Circuit Court for Baltimore City
Case No. 24-C-12-002081

UNREPORTED

IN THE COURT OF SPECIAL APPEALS

OF MARYLAND

No. 2401

September Term, 2016

JAMES ERVIN, *et al.*

v.

KENNEDY KRIEGER INSTITUTE, INC., *et al.*

Nazarian,
Beachley,
Kenney, James A., III
(Senior Judge, Specially Assigned),

JJ.

Opinion by Nazarian, J.

Filed: June 22, 2018

James Ervin, Lakeisha Ervin, Marvin Hawkins, and Shawn Johnson appeal judgments in favor of Kennedy Krieger Institute ("KKI") on claims arising from blood lead poisoning Mr. Ervin suffered while he participated in KKI's Treatment of Lead-Exposed Children Clinical Trial (the "TLC Study" or "Study"). The Circuit Court for Baltimore City granted summary judgment for KKI as to Ms. Ervin's, Mr. Hawkins's, and Mr. Johnson's (collectively, the "Relatives") claims. Mr. Ervin's claims went to trial, and he contends that the court erred when it denied his motion to exclude Dr. John Routt Reigart, KKI's medical causation expert or by declining to hold a *Frye-Reed* hearing[1] to establish the reliability of Dr. Reigart's testimony. He argues as well that the trial court's admission of Dr. Reigart's testimony wrongly sought to apportion the harm from Mr. Ervin's lead exposure. We disagree and affirm the judgments.

I. BACKGROUND

Mr. Ervin was born on October 11, 1993 and lived at 23 North Monroe Street from birth until April 1998. Within about eight months of his birth, he tested positive for elevated blood lead levels, although within acceptable norms at the time. By October 1995, however, Mr. Ervin's blood lead levels had reached a peak of 33 µg/dL for two consecutive blood tests.[2] His elevated blood lead level qualified him for a clinical trial that KKI was performing at the time, the TLC Study.

[1] *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923); *Reed v. State*, 283 Md. 374 (1978).

[2] Blood lead levels are measured in micrograms per deciliter (µg/dL) of blood. Presently, the CDC considers a blood-lead level of 5 µg/dL to be elevated to a "level of concern." *See Standard Surveillance Definitions and Classifications*, Center for Disease Control and

The TLC Study was designed to test the effects of a blood lead chelation medication, succimer, on the development of children who, at the time of enrollment, were between twelve and thirty-two months of age and had blood lead levels of 20-44 µg/dL. The Study was sponsored by the National Institute of Environmental Health Sciences ("NIEHS") and approved by the Institutional Review Boards of KKI, the University of Maryland, Johns Hopkins University, NIEHS, the Harvard School of Public Health, and the Centers for Disease Control. Children enrolled in the double-blind Study were treated with either succimer or a placebo for a period of up to six months, then had a minimum of two clinic visits and one home visit. Participation in the Study required the consent of a parent or legal guardian.

Study participants were followed for up to three years, and KKI assessed their development periodically. Children residing in the same home as a TLC Study participant could not participate in the Study during its treatment phase, but could "be sequentially entered after six months." Whether a participant received succimer or a placebo, all participants received "identical vitamin and mineral supplementation and a common lead dust management program" that could be supplemented depending on the budgets of the various clinical centers.

To be eligible for the Study, participants' homes had to be amenable to some type of clean-up; if the "residence [was] too lead-hazardous to be adequately cleaned and [the]

Prevention, https://www.cdc.gov/nceh/lead/data/definitions.htm (last updated Nov. 18, 2016).

child [could not] be relocated [to] lead-safe housing," the child could not participate. But "[i]t [was] not the objective of [the TLC Study] to carry out or oversee comprehensive lead paint abatement activities." The primary goal of the home clean-up was to reduce participant's "exposure to lead attributable to lead-based paint in poor condition and/or to lead-contaminated house-dust" for at least the six months of the treatment phase, and during "the greatest period of hand-to-mouth activity [] up to approximately 36 months of age," "[i]n order to be able to detect any long-term impact of succimer." The Study only guaranteed a "clean-up [] when a [Study participant] change[d] residences," so families of Study participants were "provided with educational materials and information on lead poisoning and how to minimize its occurrence," as well as cleaning supplies to maintain the Study's initial clean-up. The TLC Study protocol recognized that total lead abatement or relocation to lead-safe housing was usually not possible for many study participants, and that they were adopting "interim control measures" and not substituting their clean-up "for the legally mandated [lead paint abatement] activities carried out by local or state agencies in each city" or "reliev[ing] anyone of the responsibility to abate." The consent form that Mr. Ervin's mother signed provided that clean-up was intended to "reduce lead hazards in paint and dust," and that repairs would be made if "the owner or landlord [] give[s] his/her permission for the repairs" and "the owner has approval for a loan" to finance them. Likewise, the consent form for participation in the Study provided that KKI would "repair[] and/or clean[] [their home] to get rid of lead dust and chipped paint" or clean the home beyond the initial assessment only if the family notified the Study of damage.

Mr. Ervin was diagnosed with elevated blood-lead levels and referred to the TLC Study. Home inspectors provided by the Study determined that the 23 North Monroe Street residence did contain lead paint and was eligible for the TLC clean-up protocol; repairs were made in October 1995. Additional clean-up, in the form of painting deteriorated surfaces, was performed in April 1996.

Mr. Ervin and the Relatives lived at 23 North Monroe Street until April 1998. Mr. Ervin was one of the Study participants who received succimer, and although his blood lead levels experienced some fluctuations, they tended to decrease over the course of the Study;

Date Taken	Blood Lead Level
June 3, 1994	9 µg/dL
December 16, 1994	15 µg/dL
July 31, 1995	33 µg/dL
October 17, 1995[3]	**33 µg/dL**
November 8, 1995	15.8 µg/dL
December 13, 1995	22.9 µg/dL
December 28, 1995	38.3 µg/dL
December 31, 1995	33 µg/dL
February 23, 1996	12.3 µg/dL
March 15, 1996	23.1 µg/dL
May 3, 1996	26.7 µg/dL
May 31, 1996	11.1 µg/dL
June 7, 1996	11 µg/dL
June 17, 1996	15.4 µg/dL
July 1, 1996	23.2 µg/dL
October 30, 1996	22 µg/dL
April 11, 1997	22 µg/dL
October 21, 1997	16 µg/dL
June 2, 1998	21 µg/dL

[3] Mr. Ervin's first blood lead level test for the Study was conducted on October 17, 1995.

By the time of Mr. Ervin's final blood lead level test for the Study in June 1998, the family had relocated to 410 East 27th Street. After they moved, KKI conducted a lead risk assessment at the 410 East 27th Street property and determined that it presented a moderate lead risk but could be cleaned adequately using the TLC Study protocol. It does not appear that KKI ever conducted any clean-up activities at the 410 East 27th Street property, though, apparently due to scheduling issues.

The appellants filed their initial complaint against KKI on April 3, 2012. They alleged that KKI's tortious misconduct in the design and implementation of the TLC study exposed them to lead as children and permanently injured them. After extensive discovery and motions practice, trial was set for November 2016. Before trial, both sides filed motions for summary judgment. The appellants asked the trial court to decide as a matter of law that their lead-related brain injuries were indivisible and not subject to apportionment. They also argued that KKI owed all of them, including the Relatives, a duty of care. KKI's motion countered that KKI did not owe the Relatives a duty of care because they were not participants in the TLC Study. The trial court conducted a hearing, granted KKI's motion for summary judgment on the Relatives' claims, and denied both of appellants' motions.

The appellants also filed a motion *in limine* to exclude the testimony of Dr. Reigart, KKI's medical causation expert. They argued that Dr. Reigart's opinions were "novel," did not rely on accepted and reliable scientific methodology, and therefore were inadmissible. The appellants' and KKI's differences lay less in their understanding of the standards than

in the way each characterized Dr. Reigart's proposed testimony. As the appellants put it, Dr. Reigart sought to testify that children didn't suffer IQ losses from lead exposure after age two:

> This theory that all of the IQ loss from lead exposure happens – that the earliest exposures – that none of the exposure for years later, throughout childhood contributes to IQ loss is a novel scientific theory. This theory itself is not generally accepted within either the scientific or medical communities or the public health community which would be relevant here.

They asked the court to take judicial notice that this theory was not generally accepted in the medical community and to preclude Dr. Reigart from testifying:

> APPELLANTS' COUNSEL: And what I want to do, Your Honor, is when you evaluate this case, you could take judicial notice of things that are generally accepted. And, likewise, you can take judicial notice of things that are not generally accepted as reliable. And, because of that, Your Honor, you do not have to provide the proponents of Dr. [Reigart]'s theories an opportunity to have an evidentiary hearing with live expert testimony.
>
> You can shortcut this and decide this based on the evidence that's presented here and now and that's what we're going to ask you to do because there is more than enough information to eliminate Dr. [Reigart] from trying to use this all the IQ loss happens before there is TLC study theory up front.

KKI, on the other hand, contended that Dr. Reigert was opining about the timing of Mr. Ervin's injuries:

> KKI'S COUNSEL: This is not simply every single human being, anywhere under any circumstance is only injured by lead up to two years of age. That's not what [Dr. Reigart]'s saying.

> This is a case about Mr. Ervin and what [Dr. Reigart] [] [is] doing is looking at the facts related to Mr. Ervin and, then, concluding that it appears to them that the exposure to lead that injured him, occurred prior, that there was no further exposure subsequent. Therefore, the injury occurred beforehand.
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> … [O]ne of [the judge's] colleagues went through an evidentiary hearing with Dr. [Reigart] already with the exact same parties on the exact same issue. And Judge Peters found that this was generally accepted and, so, did not preclude Dr. [Reigart] from testifying.

The trial court ultimately decided not to undertake any *Frye-Reed* scrutiny of Dr. Reigart's testimony beyond considering the arguments and scientific articles presented at the *in limine* hearing, and denied the appellants' motion to exclude Dr. Reigart.

Mr. Ervin's case proceeded to trial. At trial, Dr. Reigart was admitted—without objection—as an expert in the field of pediatrics with special expertise in lead and its impact on childhood brain development, cognition, and thinking. Dr. Reigart's testimony, which we detail below, tracked KKI's characterization at the motions *in limine* hearing. The jury ultimately found that KKI did breach its duty to Mr. Ervin, but that the breach did not cause Mr. Ervin's injuries. Judgment was entered in favor of KKI on December 16, 2016. A timely notice of appeal followed.

II. DISCUSSION

The appellants raise four questions on appeal that we have consolidated into two: *first*, did the trial court err by admitting Dr. Reigart's expert testimony and *second*, did the

trial court err by granting summary judgment in favor of KKI on the Relatives' claims.[4] The appellants argue that Dr. Reigart's testimony was unreliable and prejudicial because he "assert[ed] that all injury from lead exposure curtails by the age of 2 years, and any potential injury thereafter is inconsequential," and improperly apportioned Mr. Ervin's injuries to previous exposure. They contend as well that Dr. Reigart's testimony lacked a sufficient foundation and "is contradicted by the large body of epidemiological studies currently accepted as reliable in the relevant medical and scientific community," and should have been subjected to a *Frye-Reed* hearing before the court allowed him to testify. Finally, the Relatives assert that because they lived in the same home as Mr. Ervin and

[4] In their brief, Appellants phrased the Questions Presented as follows:

1. Did the trial court err in admitting Dr. Reigart's general and specific medical causation testimony under Maryland Rule 5-702, thereby unduly prejudicing Appellants?
2. Did the trial court err in failing to hold a *Frye-Reed* hearing on Dr. Reigart's medication causation testimony, and further err in denying Appellants' motion to exclude Dr. Reigart when his testimony did not meet this standard?
3. Did the trial court err in failing to determine as a matter of law that Appellants' injuries from cumulative lead exposure during childhood are indivisible and incapable of apportionment of harm between successive intervals of exposure, and further err by admitting this prejudicial testimony into evidence?
4. Did the trial court err in ruling that Appellee, Kennedy Krieger Institute, Inc. did not owe a duty of care under common law negligence to protect relatives (Lakeisha Ervin, Marvin Hawkins and Shawn Johnson) of the registered Study participant (James Ervin) from foreseeable harm inherent in the research Study, when the relatives were vulnerable children, known to be residing in the Study home, and exposed to the same exact conditions from which researchers were collecting data?

were exposed to the same lead hazards throughout the course of the TLC Study, KKI owed them a duty of care.

A. Dr. Reigart's Testimony Regarding Mr. Ervin's Lead Damage Was Admissible And Did Not Require A *Frye-Reed* Hearing.

Appellants challenge Dr. Reigart's testimony under both MD. RULE 5-702 and *Frye-Reed*. Under either standard, the trial court did not err in admitting Dr. Reigart's testimony.

1. Dr. Reigart's testimony did not require a *Frye-Reed* hearing.

We don't disagree that if Dr. Reigart had sought to testify that lead damages children only during synaptogenesis and before the age of two years, that would be a novel scientific theory that would need to survive a *Frye-Reed* hearing (and likely would be excluded). But that's not what Dr. Reigart contended, and his actual testimony did not plow new scientific ground.

Under the *Frye-Reed* test,[5] the court may admit expert testimony if the expert witness's opinion and methodology "is generally accepted as reliable within the expert's particular scientific field." *Wilson v. State*, 370 Md. 191, 201 (2002). As part of this analysis, "the expert [must] bridge[] the 'analytical gap' between accepted science and his ultimate conclusions in [a] particular case." *Savage v. State*, 455 Md. 138, 160 (2017). The court can find this standard met without a hearing when "the validity and reliability of a

[5] "A *Frye-Reed* analysis is required, as a prerequisite to the application of Rule 5-702, only when the proposed expert testimony involves a 'novel scientific method,' in which event there must be some assurance that the novel method has gained general acceptance within the relevant scientific community." *Dixon v. Ford Motor Co.*, 433 Md. 137, 149–50 (2013).

scientific technique [is] broadly and generally accepted in the scientific community." *Reed v. State*, 283 Md. 374, 380 (1978). Of course, the reverse is also true, and the trial court may reject testimony without a hearing if the underlying theory has been rejected widely or is notoriously unreliable. *Id.* at 380. The decision whether an expert opinion is subject to a *Frye-Reed* test at all and whether the proposed testimony satisfies said test are legal issues we review *de novo*. *Wilson*, 370 Md. at 201 n.5.

In the course of their arguments on these issues, both parties use the term "judicial notice." This terminology is part of the *Frye-Reed* vernacular, but the way it's used in this context can be tricky and potentially misleading. Normally, a court may, at its discretion take judicial notice of a fact or document from an outside source, without a full evidentiary foundation, where the document or fact is undisputed and publicly available. *Abrishimian v. Washington Medical Group*, 216 Md. App. 386, 413–14 (2014). In the *Frye-Reed* context, the term has come to mean a finding (or maybe a recognition) that a particular opinion or methodology is or is not generally accepted, without the need for a hearing, because the answer is clear enough not to require one. *Id.* Maybe that's true because the scientific data point overwhelmingly in one direction, or maybe because another court already has considered it. The point is that the method or underlying science is or is not sufficiently well-accepted that the court is comfortable deciding the issue without a hearing.

In this Court, the appellants offer another gloss: they ask us to take judicial notice of scientific journal articles that hadn't been offered in the circuit court and, using these

new sources, to re-evaluate the circuit court's decision not to exclude Dr. Reigart's testimony or to require a *Frye-Reed* hearing. And indeed, "a court may take judicial notice of journal articles from reliable sources and other publications which may shed light on the ***degree of acceptance*** *vel non* by recognized experts of a particular process or view." *Montgomery Mut. Ins. Co. v. Chesson*, 399 Md. 314, 327 (2007) (emphasis added). But it overstates this notion of judicial notice to ask, as the appellants do, that we take judicial notice on appeal of the ***substantive research*** contained in peer-reviewed journal articles and determine anew, on an augmented record, whether the judgment should be vacated and the case remanded for a *Frye-Reed* hearing or a new trial.

But in any event the actual testimony at issue here doesn't test the limits of our judicial notice authority because the methodology and sources Dr. Reigart used to form his opinion were, in fact, generally accepted in the medical community. Dr. Zuckerberg, Mr. Ervin's own medical causation witness, used many of the same studies and sources for his opinion. And Dr. Reigart's testimony, read fairly, doesn't offer the extreme opinion the appellants suggest. Dr. Reigart opined that Mr. Ervin had not suffered harm from lead exposure after the age of two *because he wasn't exposed to any more lead after that time*. Additionally, Dr. Reigart's testimony was admitted and he had testified to the same expert opinion before another judge of the circuit court about Mr. Ervin's injuries. On both direct and cross-examination, he explained the science behind synaptogenesis and how that caused Mr. Ervin's IQ damage, and explained as well why Mr. Ervin wasn't damaged further after he enrolled in the TLC Study:

KKI'S COUNSEL: All right. Are there critical stages of a child's brain development?

DR. REIGART: Depending on how you categorize them, there are probably five or six critical stages and it's recognized not just with lead but with a whole variety of toxicants that these critical stages can be affected by toxic events as well as childhood stress. We mentioned toxic stress. And just to lay them out sort of real quick, the first thing that happens when you – and this, by the way I should say this is not just children. Every mammal has the same pattern and development. They occur different rates depending on whether you're a mouse, or a rat, or a human. But the first thing that happens is the very embryonic brain makes a bunch of cells and then those cells migrate. They go to the places where they will form the various structures in the brain. The third event is that those cells form connections which we call synapses. So they're sort of like in your computer the connection across the different places. The third thing – actually, they occur almost simultaneously. The third and fourth thing is the body then takes this mass of synapses and all these cells and these early structures and starts to refine them. And so the first thing it does is it gets rids [sic] of the synapses or connections that aren't doing anything, are less useful, if you will, and the cells that are involved with that die and that's called program cell death.

MR. ERVIN'S COUNSEL: Your Honor, may we approach?

THE COURT: Sure. Come on up. Excuse me, Doctor.

MR. ERVIN'S COUNSEL: I think we're getting beyond what a pediatrician and beyond his designation and more in neurology, Your Honor, than he's even indicated he has an ability to testify to.

KKI'S COUNSEL: Your Honor, I think he was accepted in the specialized –

THE COURT: Childhood brain development –

KKI'S COUNSEL: – without objection – childhood brain development, cognition and thinking.

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THE COURT: Okay. All right. But you can ask him about this.

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DR: REIGART: Okay. So we have the program cell death, the pruning of the synapses or connections, and then the final step is what we call myelination which is goes on until your teens which is the coating of the cells once they're established and to make sure they're okay to do their job…

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DR. REIGART: … And these photographs show you that when you're – when a child's born, they're basically nearly the same number of cells. There are not many connections or synapses between them. As you get a little older, you get a lot more synapses, and the peak of synapses is at age two …I'm saying that at age two, you have the most complex set of synapses. And this is a pretty good explanation for the "terrible twos," that we have all these extra connections. We have total control of them. And as I said earlier, as yet growing older, the synapse development slows down, and by age three it's almost complete, although some of it goes on into adolescence.

But what also begins to happen at age two, after age two, is you start to do that pruning of useless synapses and have the death of cells without doing anything.

KKI'S COUNSEL: Doctor, if something were to interfere with the development of the synapses, say lead gets into the brain and those synapses aren't developed, is there any other time in life where your brain can develop those synapses?

DR. REIGART: No.

MR. ERVIN'S COUNSEL: Objection.

THE COURT: Basis?

MR. ERVIN'S COUNSEL: Same basis, Your Honor.

THE COURT: Overruled. Let's continue, Mr. –

DR. REIGART: Okay. So –

MR. ERVIN'S COUNSEL: Okay. Thank you.

DR. REIGART: – this is when it happens. If it doesn't happen, it doesn't ever happen. If you think – I mentioned computers earlier. It's, like, you don't have enough to start with so if you start trying to fix it by getting rid of the ones that aren't very useful, you have less ability to do that, but you also have more cell death. So you're likely to have, in whatever region of the brain this is happening, less volume. So you get a little less brain tissue.

KKI'S COUNSEL: So if lead were to interfere with this, is that then a permanent injury?

DR. REIGART: Yes.

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KKI'S COUNSEL: Doctor, is what you're talking about here, the development of these synapses up to age two, generally accepted in the scientific and medical community?

DR. REIGART: I didn't say up to age two. I said it peaks at age two, and is tailing off by age three. And, yes, it's generally accepted.

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KKI'S COUNSEL: Let me show you Kennedy Krieger's 64. Are you familiar with this encyclopedia?

DR. REIGART: Yes.

KKI'S COUNSEL: And when something ultimately gets into an encyclopedia, does that mean it's generally accepted?

DR. REIGART: Yes, of course.

KKI'S COUNSEL: And is this information that you just shared with the jury about brain development and how lead impacts brain development during this time period generally accepted?

DR. REIGART: Yes.

KKI'S COUNSEL: In fact, is it in encyclopedias like KKI 64?

DR. REIGART: Yes, it is.

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KKI'S COUNSEL: And so, Doctor, if, in fact, something were to interfere with the brain growth, say lead, does the brain ever have an opportunity to catch up?

DR. REIGART: No, unfortunately. I think it's important to recognize that – well, I don't think your brain on – introducing – there's several review articles that look at susceptibility of the brain at various ages to various toxicants.

KKI'S COUNSEL: And when you say "articles," you're speaking of peer-reviewed journal articles?

DR. REIGART: Peer-reviewed review articles look at hundreds of papers, and in those they talk about critical periods of development where the brain is more susceptible to various toxicants, one of which is lead. That's not the only one.

KKI'S COUNSEL: But is lead, if someone were to be impacted by lead, say from birth to two years of age, would that be a permanent injury?

DR. REIGART: Yes.

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KKI'S COUNSEL: Doctor, let's talk about lead and how it impacts a young child. We've mentioned it briefly, but we've

heard about blood lead levels. Why do doctors check a young child's blood lead levels?

DR. REIGART: Well, it's really the only method we have to see how much lead is in a child. It's – the lead in the blood is actually a small proportion of the total body lead, but we – it's the only tissue we can get at easily.

KKI'S COUNSEL: Now, when we – "we," I mean doctors, test the lead – and we've talked about some of Mr. Ervin's blood lead levels. If you have a number, say 33, does that mean it's exactly 33 or is there some margin of error in that?

DR. REIGART: Well, I would answer that question with a little prelude, which is that it's one of the strongest tenets in management of lead poisoning that you never make a decision on management based on a single blood lead, particularly if it's different from ones that have occurred before.

So if you have one that's out of range of the others, or appears to be out, you do it again and make sure it's not a problem. And the problems occur from actually three directions.

One, there can be error in the lab. And the standard – back when this was going on, it's gotten a little better, was that the acceptable lab error is plus or minus 10 percent of the number you're given. So you mentioned a blood lead of 30. Even in a good lab, that 30, if you measured it three times in that lab, the real number might be plus or minus three. So it could be anywhere from 27 to 33. So that's lab.

The second, and this has been well demonstrated in some of the kinetic studies, is during the day and day-to-day, there's some variation within the child that's probably plus or minus another 10 percent. So when you stick that in any given result, your confidence, say of a 30, would be anywhere from 24 to 36. My arithmetic in my head doesn't work as well these days.

Then in addition, all sorts of things can cause a child's lead to vary from day to day. If they get dehydrated, if they go to bed for a couple of days, that causes lead to come out of the bone and may increase the blood lead….

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KKI'S COUNSEL: Doctor, while there is some variability, and what you might call a margin of error –

DR. REIGART: Right.

KKI'S COUNSEL: – in blood lead levels, is it still, kind of, the –

DR. REIGART: That's what you have to use, –

KKI'S COUNSEL: – thing that you all use?

DR. REIGART: – but you, you know, you – like I said, you don't make changes in how you manage someone or your assessment of a child on a single blood lead.

KKI'S COUNSEL: Doctor, we talked a little bit earlier when I was speaking with you this morning about IQ. Are there studies that have been developed, and published in peer-reviewed journal articles, that talk about how much IQ is associated with certain blood lead levels?

DR. REIGART: Well, we've been doing this for many, many years. One of the first really good studies was 1979, Dr. Needleman. That was cross-sectional. Then there have been a whole series of longitudinal studies.

KKI'S COUNSEL: What's a longitudinal study, briefly?

DR. REIGART: Well, there are two ways you can study. Look at a whole bunch of children at one time. That's cross-sectional. Or you can take children of a certain age and follow them over time and see what their blood lead does over time. That's a longitudinal study –

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KKI'S COUNSEL: Doctor, are there ever – you, kind of, called "review" articles. Are there ever times when scientist doctors

who are going to be studying something, like yourself, look at a lot of different studies and try to pull them together so that you can come to some kinds of conclusions?

DR. REIGART: That's what's called a meta analysis, where you try and get similar studies and combine them to have greater strength in the observations.

KKI'S COUNSEL: Has there ever been one done where multiple studies from around the world have been brought together to analyze IQ loss based on certain blood lead levels?

DR. REIGART: Yes.

KKI'S COUNSEL: And are you familiar with that document?

DR. REIGART: Yes.

KKI'S COUNSEL: Who was the lead author on that study?

DR. REIGART: That one was Bruce Lanphear.

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KKI'S COUNSEL: All right. And did they come to some conclusions with regard to how much IQ is lost at certain blood lead levels?

DR. REIGART: As – well, as you can see, I don't need to draw it out. I think the jury can see that they concluded that with a rise of blood lead between 2.4 to ten, there was about a four-point IQ loss; from ten to 20, about two; and from 20 to 30, about one.

Interesting thing about this is that this was, sort of, the best study to that date that showed that even at quite low blood lead levels there was a loss in IQ, and it was greater with the changes – the lower changes than when you get a little higher.

KKI'S COUNSEL: You mean the lower blood lead levels?

> DR. REIGART: Yeah. 'Cause if, you know, if you look at – again, what happened between two-and-a-half and ten, there was loss of four. And then you go ten to 20, which is about the same distance, you only have a loss of 2, so.
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> KKI'S COUNSEL: What peer-reviewed journal articles was this published in, Doctor?
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> DR. REIGART: That was in Environmental Health Perspectives.
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> KKI'S COUNSEL: Is this generally accepted in the scientific medical community as reasonably reliable?
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> DR. REIGART: Pretty much everybody quotes it now, so I think you can say that, yes.
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> KKI'S COUNSEL: In fact, hypothetically, if Plaintiff's own expert, Dr. Zuckerberg, said he relied on this, would that surprise you?
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> DR. REIGART: No.

We agree with the circuit court that Dr. Reigart's proffered and actual testimony relied on accepted scientific sources, and his opinion about the timing and extent of Mr. Ervin's lead injuries did not require a *Frye-Reed* hearing.

2. Dr. Reigart's testimony was admissible under Md. Rule 5-702.

Under Rule 5-702, we review the admission of expert testimony for abuse of discretion. *Brown v. Contemporary OB/GYN Assocs.*, 143 Md. App. 199, 252 (2002). To be admitted as an expert, the witness must demonstrate that he or she is "competent to express an expert opinion if he [or she] is reasonably familiar with the subject under investigation regardless of whether this special knowledge is based upon professional training, observation, actual experience, or any combination of these factors." *Radman v.*

Harold, 279 Md. 167, 169 (1977). It is unnecessary for an expert witness to have the title of "specialist" in a field if he or she is otherwise competent to testify. *Id.* at 172 ("artificial classification by title" does not determine the expert's competency to testify); *see also Deese v. State*, 367 Md. 293, 303 (2001) ("[W]hen the expert, although not a specialist in the field having the most sharply focused relevancy to the issue at hand, nevertheless could assist the jury in light of the witness's formal education, professional training, personal observations, and actual experience" it is not an abuse of the court's discretion to admit him.). Once the trial court has ascertained the expert's qualifications, it must determine if the expert's opinions will "assist the trier of fact to understand the evidence or to determine a fact in issue." MD. RULE 5-702. And the expert must "provide a sound reasoning process for inducing [his] conclusion[s] from the factual data" and have "an adequate theory or rational explanation of how the factual data led to [his] conclusion[s]." *Exxon Mobil Corp. v. Ford*, 433 Md. 426, 481 (2013); *see* MD. RULE 5-702(3). Under Rule 5-702, "[a] trial judge has wide latitude in determining whether expert testimony is sufficiently reliable to be admitted into evidence, and his sound discretion will not be disturbed on appeal unless the decision to admit the expert testimony was clearly erroneous or constituted an abuse of discretion." *Montgomery Mut. Ins. Co.*, 399 Md. at 327.

KKI offered Dr. Reigart as its medical causation expert. The trial court found him qualified to testify as an expert in the field of pediatrics with special expertise in lead and its impact on childhood brain development, cognition, and thinking—and did so after he was offered without objection. Dr. Reigart satisfied the qualifications requirement of Rule

5-702(1). His testimony was offered to help the jury understand KKI's defense that it did not contribute to Mr. Ervin's lead poisoning injuries. Dr. Reigart examined Mr. Ervin's medical records and determined that, in his opinion and to a reasonable degree of medical certainty, Mr. Ervin neither ingested nor was exposed to additional lead after being accepted into the TLC study. Over the course of direct and cross-examination, Dr. Reigart explained the factual basis upon which he made his opinion that Mr. Ervin was not further injured by lead while participating in the TLC Study, despite fluctuating blood lead levels.

> KKI'S COUNSEL: So based on the blood lead levels that Mr. Ervin had before he got into the TLC Study October 1995, based on the pooled analysis, what estimate of IQ would he have already experienced?
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> DR. REIGART: Well, now, remember this analysis didn't go above 30, and he was a 33. But we already said a 33 could be either side of that. So be approximately, on the average, a loss of about 7 IQ points. Could be more, could be less.
>
> KKI'S COUNSEL: And, Doctor, with regard to this information – just make sure – is that a permanent injury on the part of Mr. Ervin by the time he entered the TLC Study October 1995?
>
> DR. REIGART: Yes.
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> ***
>
> KKI'S COUNSEL: And have you looked at his blood lead levels that came after his involvement in the TLC Study?
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> DR. REIGART: Yes.
>
> ***
>
> KKI'S COUNSEL: So, Doctor, what I was asking you is, we see the blood lead levels you've just discussed, 9, 15, 31, 33,

33 again. Now we're in October of 1995 when he enters TLC. We see what appear to be drops going up and down. What's going on there in Mr. Ervin?

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DR. REIGART: Well, just to remind you, he was in the so-called TLC Trial where some children were given what's called placebo. And everybody says placebo is a sugar pill, but it wasn't exactly that, and some were actually given the succimer trial. And what you can tell from these is that he was one of the participants that got the active drug. And so I don't know why they didn't put it on this graph. I wouldn't have done it that way. I would have labeled it because right here (indicating) is one of the doctor's first course of either drug or placebo. And the fact that his blood dropped so much tells me, almost certainly, he got the drug rather than the placebo because the placebo kids didn't have those drops.

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DR. REIGART: I mentioned earlier that the lead in blood's only a small amount of lead in the body, and succimer is mostly taking it out of the blood. So if you took all of it out of the blood, it's still going to rebound back up.

KKI'S COUNSEL: Why? That's what I was going to ask you.

DR. REIGART: Well, –

KKI'S COUNSEL: What is this rebound that you're talking about?

DR. REIGART: – so it's coming from other tissues, and probably a lot of it actually is coming from bone because that's the biggest repository.

KKI'S COUNSEL: So if an individual like James Ervin has succimer, and his blood lead level goes down –

DR. REIGART: Yes.

KKI'S COUNSEL: – but then after he's done with that course of succimer and it goes back up, does that mean he's getting exposed to lead again or is that the rebound you're talking about?

DR. REIGART: No. I mean, I shouldn't be so blanket. I mean, it's always possible, but more likely than not in this situation it's simply rebound. Okay? So then what happens is he has his 38.3, which we explained the variability and how it can change from day to day. You don't make a decision based on a single result. It's probably not different from these. 38 is probably not different from 33.

So he gets the drug again, and no one in the trial was allowed more than three courses. And so he goes down again. He bounces back up, but not as far this time which is good, we think. But it's still in a range which justified being treated one more time, which happened. And again it rebounds, but, you know, it's way below what he was before. And then, thereon, as he gets older, it continues to decline.

***

KKI'S COUNSEL: That's okay. With regard to the blood lead levels, have you ever done any research yourself, and not just by yourself, with regard to how long it takes an individual who has an elevated blood lead level, who is now in a relatively clean environment, to have their blood lead levels come down? Have you done that research personally?

DR. REIGART: Well, there are two important papers, and mine is the least important, but Dr. Roberts is a guy I hired, and talked, and got into the lead business. One of the first jobs I had to do was go take a look at all the kids we had taken care of over the years. And at one point, we had as many as 1,200 kids that we were taking care of –

MR. ERVIN'S COUNSEL: Objection, Your Honor.

DR. REIGART: – at one point. And of all those kids, he looked at how long it took them for their blood lead to get below this action threshold of ten.

KKI'S COUNSEL: Was that published in a peer-reviewed journal?

DR. REIGART: Yes. It was published in a peer-reviewed journal. Then Dr. Dignam and his coworkers did it even on an even larger group, and their results were very similar to ours.

***

KKI'S COUNSEL: Can you come to any conclusion, based on your own research, that of Dr. Roberts and Dr. Dignam, as to whether or not [Mr. Ervin]'s continuing to be exposed to lead or not, after [October of 1995]?

DR. REIGART: His decline fit within the parameters that we would expect for someone that's in case management, and not being actively exposed.

KKI'S COUNSEL: After October of 1995?

DR. REIGART: Correct.

***

KKI'S COUNSEL: So, Doctor, in talking about the blood lead levels that we just looked at, did Mr. Ervin's blood lead levels ever go substantially above the 33 that he started out with before the – he joined the TLC study?

DR. REIGART: No.

KKI'S COUNSEL: So based on the pooled analysis that you discussed and how you've described the development of the brain, did he suffer any additional IQ loss after he joined the TLC Study in 1995?

DR. REIGART: No.

KKI'S COUNSEL: And you hold that opinion to a reasonable degree of scientific certainty?

DR. REIGART: Yes.

KKI'S COUNSEL: And is that analysis that you're using, using the pooled analysis, looking at the blood lead levels of an individual, is that generally accepted in the scientific and medical community?

DR. REIGART: Yes.

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KKI'S COUNSEL: Dr. Reigart, based on our review of all the medical records, some of which you discussed with the jury, did Mr. Ervin already have developmental issues having nothing to do with lead before he entered the TLC Study in October '95?

DR. REIGART: I would say more likely than not, yes.

KKI'S COUNSEL: And then with regard to lead exposure, was Mr. Ervin exposed to lead and had taken lead into his body before he entered the TLC Study in October 1995?

DR. REIGART: Yes.

***

KKI'S COUNSEL: Doctor, did Kennedy Krieger have anything to do with Mr. Ervin's permanent IQ loss before he had gotten into the TLC Study in October 1995?

DR. REIGART: No.

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KKI'S COUNSEL: And you hold that opinion to a reasonable degree of medical certainty?

DR. REIGART: Yes.

***

KKI'S COUNSEL: Dr. Reigart, when Mr. Ervin entered the TLC Study in October of 1995, was he two years old?

DR. REIGART: Yes, he was.

KKI'S COUNSEL: I asked you whether or not there was any IQ injury after October of 1995 due to lead. You said, "No." Was there any other injury that you saw from additional exposure to lead after October of 1995?

DR. REIGART: No.

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MR. ERVIN'S COUNSEL: Doctor, are you saying that all of the damages was done to Mr. Ervin by the time he was age 2?

DR. REIGART: All that we could measure, yes.

***

MR. ERVIN'S COUNSEL: Okay. But at least at this point, they indicate that what you – your theory of this case would not be correct if what [other experts with contrary opinions] said was true?

DR. REIGART: Let's correct something here. It's not my theory and that's a legal term not a medical term. It is my understanding that this child had suffered an IQ loss before he entered the study of approximately 7 IQ points, perhaps some more or less from lead, that he did not have additional exposure to lead during the study and, therefore, suffered no additional damage.

MR. ERVIN'S COUNSEL: Okay.

DR. REIGART: That is my opinion on this case.

MR. ERVIN'S COUNSEL: Part of your opinion is that the damage is done by the time the child is two or three years of age, correct?

DR. REIGART: I said that is the critical period where most of it. I can't say 100 percent. If you were to ask me could [Mr. Ervin] have lost one more IQ point after that, I'd say, "Yes, that's possible," but I can't measure a difference of one IQ point. You know I might be one smarter than you or one dumber than you, but we'd never be able to figure it out.

So I will say that he lost seven before he got in there and if there was any additional damage, which is possible, I won't say it's impossible, it wasn't because of additional exposure and it was too small to measure.

MR. ERVIN'S COUNSEL: Okay. Let's talk about that for a second. It's your opinion that there was no additional exposure to lead by Mr. Ervin after October of 1995?

DR. REIGART: From a medical point of view, there's no evidence that based on his blood lead levels, that he had additional lead exposure.

MR. ERVIN'S COUNSEL: Okay. Have you looked at the – Kennedy Krieger's assessment of the house at the time he was enrolled?

DR. REIGART: So I said earlier I read that. I'm not an expert in housing.

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MR. ERVIN'S COUNSEL: Okay. But as an expert in cases, you rely upon the opinions of others as part of your job, correct?

DR. REIGART: Right.

MR. ERVIN'S COUNSEL: Okay. And a lead assessor would be in a better position, who actually went to the house, would be in a better position to determine whether there was continued lead exposure in October, and November, and December of 1995?

> DR. REIGART: Well, the question would be, was there lead in the house? Now, there's two things that are important here based on all of the patients that's [sic] I've observed over the many years which is that there are many children that live in houses that you would expect them to be lead poisoned who aren't, and there are children in houses that you think are beautiful who get lead-poisoned.
>
> So as a physician, I'm forced to rely on patterns of blood lead which is what we call internal dose. Not how much is in the child's environment, but how much actually gets into it. And there's nothing there that indicates, even if there was lead in the house, and I'm not going to speak to that, that he was getting more into him.
>
> MR. ERVIN'S COUNSEL: I thought you just indicated a minute ago that there was not continued lead exposure for this –
>
> DR. REIGART: No. I said there was no internal exposure. He did not get more lead in his body. I shouldn't have used the term "exposure."

Dr. Reigart reached his medical opinion by analyzing the amount of lead in Mr. Ervin's blood which, he opined, demonstrated instead that earlier lead deposits were leaking back into his blood from other sources, such as his bones, rather than ongoing exposure. This testimony was offered by a qualified witness, supported by generally known and accepted scientific principles, and flowed directly from the record in this case. The trial court did not abuse its discretion by admitting Dr. Reigart's testimony.

3. Dr. Reigart's testimony did not apportion Mr. Ervin's harm.

The appellants also contend that Dr. Reigart attempted impermissibly to apportion the harm Mr. Ervin suffered. But again, this characterization of Dr. Reigart's testimony as apportioning is not reflected in the trial transcripts.

There are two primary tests to establish liability for lead paint poisoning in Maryland law: the "substantial factor" test and the "but for" test. *Pittway Corp. v. Collins*, 409 Md. 218, 244 (2009). "[T]he 'but for' test applies when the injury would not have occurred in the absence of the defendant's negligent act." *Yonce v. SmithKline Beecham Clinical Laboratories, Inc.*, 111 Md. App. 124, 138 (1996). Substantial factor causation is typically used "where independent causes produce an injury that would have occurred as a result of each cause alone," *Mayer v. North Arundel Hosp. Ass'n Inc.*, 145 Md. App. 235, 246 (2002), and so a defendant's negligence is a cause-in-fact of the plaintiff's injuries when it is "a substantial factor in bringing about the harm." RESTATEMENT (SECOND) OF TORTS § 431. This test eliminates the need to "rule out" or "exclude" other possible sources of the harm or "show that one cause had a greater impact than any other substantial factor causing the harm." *Levitas v. Christian*, 454 Md. 233, 250 (2017). "[T]he substantial factor test, by its very definition, permits more than one cause of injury." *Id.*; *see also Hamilton v. Kirson*, 439 Md. 501, 530 (2014); *Rogers v. Home Equity USA, Inc.*, 453 Md. 251, 268 (2017); *Levitas v. Christian*, 454 Md. 233, 250 (2017).

The appellants characterize Dr. Reigart as testifying that despite continuous lead exposure, and presumably ingestion, Mr. Ervin suffered no additional harm after the age of two years. But Dr. Reigart actually opined that Mr. Ervin did not suffer from continued lead exposure after entering the TLC study, and thus that KKI did not harm Mr. Ervin:

> DR. REIGART: Let's correct something here. It's not my theory and that's a legal term not a medical term. It is my understanding that this child had suffered an IQ loss before he entered the study of approximately 7 IQ points, perhaps some

> more or less from lead, that he did not have additional exposure to lead during the study and, therefore, suffered no additional damage.
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> MR. ERVIN'S COUNSEL: Part of your opinion is that the damage is done by the time the child is two or three years of age, correct?
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> DR. REIGART: I said that is the critical period where most of it. I can't say 100 percent. If you were to ask me could [Mr. Ervin] have lost one more IQ point after that, I'd say, "Yes, that's possible," but I can't measure a difference of one IQ point. You know I might be one smarter than you or one dumber than you, but we'd never be able to figure it out.
>
> So I will say that he lost seven before he got in there and if there was any additional damage, which is possible, I won't say it's impossible, it wasn't because of additional exposure and it was too small to measure.
>
> MR. ERVIN'S COUNSEL: Okay. Let's talk about that for a second. It's your opinion that there was no additional exposure to lead by Mr. Ervin after October of 1995?
>
> DR. REIGART: From a medical point of view, there's no evidence that based on his blood lead levels, that he had additional lead exposure.

Dr. Reigart was not attempting to apportion the amount of harm Mr. Ervin suffered from continuous lead exposure from birth to the conclusion of the TLC Study, but was instead distinguishing the source that caused his harms. We see no error in this regard.

B. Kennedy Krieger Did Not Owe A Duty To Mr. Ervin's Relatives Who Also Lived In The Home.

Finally, the Relatives challenge the entry of summary judgment on their claims, and the court's conclusion, as a matter of law, that KKI did not owe them, as non-participants

in the TLC Study a duty of care. We agree with the circuit court. The TLC Study was a therapeutic treatment designed to study the effects of succimer on individual development, not an environmental study that required families to consent to reside in lead dangerous locations and landlords to abstain from repairing known lead hazards in their properties. *White v. Kennedy Krieger Institute, Inc.*, 221 Md. App. 601, 627 (2015) ("We hold that the TLC Study at issue in this case was a therapeutic rather than a nontherapeutic study …, thus distinguishing the TLC Study from the R & M Study.").

"'In reviewing a grant of a summary judgment, we are first concerned with whether a genuine dispute of material fact exists' and then whether the movant is entitled to summary judgment as a matter of law." *Grimes v. Kennedy Krieger Institute, Inc.*, 366 Md. 29, 71 (2001) (citations omitted). "The standard of review for a grant of summary judgment is whether the trial court was legally correct." *Goodwich v. Sinai Hosp. of Balt., Inc.*, 343 Md. 185, 204 (1996) (citations omitted). We review the legal correctness of the trial court's legal conclusions *de novo*. *See Yourik v. Mallonee*, 174 Md. App. 415, 423 n. 2 (2007).

To allege personal harm a plaintiff must show "1) that the defendant was under a duty to protect the plaintiff from injury, 2) that the defendant breached that duty, 3) that the plaintiff suffered actual injury or loss, and 4) that the loss or injury proximately resulted from the defendant's breach of the duty." *Rosenblatt v. Exxon Co., U.S.A.*, 335 Md. 58, 76 (1994). Stated most generally, a duty is "an obligation, to which the law will give recognition and effect, to conform to a particular standard of conduct toward another." *Doe v. Pharmacia & Upjohn Co., Inc.*, 388 Md. 407, 415 (2005) (cleaned up). As a general rule,

"there is no duty to protect a victim ... in the absence of a statute, contract, or other relationship between the party in question and the [harmful agent], which imposes a duty to control the [harm], or between the party in question and the victim, which imposes a duty to protect the victim." *Corinaldi v. Columbia Courtyard, Inc.*, 162 Md. App. 207, 219 (2005) (citations omitted). Further, foreseeability of potential or derivative harm to third parties will not, by itself, give rise to a duty. *See Doe v. Pharmacia & Upjohn Co.*, 388 Md. 407, 417 (2005); *Dehn v. Edgecombe*, 384 Md. 606 (2005). "Whether a legal duty exists between parties is a question of law to be decided by the court." *100 Investment Ltd. Partnership v. Columbia Town Center Title Co.*, 430 Md. 197, 211 (2013).

In the context of lead paint, the Baltimore City Housing Code mandates landlords have a duty to protect their child tenants from the health hazards of lead exposure. *See Brooks v. Lewin Realty III, Inc.*, 378 Md. 70 (2003); *Allen v. Dackman*, 413 Md. 132 (2010); *Polakoff v. Turner*, 385 Md. 467 (2005); *Hamilton*, 439 Md. 501. Maryland courts have also recognized the possibility that a special relationship may form between researchers and children to be exposed to lead in the context of non-therapeutic research studies. *Compare Grimes*, 366 Md. 29 *with White*, 221 Md. App. 601. In *Grimes*, the Court of Appeals found that KKI owed a duty to the child test subjects in a different study based on the (at least potentially) non-therapeutic nature of the study and the significant risk of lead exposure from environmental conditions KKI created and controlled. *Grimes*, 366 Md. at 93.

This is a different study, and an indisputably therapeutic one. A trial court shall grant a motion for summary judgment in favor of the movant when "the motion and response show that there is no genuine dispute as to any material fact and that the party in whose favor judgment is entered is entitled to judgment as a matter of law." MD. RULE 2-501(f). The material facts are not disputed: the Relatives were not part of the TLC Study and KKI did not exert control over the conditions at the appellants' residence. Unlike *Grimes*, the lead clean-up portion of the TLC Study was a condition precedent to participation and Study participants were permitted to select their own residences and given the information and tools necessary to limit lead exposure. Landlords were permitted and encouraged to undertake lead paint abatement in Study participants' homes when possible. We have held previously that the TLC Study was a therapeutic study that did not create a special relationship between KKI and Relatives, *White*, 221 Md. App. at 627, and that precedent controls here as well.

JUDGMENT OF THE CIRCUIT COURT FOR BALTIMORE CITY AFFIRMED. APPELLANT TO PAY COSTS.