's holding that as a matter of law the Respondent's health care malpractice and strict product liability claims are statutorily barred.

The health care malpractice claim against MHS contained in Respondent's July 2024 action is statutorily barred by Shawnee's applicable four-year repose period in Sn. Rev. Stat. § 12-404; the critical date of Mr. Miller's initial Cyber MD intake and misdiagnosis in April 2018 should remain fixed and not subject to tolling for a continuous course of treatment. Applying the four-year repose period, Respondent's health care malpractice claims are therefore statutorily barred, expiring in April 2022.

Additionally, Respondent's product liability claim should be found barred due to Shawnee's four-year statute of repose for product liability, Sn. Rev. Stat. § 12-410. The repose period can prevent wrongful death actions, such as in Sn. Rev. Stat. § 12-402. Furthermore, the three statutory exceptions to the statute of repose do not apply. First, there was no express warranty to trigger § 12-410(b)(1). Second, the repose period ended before the defect was even discovered by CCS, so there was no representation to trigger § 12-410(b)(2). Also—in contrast to the Respondent's contention—the misdiagnosis was discoverable by an ordinary reasonably prudent person, and the tolling in § 12-410(b)(3) does not apply. Thus, the FDA approval for Cyber MD and integration into the MHS's platform in 2017 is the critical date; applying a four-year repose period—since no exceptions apply—Respondent's malpractice claim were statutorily barred after 2021

A. Respondent’s Health Care Malpractice Claim Against MHS is Statutorily Barred by the Repose Period in Sn. Rev. Stat. § 12-404(b)

Health care malpractice claims are controlled by Sn. Rev. Stat. § 12-404, which bars Respondent’s malpractice claims. The statute’s four-year period of repose creates an absolute bar for liability. The critical date is Mr. Miller’s initial Cyber MD intake and misdiagnosis in April 2018; the malpractice claim was brought later than the four-year repose period in July 2024. Statutes of repose are generally not tolled unless there is a statutory exception, such as the continuous course of treatment exception present in § 12-404(b). Contrary to Respondent’s assertions, the annual imaging Mr. Miller sought out after the initial intake does not constitute a continuous course of treatment. Thus—absent an acceptable exception to the repose period—Respondent’s health care malpractice claim is statutorily barred. In the event the court does not find the statute of repose period precludes the malpractice claim, the limitations period set in § 12-404(a) bar the claim because the decedent, though reasonable diligence, should have known of the injury.

1. The repose period in Sn. Rev. Stat. § 12-404(b) bars claims otherwise timely under a statute of limitations by preventing a cause of action

The health care malpractice claim repose period states “[i]n no event shall such action be brought more than four (4) years after the date on which occurred the act or omission or occurrence” Sn. Rev. Stat. § 12-404(b). Statutes of repose reflect a legislative judgment “that defendants should be free from liability;” in contrast the purpose of a statute of limitation which is intended to “promote justice”

and encourage plaintiffs to pursue claims diligently.” *CTS Corp. v. Waldburger*, 573 U.S. 1, 9–10 (2014). The repose period sets a hard limit by creating an “absolute” temporal block on the liability a defendant is exposed to, even if an injury has not been discovered. *CTS Corp. v. Waldburger*, 573 U.S. 1, 8 (2014).

Both the Circuit Court of Simmons County and Shawnee Court of Appeals for the Second District found § 12-404(b) as the applicable statute of repose for health care malpractice. (R. at 10, 24.) Statute of repose bar “any suit that is brought after a specific time.” *Statute of Repose*, *Black’s Law Dictionary* 12th ed. 2024). The meaning of “repose period” is unambiguous, and its effects match the expected purpose of a statute of repose. The finality of “[i]n no event shall an action be brought” matches bars any action, as repose periods do. The phrasing “[i]n no event” was found to provide in “clear terms” a “fixed bar against future liability” by the Supreme Court in evaluating a similar statute they determined was a statute of repose. *Cal. Pub. Emps.’ Ret. Sys. v. ANZ Sec., Inc.*, 582 U.S. 497, 505 (2017).

Decedent’s first telehealth visit with Cyber MD—initiated after experiencing shortness of breath—and missed diagnosis was in April 2018. (R. at 6.) A claim subject to the statute of repose would need to be within four years, April 2022. Respondent’s claims were brought, however in July 2024, more than two years after the repose period and statutorily barred.

The Court of Appeals of the Second District incorrectly considers whether Shawnee’s general statute of limitations for personal injury and wrongful death, § 12-402, ensure Respondents claims are available, even after the repose period. (*Id.*

at 27.) No statute of limitations, including the one in the health care malpractice statute should extend the repose period.

Within the malpractice statute, the two limitations and repose period are both time-controlling. § 12-404(a) is, by its plain text, a limitation period. The provision is directed to the claimant to encourage a timely filing, as it is based on when the claimant had or should have had knowledge. This should not extend the time bar intended to give certainty to the defendant in a repose period. The statute is clear: “in no event.”

Likewise, § 12-402 does not extend the repose period. The general language of § 12-402 should not control over the more specific language related to malpractice claims in § 12-404. *See Ehrenfelt v. Janssen Pharms., Inc.*, 737 F. App'x 262, 265 (6th Cir. 2018) (“If we are unable to harmonize two statutes, then we apply the well-settled rule of law that [statutes] complete in themselves, relating to a specific thing, take precedence over general statutes.”) (citation modified). If the legislature intended to have a wrongful death cause of action beyond the repose period, they could have codified such an exception. *See Arrowood v. Gen. Motors Corp.*, 539 F.2d 1321, 1325 (4th Cir. 1976) (finding an exception to a time bar due to a specific statutory cause of action). §12-404(a) rather than § 12-402 applies statutory limitations to health care malpractice claims, and—even if it was applicable—it would not overcome the absolute bar a defendant is entitled to with a repose period.

§ 12-404(b) sets a repose period of four years for health care malpractice claims. Repose periods are time bars set by the legislature to provide defendants

with certainty in temporal liability. This period—irrespective of other statutory limitations—precludes Respondent’s claim. Expanding it would also unfairly expose health care providers to increased liability, forcing greater stress to doctors as claims come years after treatment. At the conclusion of the repose period, no cause of action for wrongful death or injury due to health care malpractice existed.

2. Mr. Miller’s annual diagnostic evaluations did not toll the repose period as a continuous course of treatment because they were routine, not treatment, and do not interfere with a patient-doctor relationship

Respondent’s claims were brought more than four years—the length of the health care malpractice repose period—after the initial intake, mobile scan, and misdiagnosis. Respondent asserts the repose period should toll due to the statutory continuous course of treatment exception where a repose “period shall not bar an action” when a provider is engaged in treatment. Sn. Rev. Stat. § 12-410. The annual diagnostic imaging decedent received, however, does not trigger this exception as Respondent hopes. Jurisdictions with similar statutory frameworks have found repeated visits following a misdiagnosis do not constitute a continuous course of treatment; no specific illness is being treated, rendering visits discrete. Likewise, routine and annual visits do not constitute a continuous course of treatment. Thus, decedents subsequent, annual visits not tied to a specific illness or symptom do not qualify as a continuous course of treatment to toll the statute of repose. Respondent’s malpractice claims are statutorily barred

Statutes of repose are intended to be absolute bars and not subject to tolling, but legislatures can add express exceptions. *Cal. Pub. Emps.’ Ret. Sys. v. ANZ Sec.*,

Inc., 582 U.S. 497, 507–08 (2017). These statutory carve outs overcome the disfavor in court-created equitable tolling as the “unqualified nature” of statutes of repose “override customary tolling rules arising from the equitable powers of courts.” *Cal. Pub. Emps.’ Ret. Sys. v. ANZ Sec., Inc.*, 582 U.S. 497, 508 (2017).

While a few courts have established equitable tolling for a continuous course of treatment, *see Borgia v City of New York*, 204 N.E.2d 207 (N. Y. 1962) (recognizing equitable tolling for a limitation period due to a continuous course of treatment), jurisdictions—such as New York—have also enacted statutory exceptions to their repose period to Shawnee’s. *See* N.Y. CLS CPLR § 214-a (LexisNexis 2026); *see also* 27 V.I. CODE ANN. Tit. 27, § 166d (2026). The continuous course of treatment doctrine has two primary rationales; it is “not reasonable to expect a patient who is in the continuing care of a doctor to discover that the doctor’s acts may be the cause of his injuries” and that it is “it absurd to expect a patient being treated by a doctor or hospital to interrupt corrective treatment by instituting suit against either while under their continuing care.” *Ulrich v. Veterans Admin. Hosp.*, 853 F.2d 1078, 1081–82 (2d Cir. 1988).

Neither of the foundational reasons for the continuous course of treatment doctrine—interrupting the doctor-patient relationship or interrupting corrective treatment—apply to Respondent’s situation for this exception to apply. First, decedent was interacting with software, not a human medical professional. Investigating or questioning a software’s results by asking for a second opinion or sharing the results with another provider would have done nothing to sour the

relationship or affect future interactions with the Cyber MD chatbot. Second, there was no corrective treatment being provided by Cyber MD. Decedent only reported symptoms on the first visit and not follow-up visits. (R. at 6.) Cyber MD also referred decedent to a different provider and only suggested—not required—annual follow-up imaging. (*Id.*) The recommendation of follow-up imaging is not treatment for an injury, simply advisement. Both the foundational concern of disrupting a corrective treatment and the hesitancy to interfere with the doctor-patient relationships are not raised here. This Court should not stretch the continuous course of treatment doctrine to cover situations that have no treatment to interrupt and no doctor-patient relationship to interfere with.

The courts of New York—evaluating similar statutory language to Shawnee’s continuous course of treatment exception—have repeatedly found in similar cases that the exception should not apply. In a case involving an initial visit for endometriosis where the physician said a lump was noncancerous, subsequent visits related to treatment for endometriosis were not found to toll a malpractice claim for misdiagnosing the cancerous lump even though lumps were noted during examination. *Nykorchuck v. Henriques*, 577 N.E.2d 1026, 1027 (N.Y. 1991). Shortly thereafter, the court also declined to extend the continuous course of treatment doctrine to a patient initiating a routine follow-up visit related to an initial procedure. *Massie v. Crawford*, 583 N.E.2d 935, 938 (1991) (“Routine examinations of a patient who appears to be in good health or diagnostic examinations, even when conducted repeatedly over a period of time, are not a ‘course of treatment.’”)

The principle that repeated misdiagnoses and routine care is not sufficient to toll statutory periods has continued to stand in New York courts. In a more recent case regarding regular visits and repeated missed diagnoses, the court did not find repeated diagnostic visits established a continuous course of treatment. *Shiffman v. Harris*, 720 N.Y.S.2d 262, 262–63 (N.Y. App. Div. 2001). Plaintiff had surgery performed and a physician noticed an abnormality, referring the plaintiff to the defendant. After examining the patient and ordering diagnostic imaging, no diagnosis was made, though follow-up diagnostic visits were recommended. Only on the fourth visit, after multiple examinations and diagnostic testing, was patient’s ruptured implant diagnosed. Even with repeated visits, the court found there was no continuous course of treatment and only that the “defendant recommended annual diagnostic examinations to determine whether any treatment would be required at some future time.” *Shiffman v. Harris*, 720 N.Y.S.2d 262, 262–63 (N.Y. App. Div. 2001).

Contrary to the Shawnee Court of Appeals for the Second District assertion, the annual imaging was not a continuous course of treatment. *See* (R. at 25.) The follow-up imaging protocol was simply recommended and akin to the annual visits in *Shiffman*; they were not “treatment” for an illness. Though decedent had occupational asbestos exposure, this was not a diagnosed condition. Furthermore, no diagnosis of any sort was established or affirmed in subsequent visits. (*Id.* at 20.)

In one New York case, a patient-initiated follow-up was found to be a continuous course of treatment. There, the patient had repeated contact with a

physician, including surgery, and eventually followed up due to pain. *Lohnas v. Luzi*, 94 N.E.3d 892, 893–894 (N.Y. 2018). In contrast, decedent here did not report continuous symptoms and was not attending follow-up visits in response to any medical intervention.

This Court should adopt the reasoning and interpretation present in New York courts and find there was no continuous course of treatment to toll the repose period. New York has similar statutory language to Shawnee and a robust history of both respecting the continuous course of treatment doctrine—such as initially instituting it through the court’s equitable powers before statutorily embracing it—and keeping it bounded to deserving situations. To extend the continuous course of treatment doctrine to this situation would go against the absolute nature inherent to a repose period. Neither of the foundational reasons for the doctrine apply here; there is no doctor-patient relationship to interrupt with a software program, and there is no intervention or corrective treatment to disrupt for a misdiagnosis. There was not a continuing course of treatment but a failure to establish treatment. Since the repose period is not tolled, Respondent’s malpractice claim is statutorily barred.

3. The malpractice claim is also barred under the statute of limitations in Sn. Rev. Stat. § 12-404(a)

In the event this Court finds the repose period for health care malpractice claims should be tolled, this Court should instead find the claims to be statutorily barred by to the two-year limitation period in Sn. Rev. Stat. § 12-404(a). Statutes of limitation start at the point of patient care that led to the injury. Even if a patient later dies, a wrongful death suit may be barred if the statute of limitations from the

original point of patient care has expired. Additionally, the decedent could have discovered the misdiagnosis by exercising reasonable diligence. Thus, the critical date is April 2018 when the decedent was first serviced by Cyber MD, and Respondent's malpractice claims were barred after April 2020.

State supreme courts have recognized that a wrongful death claim can be barred if the limitation period for an underlying malpractice claim has expired. *See Okeke v. Craig*, 782 So. 2d 281 (Ala. 2000) ("A wrongful-death action is barred by the statute of limitations if the decedent, on the date of her death, would have been time-barred from filing a medical-malpractice claim based on the medical malpractice that is alleged to have caused the death.").

The critical date in Shawnee for beginning the statute of limitations on health care malpractice is "the date on which the claimant knew, or through reasonable diligence should have known, of the injury or death." Sn. Rev. Stat. § 12-404(a). Respondent's claims should begin not at the time of death but the initial intake and diagnostic evaluation as the misdiagnosis could have been discovered through "reasonable diligence."

Other states have found that discovery of an injury—whether by direct knowledge or by reasonable diligence—put a "reasonable person on inquiry notice of his cause of action." *Massey v. Litton*, 669 P.2d 248, 252 (1983). The inquiry notice would lead an "ordinarily prudent person to investigate the matter further." *Winn v. Sunrise Hosp. & Med. Ctr.*, 277 P.3d 458, 462 (Nev. 2012). For instance, access to

medical records could provide inquiry notice. *Winn v. Sunrise Hosp. & Med. Ctr.*, 277 P.3d 458, 462 (Nev. 2012).

A reasonably diligent person would have accessed their medical records after receiving medical care by an automated software program that repeatedly warned the user it was not a health care professional. Patients have a general right to access their health care records. 45 C.F.R. § 164.524 (2026). Before each visit with Cyber MD, decedent was warned and accepted that Cyber MD is not a health care professional. (R. at 6–7.) By law, decedent had a right to request the imaging and seek a second opinion from a licensed healthcare professional—yet did not. 45 C.F.R. § 164.524 (2026). After receiving a diagnosis of asthma, despite having no prior individual or family history of asthma, decedent did not request his records or seek a second opinion. (R. at 3–7.) After having been exposed to asbestos in a work environment with loose safety protocols and frequently working without any protective equipment, a reasonably diligent person would have spoken with a licensed health care professional subsequent to receiving the mobile scans. Decedent did not choose to access his records or get a second opinion—which would allow him to know of the misdiagnosis—but someone with his health history receiving health care from a non-licensed software program employing reasonable diligence would have taken that course of action. Thus, the critical date for the statute of limitations period was the initial visit and misdiagnosis in April 2018. The two-year statute of limitations for health care malpractice would bar Respondent’s July 2024 claim.

B. Respondent's Product Liability Claim Against CCS is Barred by the Repose Period in Sn. Rev. Stat. § 12-410(a)

The product liability repose period in Sn. Rev. Stat. § 12-410 can preclude wrongful death and personal injury claims in § 12-402 that have an underlying product liability theory. The Court of Appeals for the Second District's assertion that Shawnee's limitation of actions statute for injury and wrongful death, Sn. Rev. Stat. § 12-402, permits Respondent's claim after a repose period has ended is incorrect as a matter of law. *See* (R. at 26–27.) The greater specificity in the product liability statute, *inter alia*, indicate it governs such claims and sets a strict limit with its repose period. That repose period bars Respondent's product liability claims. The critical dates of CCS's FDA approval for Cyber MD and the integration of Cyber MD into the MHS branded telehealth platform occurred in 2017. Thus, the repose period would have ended in 2021, and Respondent's July 2024 claim is barred by the four-year repose period. Statutes of repose are intended to be absolute bars, with exceptions often needing to be statutory. Shawnee has three exceptions to the product liability statute of repose: (1) in the case of express warranties longer than the repose period; (2) if a seller misrepresents facts or fraudulently conceals information; and (3) if the injury-causing aspect is hidden or latent. The record does not suggest an express warranty, and the accuracy error was discovered after the repose period ended, so there was no misrepresentation. Additionally, the diagnostic error was discoverable by a reasonably prudent person. Thus, no statutory exception applies, and repose period should not toll, and the product liability claim is statutorily barred.

1. *The repose period in Sn. Rev. Stat. § 12-410(a) can prevent a wrongful death action*

Statutes of repose are intended to be absolute bars of liability for defendants and equitable court-created exceptions to them are disfavored. *Cal. Pub. Emps.' Ret. Sys. v. ANZ Sec., Inc.*, 582 U.S. 497, 507–08 (2017). The imposed time limit decided by the legislature divides tortfeasors into classes which fall within the time limit and those that fall outside of it, but that decision is “within the purview of the legislature.” *Fields v. Legacy Health Sys.*, 413 F.3d 943, 960 (9th Cir. 2005).

Both the Circuit Court of Simmons County and Shawnee Court of Appeals for the Second District recognize that Sn. Rev. Stat. § 12-410 applies a repose period to product liability claims. (R. at 10, 11, 26.) The Shawnee Court of Appeals for the Second District errs in its subsequent application of Shawnee’s limitation of actions statute, Sn. Rev. Stat. § 12-402, by seemingly suggesting the claims are permitted due to its limitation periods. *See (Id. at 26–27.)* As a matter of law, this limitation period does not revive a claim after the repose period.

Repose periods—as strict legislatively-imposed bars—may prevent a cause of action, such as a wrongful death claim, from ever being available to a plaintiff. In *Ehrenfelt v. Janssen Pharms., Inc.*, the Sixth Circuit evaluated which of two Kansas statutes controlled in a product liability suit. *Ehrenfelt v. Janssen Pharms., Inc.*, 737 F. App'x 262, 264 (6th Cir. 2018). As noted by the Shawnee Court of Appeals for the Second District, Kansas’ product liability statutes are analogous to Shawnee’s. (R. at 26.) The Sixth Circuit, applying canons of construction—such as *pari materia*—found the more specific statute of repose for product liability applied

rather than the more general and flexible statute in a product liability case. 737 F. App'x at 264–65.

The Sixth Circuit notes “a specific statute should control over a general statute,” and that logic should likewise apply to the analogous statutes in this case. *Id.* at 266. If the Shawnee legislature had intended there to be an exception for wrongful death beyond the repose period for product liability claims, they could have framed the cause of to action accrue on the date of injury, rather than on the date the first date of sale. *See* TENN. CODE ANN. § 28-3-104 (2026) (stating the cause of action accrues on the date of injury in products liability cases).

§ 12-410 addresses product liability theories of injuries much more directly, than § 12-402. In examining the plain text of § 12-404, references to products are made throughout the statute and title. On the other hand, § 12-402 is a more general statute and only applies a statute of limitations.

Though § 12-404 never mentions death, even if § 12-402 were explicitly referring to product liability, a statute of limitations does not extend a repose period. A statute of limitations is to encourage a claimant to bring a timely action, whereas a repose period is to give a defendant certainty on liability. *CTS Corp. v. Waldburger*, 573 U.S. 1, 9–10 (2014). Due to the statute of repose, decedent was not entitled to maintain an action. *See Kirchner v. Aviall, Inc.*, 513 So. 2d 1273, 1273–74 (Fla. Dist. Ct. App. 1987) (holding that a wrongful death action could not be brought due to a repose period precluding the claim).

§ 12-410(a) sets a repose period of four years for product liability claims.

Repose periods are time bars set by the legislature to provide defendants with temporal certainty for their liability. Expanding it to have wrongful death actions accrue after the period has passed would indefinitely expose companies to liabilities for their products. After a repose period for product liability ends—absent statutory exceptions—cause of actions for wrongful death under that theory do not accrue; this Court should reject the reasoning by the Court of Appeals as a matter of law.

2. Non-statutory exemptions to reposed periods recognized in other jurisdictions should not apply because they go against the purpose of statutory repose periods and would unfairly expose liability to health care companies

Exceptions for repose periods are typically codified, and equitable tolling exceptions are generally disfavored. Some courts have still found issues with repose periods or created equitable exceptions. This Court should not adopt any of these rare judicial carve outs, as it would go against the foundational nature of repose periods and unfairly open-up liability to defendants that the legislature has seen fit to give a degree of temporal certainty to the liability they are exposed to.

The Supreme Court of Utah found a repose period in a product liability statute to be unconstitutional. *Berry v. Beech Aircraft Corp.*, 717 P.2d 670, 685–86 (Utah 1985). There, a repose period precluded a wrongful death action by decedents’ family member against a plane manufacturer. *Id.* at 671–72. The Utah Constitution has a specific wrongful death provision, which the repose period violated. *Id.* at 683–85.

No other state has found a repose period such as this to be unconstitutional. The unconstitutionality of repose periods in *Berry v. Beech Aircraft Corp.* may thus be unique to the Utah Constitution. This Court should not adopt such rare language that would greatly expand liability to product manufacturers. Here, CCS was enabling health care access in an area that had already lost multiple health care providers. (R. at 3–4.)

Expanding liability may lead to a further decrease in providers servicing the area. Cyber MD had an accuracy rate of 97% overall with a dip to 85% for more complex and rare scenarios. (*Id.* at 5–6.) Even the lower level of specificity in complex presentations has surpassed other FDA-cleared AI systems in image diagnostics. See Putu Irma Wulandari, et al., *Diagnostic Performance of FDA-cleared and CE-marked AI Systems for Mammography Screening: A Systematic Review and Meta-analysis*, 204 EUROPEAN J RADIOLOGY (2026). Expanding liability to manufacturers will decrease the availability of helpful, care-expanding tools such as these.

The Fourth Circuit created an exception to a product liability statute of repose for injuries stemming from disease. *Silver v. Johns-Manville Corp.*, 789 F.2d 1078, 1079–80 (4th Cir. 1986). There, decedent developed mesothelioma after occupational exposure to asbestos products. *Id.* at 1079–80.

On the face, the facts of *Silver* may seem similar to this case. Here, decedent also had occupational asbestos exposure, likely leading to the adenocarcinoma. (R. at 3–6.) In *Silver*, however, the product was the disease-causing agent; here the

product is a diagnostic tool that can be used to identify disease. A court-created exception for this would effectively bar any medical device from having a statute of repose. This would increase liability for health care technology companies and likely raise costs for health care, further harming resource-strapped communities like Cartersville. It is precisely these economic and liability concerns that lead legislatures to institute repose periods whose “purpose and effect of a statute of repose, by contrast, is to override customary tolling rules arising from the equitable powers of courts.” *Cal. Pub. Emps.’ Ret. Sys. v. ANZ Sec., Inc.*, 582 U.S. 497, 508 (2017).

3. The product liability repose period should not toll for any statutory exception because there was no warranty, no evidence of fraudulent concealment, and the diagnostic error was discoverable by an ordinary reasonably prudent person after the first diagnostic imaging test

There are three statutory exceptions to the repose period for product liability actions in § 12-410: (1) an express warranty that the product can be used for longer than the repose period; (2) an intentional misrepresentation or fraudulent concealment regarding the product; and (3) if there the injury-causing aspect of the product was hidden or latent. None of these exceptions apply to Respondent’s claims.

Rightfully, neither lower court considered whether the warranty and misrepresentation exception applied to decedent’s use of Cyber MD. There is no evidence in the record of an express warranty, meaning that exception cannot apply. There is also very limited evidence to suggest CCS fraudulently concealed

information regarding Cyber MD. CCS also did not know about the issue until October 2022, more than four-years—the length of the repose period—after Cyber MD was integrated into MHS’s telehealth platform. Fraudulent concealment would not apply to the time between the discovery of the diagnostic issue and deployment of the update, as it was after the repose period; there was no repose period to toll.

Respondent asserts that the product defect was latent and the repose period should toll until decedent’s death. However, the diagnostic error was discoverable by an ordinary reasonably prudent person. Decedent was repeatedly warned that the software was not a health care professional and had a legal right to his healthcare records to verify if there were any malignancies. The repose period should not toll since it was discoverable.

The FDA cleared Cyber MD in February 2017, and the software was integrated into MHS’s telehealth platform in March 2021. (R. at 5). Since the repose period is not tolled by any of the statutory exceptions, claims after 2022—such as Respondent’s July 2024 claim—are statutorily barred.

Other jurisdictions also have exceptions in their product liability statutes of repose for latent defects. *See Koch v. Shell Oil Co.*, 52 F.3d 878, 884 (10th Cir. 1995); *Pate v. Columbia Mach.*, 930 F. Supp. 451, 465 (D. Idaho 1996). The Shawnee Court of Appeals for the Second District found the design defect to be hidden, focusing on the accessibility of the code for the software. (R. at 26–27.) However, one does not need to be a software engineer to access their own medical records and

have a health care provider look at them when warned multiple times that the software program is not a health care provider.

In looking at if a reasonably prudent person could have discovered a defect, courts have looked at if any “scientific, technical, or other specialized knowledge . . . would assist” in the determination. *Oats v. Nissan Motor Corp. in the United States*, 879 P.2d 1095, 1100 (Idaho 1994). In judging efficacy of a product, however, the code is not what is examined but the results. Here, the exact training of the program and software is not material; it’s efficacy in diagnosing is. To hold otherwise would mean that any product with software would be perpetually exposed to liability. Decedent had the right to request access to his medical records for the full statute of repose period, and a prudent person would have taken additional investigation into if the diagnosis was accurate.

There are limited product liability cases regarding diagnostic devices to look to for guidance for what a prudent person would do. Instead, this Court should look to the malpractice world for analogous inspiration. In a Wisconsin medical malpractice case, the court found that parents did not exercise reasonable diligence in discovering the cause of an injury to their child. There, the expectation was that they were expected to access the medical records to discover the cause of the injury. *Awve v. Physicians Ins. Co.*, 512 N.W.2d 216, 217 (Wis. Ct. App. 1994).

Decedent was warned before every visit that Cyber MD is not a health care professional. (R. at 5–6.) Patients also have a right to their medical records. 45 C.F.R. § 164.524 (2026). Prudent is defined as “wise or judicious in practical affairs;

discreet or circumspect.” *Prudent*, Dictionary.com, <https://www.dictionary.com/browse/prudent> (last visited Oct. 2, 2026). A wise or judicious person with repeated exposure to asbestos and no history of asthma would have consulted a physician or other health care professional regarding the diagnostic imaging patient had a right to. Similar as to in *Awve*, decedent did not pay “good faith . . . attention” to the medical information in his reach. 512 N.W.2d at 219.

This Court should restore the conclusion that the Circuit Court of Simmons County reached; the repose period precludes any product liability claims and should not be tolled. Decedent was repeatedly warned that Cyber MD is not a health care professional and had a right to his patient data. However, he was not reasonably prudent—keeping this and his prior history in mind—to follow-up with a real health care professional. Expanding liability to this will limit the willingness for care-expanding initiatives like telehealth, which are frequently used to help underserved regions like Simmons County.

CONCLUSION

This case asks whether to greatly expand liability to organizations that have been providing care to the underserved population of Simmons County. The Circuit Court of Simmons County understood these concerns and previously granted summary judgement for Appellants. Expanding liability through apparent agency to a healthcare provider would be a dangerous step toward treating software as a person rather than a tool and likely diminish cost-effective efforts to expand care to underserved regions. Furthermore, affirming the Shawnee Court of Appeals for the

Second District's decision on the statutory bars would shift the meaning of those repose periods away from the considered and reasoned plain meaning of the legislature and greatly expose liability in the health care context, raising costs for an already economically challenged reason. We ask this Court to reverse the Court of Appeals ruling and grant summary judgement for the Appellants on both issues.

Respectfully submitted,

/s/

Attorneys For Petitioner

APPENDIX A

I. STATUTORY PROVISIONS

Sn. Rev. Stat. § 12-402. Limitations of Actions: Personal Injury and Wrongful Death; Discovery Rule.

- (a) *Personal Injury*. Except as otherwise provided in this section, and except as provided in section 12- 404 of this chapter, an action for damages for personal injury caused by the wrongful act, neglect, or default of another shall be commenced within two (2) years after the cause of action accrues.
- (b) *Wrongful Death*. An action for wrongful death shall be commenced within two (2) years from the date of the decedent's death.
- (c) *Discovery Rule Exception*. If the injury or its causal relationship to the conduct of another is not immediately discoverable through the exercise of reasonable diligence, the limitation period shall not begin to run until the claimant knows, or reasonably should have known, of the injury and the tortfeasor's identity.

Sn. Rev. Stat. § 12-404. Limitations – Health Care Malpractice.

- (a) *Limitations Period*. No action for damages for injury or death against any physician, hospital, or healthcare provider arising out of patient care shall be brought more than two (2) years after the date on which the claimant knew, or through reasonable diligence should have known, of the injury or death.
- (b) *Repose Period*. In no event shall such action be brought more than four (4) years after the date on which occurred the act or omission or occurrence alleged to have been the cause of such injury or death. However, such period shall not bar an action where the defendant healthcare provider engaged in a

continuous course of treatment of the patient for the same illness, injury, or condition that gives rise to the claim of negligence.

Sn. Rev. Stat. § 12-410. Statute of Repose – Product Liability.

(a) *Repose Period.* No product liability action based on strict liability in tort shall be commenced except within the applicable limitations period in Section 12-402, and in any event, within four (4) years from the date of first sale, lease, or delivery of possession to its initial user or consumer.

(b) *Exceptions to Statute of Repose.* The four (4) year period of repose shall not apply if:

1. The product seller expressly warrants that its product can be utilized safely for a period longer than four (4) years;
2. The product seller intentionally misrepresents facts about its product, or fraudulently conceals information about it; or
3. The harm was caused by prolonged exposure to a defective product, or if the injury-causing aspect of the product that existed at the time of delivery was not discoverable by an ordinary reasonably prudent person until more than four (4) years after the time of delivery, or if the harm, caused within four (4) years after the time of delivery, did not manifest itself until after that time.