Circuit Court for Montgomery County
Case No. 482305V

UNREPORTED*

IN THE APPELLATE COURT

OF MARYLAND

No. 2412

September Term, 2023

DEIDRE DEMIZIO, *et al.*

v.

JOHNS HOPKINS HEALTH SYSTEM CORP., *et al.*

Reed,
Friedman,
Sharer, J. Frederick,
(Senior Judge, Specially Assigned),

JJ.

Opinion by Reed, J.

Filed: May 8, 2026

* This is an unreported opinion. This opinion may not be cited as precedent within the rule of stare decisis. It may be cited for its persuasive value only if the citation conforms to Rule 1-104(a)(2)(B).

Deidre DeMizio and her son Peter S. DeMizio, DDS, ("Appellants"), filed a medical malpractice claim for the death of Peter L. DeMizio, DDS, the Decedent, in the Circuit Court of Montgomery County on May 22, 2020. Appellees were Johns Hopkins Health System Corporation and Johns Hopkins Community Physicians, Inc. ("Johns Hopkins Appellees") along with Michael Lee, M.D., Cardiology Associates, LLC, and Montgomery General Hospital, Inc. ("MedStar Appellees"). The claim alleged that Appellees failed to diagnose the Decedent with cardiac amyloidosis before his death on December 15, 2017. The claim was heard before a jury from January 8 to January 22, 2024. The jury found that neither Appellees breached their standard of care. Appellants then filed a timely appeal.

In bringing their appeal, Appellants present four questions for appellate review:

I. Did the trial court abuse its discretion when denying Appellants' motion to reopen discovery?

II. Did the trial court abuse its discretion in restricting the testimony of Appellants' expert witness regarding tafamidis?

III. Did the trial court err by excluding a medical article from evidence?

IV. Did the trial court err in preventing the Appellants from calling a fact witness?[1]

[1] Appellants filed an informal brief and did not have a formal set of presented questions. We rephrase the questions proposed by the Johns Hopkins Appellees, which were originally phrased as:

I. In its oral ruling and written order on September 6, 2023, did the Trial Court abuse its discretion in denying Appellants' Motion to Reopen Discovery, which Appellants filed over eighteen (18) months after the Trial Court had already denied Appellants' previous attempt to reopen discovery?

For the following reasons, we affirm the judgment of the Circuit Court for Montgomery County.

FACTUAL & PROCEDURAL BACKGROUND

The Decedent began experiencing shortness of breath and lightheadedness in February of 2015 and went to MedStar Montgomery Medical Center ("MMMC") for

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II. In its November 13, 2023 Order and Opinion, did the Trial Court abuse its discretion in restricting Appellants' standard-of-care expert's testimony regarding tafamidis and its availability to cardiac amyloid patients during the relevant period of 2015 through 2017?

III. Did the Trial Court commit legal error or abuse its discretion in precluding Appellants from establishing the standard of care through the introduction into evidence of a medical article published after the relevant care Appellees rendered in this case?

IV. Did the Trial Court abuse its discretion in denying Appellants' attempt to call an untimely disclosed "fact witness" where the Trial Court determined that the proposed testimony was irrelevant under Maryland Rule 5-401, the prejudice of the proposed testimony substantially outweighed any potential relevance under Maryland Rule 5-403, and the proposed testimony was improper expert opinion from a lay witness?

Additionally, Appellees had additional questions on a conditional cross-appeal, which were:

V. For the purposes of conditional cross-appeal, did the trial court err in permitting Appellants' experts to testify about certain matters that lacked a sufficient factual basis; and if so, did the court err by denying Appellees' Motion for Summary Judgment?

VI. Did the Circuit Court err in denying the MedStar Appellees' Motion for Judgment?

As we uphold the rulings of the lower court, we need not address the questions presented in the cross-appeal.

treatment. The Decedent then went to Johns Hopkins Community Physicians, Inc. ("JHCP") Heart Care in Rockville on February 25, 2015, where he was treated by Dr. Daniel J. Fernicola. Over the next two years, the Decedent visited Appellees and Dr. Fernicola specifically multiple times. He was hospitalized for pneumonia twice in the summer of 2016. The Decedent only visited Dr. Michael Lee once on June 6, 2016, with complaints of dyspnea, who recommended further echocardiograms for the Decedent. The Decedent's final visit to Dr. Fernicola on was July 31, 2017, due to leg pain.

The Decedent was found dead on December 15, 2017, at the age of 66. An autopsy was performed shortly after, which concluded that the Decedent "experienced sudden cardiac death, most likely due to an arrhythmia from cardiac amyloidosis." The diagnosis of cardiac amyloidosis was based on a finding of left ventricular hypertrophy and impaired diastolic filling, along with the electrocardiogram showing diffuse low voltage and impaired conduction.

Amyloidosis is a disease process involving abnormally folded proteins that deposit in various organs. Amyloidosis effects the heart when amyloid fibrils deposit in the heart tissue. Amyloidosis can lead to thickening of the ventricles in the heart, which can result in impaired filling of the heart or arrythmias. There are two different types of cardiac amyloidosis. The first, immunoglobin light chain amyloidosis (AL), is caused by the overproduction of light chains by a clonal plasma cell population. The second, transthyretin amyloidosis (ATTR), is caused by transthyretin, a protein produced by the liver, misfolding and depositing in the heart. This version can be hereditary or age-related. The Decedent had age-related ATTR. Prior to his death, the Decedent was not diagnosed with cardiac

amyloidosis.

On May 20, 2020, Appellants filed their complaint against Appellees, claiming medical negligence resulting in death, wrongful death, survival action, and loss of consortium. The medical negligence was based on a failure by Appellees to diagnose and treat the Decedent's cardiac amyloidosis in the years leading up to his death. The relevant treatment period was from February of 2015 until his death in December of 2017.

The case was delayed for many years, part of which was attributable to successive counsels for Appellants withdrawing.[2] The claim was finally heard before a jury from January 8 to January 22, 2024, with Judge Louis Leibowitz of the Circuit Court for Montgomery County presiding. The jury found that neither Appellees breached their standard of care. Appellants then filed this timely appeal.

A. Motion to Reopen Discovery

After some of the initial delays in moving this case to trial, discovery was set to end on January 27, 2022. However, Appellees moved to compel discovery related to the decedent's employment records in order to determine lost future earnings. At a hearing on February 24, 2022, the trial court allowed discovery to remain partially open to allow

[2] Appellants' first counsel, Patrick M. Regan and Jacqueline T. Colclough, who filed the initial complaint, withdrew on December 21, 2020 and were removed on January 5, 2021. This pushed the first trial date back from July 12, 2021, to March 21, 2022. David Greene joined the case on April 7, 2021, with David J. Kaminow joining as co-counsel on November 15, 2021. Further delays pushed the trial date back to May 15, 2023. Mr. Kaminow then withdrew his appearance on February 5, 2023, with Mr. Greene also withdrawing on April 14, 2023, citing illness. These withdrawals pushed the trial date again to January 9, 2024. Bruce M. Bender entered his appearance on July 28, 2023, and was the attorney for the relevant proceedings on appeal.

Appellees to depose Appellants' experts. The next day, the trial court set a new discovery deadline of May 31, 2022.

More than a year after discovery closed, Appellants, now represented by Bruce M. Bender, made a motion to reopen discovery on July 28, 2023. Appellants sought leave to reopen discovery in order to depose two of Appellees' witnesses.[3] A hearing was held on this motion on September 6, 2023. At the hearing, Appellants argued that Appellants' prior attorneys did not take these depositions and there was still time to take the depositions with months left before the trial was scheduled to start.

Judge Leibowitz denied Appellants' motion. He described how even without Appellants' counsel's health issues, the prior counsel chose not to depose the defense experts when discovery was open. Judge Leibowitz was concerned about reopening discovery and setting other deadlines off track.

B. Restriction of Expert Testimony

On October 20, 2023, there was a hearing held for Appellees' motion to exclude the testimony of Appellants' expert, Dr. Emil Hayek. Dr. Hayek came to three expert opinions, the relevant one on appeal being that the failure to treat the Decedent with tafamidis was a breach of standard of care.[4] Dr. Hayek was Appellant's expert cardiologist, who would

[3] The motion originally also sought to add an extra expert witness for Appellants, who would testify about the standard of care and causation related to cardiology. However, this request was withdrawn prior to the hearing.

[4] Dr. Hayek's other opinions were, first, that Appellees failed to treat the Decedent's ventricular tachycardia and should have implanted the Decedent with an implantable cardio-defibrillator (ICD), which would have extended his life to get tafamidis treatment

testify to the standard of care and causation. Dr. Hayek was board certified in internal medicine and cardiology. For the purpose of the hearing, the parties stipulated he was an expert in cardiology. He had previously treated approximately four patients with cardiac amyloidosis.

Regarding the drug tafamidis, over objections, Dr. Hayek said there were studies conducted in 2015 and 2016 showing their effectiveness, and these studies were "known and available to cardiologists . . . in the United States." During that time period, the drug was approved in the European Union and Japan for the treatment of cardiac amyloidosis. Meaning that patients could travel abroad and receive treatment with tafamidis if they had the means. The FDA did not approve the drug in the United States until 2019. Even prior to the FDA's approval, Dr. Hayek said tafamidis was "known to be out there." To be prescribed tafamidis in the United States, there were amyloid centers across the county where the drug could be prescribed off-label.[5] Dr. Hayek claimed that he offered those centers to his patients diagnosed with cardiac amyloidosis around 2015 and 2016. Dr. Hayek concluded by testifying that if the doctor did not want to prescribe tafamidis off-label then the standard of care would be to send the patient to a specialist in cardiac amyloidosis at an amyloid center. Dr. Hayek did not cite to any publications or outside materials to support his conclusions about the standard of care.

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and, second, had either of these treatments led to extensions in the Decedent's life, he would have received a heart transplant that extended his life. The trial court allowed Dr. Hayek to testify to these two conclusions.

[5] Dr. Hayek mentioned centers at Harvard, Johns Hopkins, and Stanford where they had "amyloid experts" prescribing tafamidis.

The trial court entered its written order on the motion on November 13, 2023. The trial granted the motion to exclude in part and denied the motion in part. Regarding the tafamidis opinion, the trial court analyzed the opinion under the *Daubert-Rochkind* standard for testing the reliability of expert testimony. The court wrote that "[o]ther than Dr. Hayek's deposition testimony, [Appellant] has not produced any evidence showing that tafamidis was standard of care treatment for cardiac amyloidosis from 2015-2017." Applying the *Daubert-Rochkind* factors, the trial court found that Dr. Hayek did not provide any peer reviewed or published literature to support his conclusion, and his claims were insufficient to show general acceptance. In favor of the conclusion, the trial court noted that Dr. Hayek had kept up with treating patients and that medical experts are generally known for sound opinions regarding the standard of care. Lastly, the trial court found Dr. Hayek's opinion that tafamidis was the standard of care to be an unjustified extrapolation where during the relevant treatment period the treatment with tafamidis was not FDA-approved for any purpose. As a result, the court concluded that Dr. Hayek could not testify that tafamidis was the standard of care treatment during the relevant period.

C. Admissibility of Cleveland Clinic Article

At trial, Dr. Hayek testified on behalf of Appellants on January 9, 2024. During his testimony, Appellants attempted to enter an article (the "Cleveland Clinic Article") about the standard of care of patients with cardiac amyloidosis. The article, entitled *Cardiac*

amyloidosis: An update on diagnosis and treatment, was published in December 2017.[6] When asked about the relevance of the article, Appellants' attorney said that the article describes the classic hallmarks to diagnose cardiac amyloidosis as "low voltage and left ventricular heart wall thickening," which is what Dr. Hayek was testifying to in court. The article listed those symptoms as "Red Flags for Cardiac Amyloidosis" in a table.

Judge Leibowitz asked Appellants how the article could reflect the standard of care in 2015 or 2016 if it was published in December of 2017. Appellants responded that Dr. Hayek would say "that it was the standard of care for 20 years" and the article restates that standard. Judge Leibowitz responded that "this article can't be a standard of care because it was published contemporaneously with the decedent's death." He said that Dr. Hayek would be free to testify to the standard of care based on his training and experience. Appellees argued that Dr. Hayek's testimony cannot be bolstered with a post-dated article, which Judge Liebowitz agreed with. After Judge Leibowitz asked Appellees if they were objecting, they objected to the release of the article, which Judge Leibowitz sustained.

Appellants then attempted to ask about what the medical literature says about diagnostic criteria for cardiac amyloidosis. Appellees objected again and argued that they were not alerted to Dr. Hayek relying on any literature. Prior to trial, when Dr. Hayek was being deposed, he stated he would not be relying on any specific pieces of literature and would only use anything used by the defense experts as rebuttal. As a result, Appellees

[6] The full citation for the article is: Joseph P. Donnelly, M.D. and Mazen Hanna, M.D., *Cardiac Amyloidosis: An update on diagnosis and treatment*, 84 CLEVELAND CLINIC J. OF MED. 3 SUPP. 12 (2017).

claimed they were not shown this specific article before trial.[7] Judge Leibowitz again sustained Appellees' objection. Appellants then continued with the direct of Dr. Hayek.

D. Denial of Testimony of Mike Lane

On November 28, 2023, Appellants sent an email with proffers about five fact witnesses, two of whom were disclosed for the first time. One of these witnesses was Mike Lane, who Appellants described as "someone who has been diagnosed with cardiac amyloidosis" who would "testify about his treatment with Tafamidis before FDA approval and other facts in his statement relating to his symptoms and remission of symptoms as well as his ability to work." Mr. Lane had a sworn affidavit, where he described how he accessed tafamidis through Pfizer and "a process for compassionate use" in May or June of 2018. Mr. Lane stated that tafamidis had stabilized his heart condition and improved his quality of life.

Appellees filed a motion to strike all five fact witnesses.[8] Regarding Mr. Lane, Appellees argued that he has no personal knowledge of the case, and his testimony would be irrelevant. Appellees claimed the testimony was meant to circumvent the ruling against Dr. Hayek regarding treatment with tafamidis.

[7] This article was cited in the Decedent's autopsy report. This fact does not alter Dr. Hayek's testimony that he was not planning on relying on any specific literature, but it was relied on by the medical personnel performing the Decedent's autopsy in describing and diagnosing the Decedent's cause of death.

[8] Appellants decided against calling one of the five witnesses, Isabel Lousada, prior to the motion being filed. The other three witnesses were all fact witnesses who knew the Decedent in various capacities. Judge Leibowitz ruled that those three witnesses' testimony was admissible, if "unremarkable."

A hearing on the motions was held on December 21, 2023. After hearing from both parties, Judge Leibowitz first found that Mr. Lane's testimony was not relevant because Mr. Lane's outcome with tafamidis does not make it more or less probable that the Decedent would have the same outcome. Additionally, Judge Leibowitz said that as a lay witness, Mr. Lane cannot testify to the efficacy of tafamidis and even if Mr. Lane's testimony was relevant there would be unfair prejudice that bars the testimony. As a result, Mr. Lane was barred from testifying.

DISCUSSION

Motion to Reopen Discovery

A. Parties' Contentions

Regarding Appellants' motion to reopen discovery to depose Appellees' experts, Appellants argue that discovery would have only been opened for a short time to perform those depositions. Appellants argue that when the motion was made the trial was still months away. They claim prejudice from the decision because Appellees' experts were able to adapt their trial testimony to benefit Appellees.

Appellees argue there was no good faith basis to reopen discovery and given the complete history of the case regarding prior delays from Appellants, the court properly ruled not to reopen discovery. Appellees assert that the trial court properly considered the prejudicial effect reopening discovery could have on Appellants and the risk of further delays.

B. Standard of Review

The denial of discovery is reviewed under an abuse of discretion standard. *Yacko v.*

Mitchell, 249 Md. App. 640, 690 (2021) (citing *Sibley v. Doe*, 227 Md. App. 645, 658 (2016)); *see also Asmussen v. CSX Transportation, Inc.*, 247 Md. App. 529, 551 (2020) (citing *Admiral Mortgage, Inc. v. Cooper*, 357 Md. 533 (2000)) ("[W]hether to modify a scheduling order . . . [is] committed to the circuit court's discretion."). The circuit court abuses its discretion "where no reasonable person would take the view adopted by the [trial] court[ ] . . . or when the court acts without reference to any guiding principles, and the ruling under consideration is clearly against the logic and effect of facts and inferences before the court [ ] . . . or when the ruling is violative of fact and logic." *Sibley*, 227 Md. App. at 658 (quoting *Bacon v. Arey*, 203 Md. App. 606, 667 (2012)).

C. Analysis

For cases in Maryland circuit courts, a scheduling order must be entered to control deadlines. Md. Rule 2-504(a)(1). This order includes a date when discovery must be completed. Md. Rule 2-504(b)(1)(D). The purpose of this order is "to move the case efficiently through the litigation process by setting specific dates or time limits for anticipated litigation events to occur." *Asmussen*, 247 Md. App. at 546–47 (quoting *Dorsey v. Nold*, 362 Md. 241, 255 (2001)). Despite this goal, "absolute compliance with scheduling orders is not always feasible" and extraordinary circumstances may warrant modification. *Id.* at 547 (quoting *Naughton v. Bankier*, 114 Md. App. 641, 653 (1997)). The Maryland rules recognize this reality and state that scheduling orders "shall be modified by the court to prevent injustice." Md. Rule 2-504(c).

In *Asmussen v. CSX Transportation, Inc.*, this Court compared modifications of scheduling orders to decisions about striking or admitting evidence based on untimely

designations or disclosures. *Amussen*, 247 Md. App. at 548. Relying on those cases, this Court stated that to prevent injustice, the party unable to meet the deadlines needs to show "substantial compliance and good cause." *Id.* Substantial compliance will be "less likely the later the disclosure and the less 'technical' the violation at issue." *Id.* at 550. Good cause will be "more likely when the party seeking an accommodation has a good reason for noncompliance, where the prejudice he suffers from non-admission is great, and where the prejudice his opponent suffers from admission is less severe." *Id.* at 550-51.

We apply these two factors to Appellants' motion to reopen discovery. Starting with substantial compliance, here Appellants' delay in making the motion was not the result of a technical violation and came well after the close of discovery. Discovery substantially closed to Appellants on January 27, 2022.[9] The motion to reopen discovery was not made until over a year later, on July 28, 2023. This was after Appellants' prior attorneys had withdrawn earlier in the year. Appellants then acquired new counsel who described the lack of depositions being taken as "a big disservice" to Appellants. However, that reasoning does not make the delay a technical violation and a delay of over a year is not close to the end of discovery. Based on this delay, we do not hold there was substantial compliance on the part of Appellants in requesting to depose the experts.

On the issue of good faith, both sides made arguments related to the prejudice from

[9] On this day, Appellants filed a motion to modify the scheduling order. That motion was heard at a February 24, 2022, hearing where Judge Storm agreed to extend the discovery deadline for the limited purpose of allowing Appellees to depose Appellants' experts. This was because there were multiple cancellations and ongoing difficulties in getting discovery materials and depositions from Appellants' experts. Discovery was opened for that limited purpose until May 31, 2022.

opening or not opening discovery. Appellants argued that there would be prejudice from not re-opening discovery because they wanted to hear what the defense experts have to say before trial. However, as a part of discovery, Appellees' experts had already filed "detailed expert reports." Additionally, during the original discovery period, there was ample opportunity to depose the experts but that did not occur. The change in trial strategy and decision to now depose Appellees' experts is not sufficient to constitute a good reason for noncompliance with the discovery deadline. Appellees argued there would be prejudice from the potential of further delays as a result of reopening discovery, with the trial only four months away. The trial court could properly balance the potential prejudice of further delays after reopening discovery impacting the already delayed trial date.

There was a not good reason for noncompliance in failing to take the experts' depositions while discovery was open and there was little evidence presented for prejudice when the expert reports were already available to Appellants. As a result, we hold that Judge Leibowitz properly considered the motion to reopen discovery and did not abuse his discretion in denying that request.

Restriction of Expert Testimony

A. Parties' Contentions

Appellants contend that the trial court's order was too specific in limiting Dr. Hayek's testimony. Appellants believed Dr. Hayek's testimony was based on years of clinical experience and current medical literature. They argue prejudice was shown in not allowing this expert testimony because it was crucial to showing the lapse in professional capabilities related to not prescribing tafamidis.

Appellees argue that the trial court properly analyzed the factors related to the admissibility of an expert opinion. Appellees contend the trial court properly distinguished which opinion by Dr. Hayek were supported and admissible and which were not. Additionally, Appellees argue there was no prejudice from this ruling because Dr. Hayek still found opportunities at trial to discuss tafamidis.

B. Standard of Review

We review a trial court's decision to admit or exclude expert opinions for an abuse of discretion. *Oglesby v. Balt. Sch. Assocs.*, 484 Md. 296, 326-27 (2023) (citing *Rochkind v. Stevenson*, 471 Md. 1, 37 (2020)).

C. Analysis

Expert testimony in Maryland is governed by Rule 5-702, which states:

> Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine:
>
> (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education,
>
> (2) the appropriateness of the expert testimony on the particular subject, and
>
> (3) whether a sufficient factual basis exists to support the expert testimony.

Md. Rule 5-702. The existence of a sufficient factual basis is based on two sub-factors: whether the expert had an adequate supply of data and whether the expert's methodology was reliable. *Oglesby*, 484 Md. at 327–28 (citing *Sugarman v. Liles*, 460 Md. 396, 415 (2018)). Both sub-factors must be shown in order to admit the expert's testimony. *Id.* at

328 (citing *Rochkind*, 471 Md. at 22). Testimony should not be the *ipse dixit* assertion of the expert, where we only have the expert's words, and instead the expert needs to be able to articulate the reliable methodology they used to reach the conclusion. *Id.* (quoting *Sugarman*, 460 Md. at 415).

To help interpret these rules, the Supreme Court of Maryland adopted the *Daubert-Rochkind* factors. *Rochkind v. Stevenson*, 471 Md. 1, 35–36 (2020) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593–95 (1993)). These ten factors[10] are useful in determining whether an expert's proffered testimony is sufficiently reliable. *Abruquah*

[10] The full list of factors is:

> (1) whether a theory or technique can be (and has been) tested;
> (2) whether a theory or technique has been subjected to peer review and publication;
> (3) whether a particular scientific technique has a known or potential rate of error;
> (4) the existence and maintenance of standards and controls; . . .
> (5) whether a theory or technique is generally accepted[;]
> . . .
> (6) whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying;
> (7) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion;
> (8) whether the expert has adequately accounted for obvious alternative explanations;
> (9) whether the expert is being as careful as [the expert] would be in [the expert's] regular professional work outside [the expert's] paid litigation consulting; and
> (10) whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.

Abruquah, 483 Md. at 654 (quoting *Rochkind*, 471 Md. at 35–36).

v. State, 483 Md. 637, 653 (2023) (quoting *State v. Matthews*, 479 Md. 278, 310 (2022)). All ten factors are relevant, but no single factor is dispositive, and a court may apply "some, all, or none of the factors depending on the particular expert testimony at issue." *Matthews*, 479 Md. at 312 (quoting *Rochkind*, 471 Md. at 37).

The trial court noted that factors two, five, six, seven, and ten were relevant to Dr. Hayek's opinion. These factors are:

> (2) whether a theory or technique has been subjected to peer review and publication;
>
> (5) whether a theory or technique is generally accepted[;]
>
> (6) whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying;
>
> (7) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; . . . and
>
> (10) whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.

Abruquah, 483 Md. at 654 (quoting *Rochkind*, 471 Md. at 35–36).

Judge Leibowitz noted that two factors weighed in favor of admissibility. First, on factor six, whether opinions emerged independently or were developed for litigation, Judge Leibowitz described how Dr. Hayek "kept up with literature and treated patients with cardiac amyloidosis as a part of his regular practice." **(R. at 273).** Based on this, the testimony grew naturally out of research independent for litigation and this factor would not weigh against admissibility. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies based on research he has conducted

independent of the litigation provides important, objective proof that the research comports with the dictates of good science."). Second, on factor ten, whether the field of expertise is known to reach reliable results, Judge Leibowitz said, "medical experts are generally known for sound opinions on standard of care treatment." We agree that medical experts are a proper source of opinions on the standard of care, and Dr. Hayek was testifying to an opinion about the treatment of a heart-related disease as a cardiologist, so he was within his field of expertise. Thus, the trial court judge did not commit an abuse of discretion in its assessment of factors six and ten.

On factor two, whether a theory or technique has been subjected to peer review and publication, Judge Leibowitz noted that "Dr. Hayek produced no peer reviewed or published literature indicating that tafamidis was the standard of care for cardiac amyloidosis patients in 2015-2017." This factor analyzes "whether a methodology has been submitted 'to the scrutiny of the scientific community,' under the belief that doing so 'increases the likelihood that substantive flaws in methodology will be detected.'" *Abruquah*, 483 Md. at 681–82 (quoting *Daubert*, 509 U.S. at 593). Here, Dr. Hayek's assertions were not shown to have been submitted to the scrutiny of the scientific community because he did not provide any evidence of peer reviewed or published literature. In the absence of that evidence, Judge Leibowitz did not abuse his discretion in finding that this factor weighs against reliability.

On factor five, whether a theory or technique is generally accepted, Judge Leibowitz said that Dr. Hayek did not have sufficient evidence of general acceptance. At the hearing, Dr. Hayek testified that tafamidis was "out there," "known," and available at specialty

clinics in the United States. General acceptance, while no longer the primary consideration, is still important in analyzing reliability. *Rochkind*, 471 Md. at 30. "[A] known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594 (internal quotations and citation omitted). Here, the relevant community is medical providers in the United States, as that is where the Decedent was receiving his treatments. Between 2015 and 2017, the relevant time period for this case, Dr. Hayek did not provide evidence of widespread acceptance of using tafamidis to treat cardiac amyloidosis. The standard of care for a physician is based on "what a reasonably competent similar practitioner would do in the same circumstances." *Street v. Upper Chesapeake Med. Ctr., Inc.*, 260 Md. App. 636, 683 (2024), *cert. denied*, 487 Md. 457 (2024) (quoting *Armacost v. Davis*, 462 Md. 504, 527 (2019)). A technique being "out there" does not mean that the community generally accepts it or that a reasonably competent similar practitioner would recommend it. As a result, this factor does not weigh in favor of admissibility when Dr. Hayek did not show evidence of general acceptance within the relevant community during the treatment period.

Lastly, on factor seven, whether there was an unjustified extrapolation from an accepted premise to an unfounded conclusion, Judge Leibowitz found that Dr. Hayek went too far in concluding that tafamidis was the standard of care when it was not FDA approved for any purpose before 2019. This factor is related to the concept of an "analytical gap," which originated from the Supreme Court's opinion in *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). *See Rochkind*, 471 Md. at 17–18 (discussing the adoption of the analytical gap framework in Maryland). An expert's opinion has an analytical gap when the expert

fails "to bridge the gap between his or her opinion and the empirical foundation on which the opinion was derived." *Matthews*, 479 Md. at 317 (quoting *Savage v. State*, 455 Md. 138, 163 (2017)). A trial court is not required to admit an opinion "that is connected to existing data only by the *ipse dixit* of the expert." *Rochkind*, 471 Md. at 36 (quoting *Joiner*, 522 Md. at 146). Here, Dr. Hayek's opinion that using tafamidis was the standard of care, when the drug was not yet FDA-approved for any purpose[11] and Dr. Hayek did not point to other evidence supporting his conclusion beyond his own testimony, had too wide of an analytical gap between the empirical foundation and the opinion. As a result, Judge Leibowitz did not abuse his discretion in finding this factor weighed against the testimony's admissibility.

At the hearing, Dr. Hayek failed to present sufficient evidence to support the reliability of his conclusion on tafamidis. Instead, Dr. Hayek's testimony on this issue was precisely the kind of *ipse dixit* opinion that Maryland courts have said is not sufficiently reliable for admission. *Oglesby*, 484 Md. at 327–28 (quoting *Sugarman*, 460 Md. at 415). By contrast, his conclusions on his related opinions had additional facts and data to support them and the trial court allowed Dr. Hayek to testify to those conclusions. In reviewing the trial court's opinion, we hold Judge Leibowitz did not abuse his discretion in barring Dr.

[11] We recognize that off-label use is permitted. The Supreme Court of the United States has recognized "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). However, Dr. Hayek would have then needed to provide evidence, beyond his own assertions, that the off-label use of tafamidis was the standard of care.

Hayek's testimony on tafamidis.[12]

Admissibility of Cleveland Clinic Article

A. Parties' Contentions

Regarding the Cleveland Clinic article, Appellants argue that the article supported Dr. Hayek's testimony. Appellants contend the article would apply to the standard of care in the critical period of 2015 to 2016. They claim prejudice from the article being excluded because it would have been a critical piece of information for the jury.

Appellees argue that the trial court properly excluded the article because it postdated the time period when the Decedent's treatment would have been administered. Additionally, Appellees argue there was no prejudice to Appellants because Dr. Hayek could still testify about the standard of care without the article being admitted into evidence.

B. Standard of Review

"[W]hether a particular item of evidence should be admitted or excluded is committed to the considerable and sound discretion of the trial court" and we review that decision under the abuse of discretion standard. *Perry v. Asphalt & Concrete Servs., Inc.*, 447 Md. 31, 48 (2016) (quoting *Ruffin Hotel Corp. of Md., Inc. v. Gasper*, 418 Md. 594, 619 (2011)). However, the circuit court's determination that a piece of evidence is relevant

[12] Because we find the opinion on tafamidis opinion was properly excluded from trial, we do not analyze whether the ruling was prejudicial. We will note that the record was replete with instances of Dr. Hayek attempting to discuss tafamidis in direct opposition to the trial court's ruling. As a result, Appellants still had evidence on the record about tafamidis without Dr. Hayek's specific conclusion.

or irrelevant is reviewed *de novo* because it is a legal conclusion. *Williams v. State*, 457 Md. 551, 563 (2018). Trial judges have wide discretion "in weighing relevancy in light of unfairness or efficiency considerations, [but] trial judges do not have discretion to admit irrelevant evidence." *Perry*, 447 Md. at 48 (quoting *State v. Simms*, 420 Md. 705, 724 (2011)).

Even if the circuit court errs in its evidentiary ruling, this Court will not reverse the lower court for harmless error. *Id.* at 49 (citing *Crane v. Dunn*, 382 Md. 83, 91 (2004)). The complaining party must show that the error was prejudicial and "likely to have affected the verdict below." *Id.* (quoting *Crane*, 382 Md. at 91). Our inquiry focuses on "not the possibility, but the probability, of prejudice." *Id.* (quoting *Crane*, 382 Md. at 91).

C. Analysis

Maryland Rule 5–401 defines "relevant evidence" as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." The Cleveland Clinic article was being entered during Dr. Hayek's testimony to help establish the standard of care for patients with cardiac amyloidosis. This purpose would have been of consequence in determining the action, but the question for the court was whether the Cleveland Clinic article would have had a tendency to make facts related to that standard of care more or less probable.

Maryland statutes define the standard of practice used in lawsuits against health care providers. In those actions, the plaintiff must establish "that the care given by the health care provider is not in accordance with the standards of practice among members of the

same health care profession with similar training and experience situated in the same or similar communities *at the time of the alleged act giving rise to the cause of action*." Md. Cts. & Jud. Proc. § 3-2A-02(c)(1) (emphasis added). "[T]he standard of care applicable to a physician in a negligence action is derivative of the general standard of care in negligence actions, *as informed by expert testimony about what a reasonably competent similar practitioner would do in the same circumstances*." *Street v. Upper Chesapeake Med. Ctr., Inc.*, 260 Md. App. 636, 683, *cert. denied*, 487 Md. 457 (2024) (quoting *Armacost*, 462 Md. at 527) (emphasis in original).

In this case, the time of the alleged acts that gave rise to the cause of action was the period between 2015 and 2017 when Appellees provided treatment to the Decedent. The Cleveland Clinic article was published in December of 2017, the same month that the Decedent died. Based on this timeline, Judge Leibowitz ruled that the article cannot be the standard of care "because it was published contemporaneously with the decedent's death." The trial court explicitly said that Dr. Hayek could rely on his training and experience to describe the same evidence, just not the article itself. We agree with Judge Leibowitz's reasoning and find that the article itself was inadmissible for the purpose of establishing the standard of care during the relevant time period when it was not published until the end of that period and therefore inaccessible to Appellees whose conduct and knowledge was at issue in the case.[13]

[13] Even though the Cleveland Clinic article was excluded, we agree with Appellees that there was no harm as a result, as Dr. Hayek was still able to testify to the "hallmark" diagnostic criteria for cardiac amyloidosis. As a result, any error was unlikely to be

Judge Leibowitz's decision is further supported by a similar question faced by the United States District Court for the District of Maryland in *Ford v. United States*, No. GJH-11-3039, 2015 WL 11070248 (D. Md. Nov. 12, 2015). [14] In that case, the court granted a motion to exclude articles about the standard of care that were published after the alleged negligence. *Id.* at *4. The prejudicial effect of admitting the articles was not substantially outweighed by their probative value. *Id.* (citing Fed. R. Evid. 703). Relying on the Maryland statute for standard of care, the court wrote, "[a]llowing the admission of articles that postdate the 'act giving rise to the cause of action' to substantively establish the standard of care in effect at that time would only cause confusion." *Id.* (quoting Md. Cts. & Jud. Proc. § 3-2A-02(c)(1)). The court drew the same balance as Judge Leibowitz, where the expert could testify to his opinion about the standard of care and materials he relied on when formulating the opinion, but the document itself was not admissible. *Id.*

We hold the trial court properly excluded the Cleveland Clinic article from evidence where the article trying to establish the standard of care in a medical malpractice case came from the end of the relevant period of treatment and as a result could not inform the

prejudicial, since Dr. Hayek was still able to provide testimony about the standard of care for diagnosing cardiac amyloidosis, and the jury still returned a verdict in favor of Appellees. *Perry*, 447 Md. at 49. We do not hold that the entry of the Cleveland Clinic article into evidence created a possibility of prejudice against Appellants. *Id.* (quoting *Crane*, 382 Md. at 91).

[14] "An unreported or unpublished opinion . . . issued by a federal court . . . may be cited as persuasive authority if the jurisdiction in which the opinion was issued would permit it to be cited as persuasive authority or as precedent." Md. Rule 1-104(b). As the federal courts may not prohibit the citation of federal judicial opinions or designate them as "non-precedential" this case will be persuasive in our court. Fed. R. App. Proc. 32.1(a).

treatment of any of Appellees.[15]

Denial of Testimony of Mike Lane

A. Parties' Contentions

Lastly, Appellants contend Mike Lane's testimony would have been valuable regarding the availability and treatment protocols existing when the Decedent passed. Appellants argue that the trial court did not apply the standard for witnesses correctly and Mike Lane should have been permitted to testify.

Appellees argue that Mike Lane had no personal knowledge of the Decedent and would only be testifying to his own personal experience with the same disease, which would not be relevant to the jury.

B. Standard of Review

The standard of review for this issue is the same as the prior section on the Cleveland Clinic article. When a trial court excludes evidence based on relevance, the *de novo* standard of review applies to a conclusion of law that the evidence at issue is or is not "of consequence to the determination of the action." *Ruffin Hotel Corp. of Maryland,* 418 Md.

[15] There was an additional issue with this article not being shared with Appellees prior to Dr. Hayek's testimony. At Dr. Hayek's deposition, he stated he would rely on any specific pieces of literature at trial, and would only use anything used by the defense experts as rebuttal. As a result, the Cleveland Clinic article was not shown to Appellees prior to the trial. "It is especially crucial for the trial court to exclude" evidence that did not comply with discovery obligations "on the eve of trial . . . [where] the injury inherent in failure to make discovery is unfair surprise." *Hill v. Wilson*, 134 Md. App. 472, 485 n.11 (2000) (internal quotes and citations omitted). With the Cleveland Clinic article not being disclosed by Dr. Hayek or Appellants prior to trial, Appellees had no ability to review the contents of the article in order to object to its admission or cross examine Dr. Hayek on its conclusions. This provided Judge Leibowitz with further support to keep the Cleveland Clinic article out of evidence outside of the standard of review timeline.

at 619 (citing *Parker v. State*, 408 Md. 428, 437 (2009)).

C. Analysis

"Relevant evidence" is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Md. Rule 5-401. The evidence at issue was the testimony of Mike Lane. Appellants first emailed about calling Mike Lane to testify on November 28, 2023, stating that he had been diagnosed with cardiac amyloidosis and Appellants planned for him to testify about his treatment with tafamidis before they were approved by the FDA. Judge Leibowitz ruled that Mr. Lane's testimony was not relevant because his testimony would not "make it more probably or less probably that [the Decedent] would have had [the] same outcome." He compared it to Appellees calling a witness to say that someone they knew took tafamidis and died anyway.

We agree with Judge Leibowitz's ruling that Mr. Lane's testimony was not relevant to the proceeding. Another patient's experience with a disease does not make a fact more or less likely in a case of medical negligence. Further, Mr. Lane's testimony would not have established that he was treated by any of Appellees, if he had a comparable medical history or disease state to the Decedent, or any other testimony that would require an expert medical practitioner. Unlike the other fact witnesses that were at issue in this motion, Mr. Lane had no relationship to the Decedent or the Decedent's family and would be unable to testify to any personal knowledge about the facts of this specific case. On Appellants' specific argument that Mr. Lane could testify to the availability and treatment protocols existing when the Decedent passed, we hold Mr. Lane's testimony would not be relevant

for that purpose because he was not diagnosed until 2018, after the Decedent had passed and after the relevant period for determining the standard of care. As a result, Mr. Lane's testimony was irrelevant in this particular case and would make no fact of consequence more or less probable.

We hold that Judge Leibowitz did not err in barring the testimony of Mr. Lane.[16]

CONCLUSION

We find no error or abuse of discretion in any of the decisions that Appellants took issue with. As a result, we affirm the judgment of the Circuit Court for Montgomery County.[17]

JUDGMENT OF THE CIRCUIT COURT FOR MONTGOMERY COUNTY AFFIRMED; COSTS TO BE PAID BY APPELLANT.

[16] Because we find that the testimony of Mike Lane was not relevant, we do not address the additional arguments of whether there was a violation of Maryland Rule 5-403 for his testimony being substantially more prejudicial or confusing to the jury than it was probative, or a violation of Maryland Rule 5-702 for an inability for a lay witness to come to an expert conclusion about the causes of changes in his disease.

[17] Since we affirm the judgment of the trial court, we do not need to address the questions related to Appellees' conditional cross-appeal.