[J-92A-2019, J-92B-2019, J-92C-2019, J-92D-2019 and J-92E-2019]
IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

SAYLOR, C.J., BAER, TODD, DONOHUE, DOUGHERTY, WECHT, MUNDY, JJ.

RICHARD THOMAS WALSH, EXECUTOR OF THE ESTATE OF THOMAS J. WALSH, DECEASED	:	No. 14 WAP 2019
	:	Appeal from the Order of the Superior Court entered June 20, 2018 at No. 1661 WDA 2016 vacating the Order of the Court of Common Pleas of Allegheny County entered October 14, 2016 at No. GD 10-018588, and remanding
v.	:	
BASF CORPORATION; BAYER CORPORATION D/B/A BAYER CROPSCIENCE, L.P., AND BAYER CROPSCIENCE HOLDING, INC., AND/OR BAYER CROPSCIENCE, L.P. AND BAYER CROPSCIENCE HOLDING, INC., IN THEIR OWN RIGHT; BIOSAFE SYSTEMS, L.L.C.; CHEMTURA CORPORATION; CLEARY CHEMICAL CORP.; DOW AGROSCIENCES, L.L.C.; E.H. GRIFFITH, INC.; E.I. DU PONT DE NEMOURS AND CO., INC.; G.B. BIOSCIENCES CORPORATION; JOHN DEERE LANDSCAPING, INC., SUCCESSOR TO LESCO, INC.; MONSANTO COMPANY; NUFARM AMERICAS, INC.; REGAL CHEMICAL CO.; SCOTTS-SIERRA CROP PROTECTION CO.; AND SYNGENTA CROP PROTECTION, INC.	:	ARGUED: October 16, 2019
APPEAL OF: DOW AGROSCIENCES, LLC, BAYER CROPSCIENCE, LP, BAYER CORPORATION, AND BAYER CROPSCIENCE HOLDING, INC.	:	
RICHARD THOMAS WALSH, EXECUTOR OF THE ESTATE OF THOMAS J. WALSH, DECEASED	:	No. 15 WAP 2019
	:	Appeal from the Order of the Superior Court entered June 20, 2018 at No.

	:	1661 WDA 2016, vacating the Order
v.	:	of the Court of Common Pleas of
	:	Allegheny County entered October
	:	14, 2016 at No. GD 10-018588, and
BASF CORPORATION; BAYER	:	remanding
CORPORATION D/B/A BAYER	:	
CROPSCIENCE, L.P., AND BAYER	:	ARGUED: October 16, 2019
CROPSCIENCE HOLDING, INC.,	:	
AND/OR BAYER CROPSCIENCE, L.P.	:	
AND BAYER CROPSCIENCE HOLDING,	:	
INC., IN THEIR OWN RIGHT; BIOSAFE	:	
SYSTEMS, L.L.C.; CHEMTURA	:	
CORPORATION; CLEARY CHEMICAL	:	
CORP.; DOW AGROSCIENCES, L.L.C.;	:	
E.H. GRIFFITH, INC.; E.I. DU PONT DE	:	
NEMOURS AND CO., INC.; G.B.	:	
BIOSCIENCES CORPORATION; JOHN	:	
DEERE LANDSCAPING, INC.,	:	
SUCCESSOR TO LESCO, INC.;	:	
MONSANTO COMPANY; NUFARM	:	
AMERICAS, INC.; REGAL CHEMICAL	:	
CO.; SCOTTS-SIERRA CROP	:	
PROTECTION CO.; AND SYNGENTA	:	
CROP PROTECTION, INC.	:	
	:	
	:	
APPEAL OF: DEERE & COMPANY	:	
RICHARD THOMAS WALSH,	:	No. 16 WAP 2019
EXECUTOR OF THE ESTATE OF	:	
THOMAS J. WALSH, DECEASED	:	Appeal from the Order of the Superior
	:	Court entered June 20, 2018 at No.
	:	1661 WDA 2016, vacating the Order
v.	:	of the Court of Common Pleas of
	:	Allegheny County entered October
	:	14, 2016 at No. GD 10-018588, and
BASF CORPORATION; BAYER	:	remanding
CORPORATION D/B/A BAYER	:	
CROPSCIENCE, L.P., AND BAYER	:	ARGUED: October 16, 2019
CROPSCIENCE HOLDING, INC.,	:	
AND/OR BAYER CROPSCIENCE, L.P.	:	
AND BAYER CROPSCIENCE HOLDING,	:	
INC., IN THEIR OWN RIGHT; BIOSAFE	:	
SYSTEMS, L.L.C.; CHEMTURA	:	
CORPORATION; CLEARY CHEMICAL	:	
CORP.; DOW AGROSCIENCES, L.L.C.;	:	

E.H. GRIFFITH, INC.; E.I. DU PONT DE NEMOURS AND CO., INC.; G.B. BIOSCIENCES CORPORATION; JOHN DEERE LANDSCAPING, INC., SUCCESSOR TO LESCO, INC.; MONSANTO COMPANY; NUFARM AMERICAS, INC.; REGAL CHEMICAL CO.; SCOTTS-SIERRA CROP PROTECTION CO.; AND SYNGENTA CROP PROTECTION, INC. APPEAL OF: SYNGENTA CROP PROTECTION, INC.	:	
RICHARD THOMAS WALSH, EXECUTOR OF THE ESTATE OF THOMAS J. WALSH, DECEASED v. BASF CORPORATION; BAYER CORPORATION D/B/A BAYER CROPSCIENCE, L.P., AND BAYER CROPSCIENCE HOLDING, INC., AND/OR BAYER CROPSCIENCE, L.P. AND BAYER CROPSCIENCE HOLDING, INC., IN THEIR OWN RIGHT; BIOSAFE SYSTEMS, L.L.C.; CHEMTURA CORPORATION; CLEARY CHEMICAL CORP.; DOW AGROSCIENCES, L.L.C.; E.H. GRIFFITH, INC.; E.I. DU PONT DE NEMOURS AND CO., INC.; G.B. BIOSCIENCES CORPORATION; JOHN DEERE LANDSCAPING, INC., SUCCESSOR TO LESCO, INC.; MONSANTO COMPANY; NUFARM AMERICAS, INC.; REGAL CHEMICAL CO.; SCOTTS-SIERRA CROP PROTECTION CO.; AND SYNGENTA CROP PROTECTION, INC. APPEAL OF: MONSANTO COMPANY	:	No. 17 WAP 2019 Appeal from the Order of the Superior Court entered June 20, 2018 at No. 1661 WDA 2016, vacating the Order of the Court of Common Pleas of Allegheny County entered October 14, 2016 at No. GD 10-018588, and remanding ARGUED: October 16, 2019

RICHARD THOMAS WALSH, EXECUTOR OF THE ESTATE OF THOMAS J. WALSH, DECEASED	:	No. 18 WAP 2019
	:	Appeal from the Order of the Superior Court entered June 20, 2018 at No. 1661 WDA 2016, vacating the Order of the Court of Common Pleas of Allegheny County entered October 14, 2016 at No. GD 10-018588, and remanding
v.	:	
BASF CORPORATION; BAYER CORPORATION D/B/A BAYER CROPSCIENCE, L.P., AND BAYER CROPSCIENCE HOLDING, INC., AND/OR BAYER CROPSCIENCE, L.P. AND BAYER CROPSCIENCE HOLDING, INC., IN THEIR OWN RIGHT; BIOSAFE SYSTEMS, L.L.C.; CHEMTURA CORPORATION; CLEARY CHEMICAL CORP.; DOW AGROSCIENCES, L.L.C.; E.H. GRIFFITH, INC.; E.I. DU PONT DE NEMOURS AND CO., INC.; G.B. BIOSCIENCES CORPORATION; JOHN DEERE LANDSCAPING, INC., SUCCESSOR TO LESCO, INC.; MONSANTO COMPANY; NUFARM AMERICAS, INC.; REGAL CHEMICAL CO.; SCOTTS-SIERRA CROP PROTECTION CO.; AND SYNGENTA CROP PROTECTION, INC.	:	ARGUED: October 16, 2019
APPEAL OF: BASF CORPORATION	:	

OPINION

JUSTICE DONOHUE **DECIDED: JULY 21, 2020**

Appellants, the manufacturers of various pesticides, appeal from the decision of the Superior Court reversing the trial court's grant of summary judgment in their favor following the trial court's determination that the testimony of the experts proffered by Appellee, the Executor of the Estate of Thomas J. Walsh ("Walsh"), failed to satisfy the

test set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). For the reasons set forth herein, we affirm the Superior Court's ruling, with instructions that on remand to the trial court, the Appellants should be given the opportunity to renew their *Frye* motions for the reasons addressed in this Opinion.

Factual and Procedural Background

For nearly forty years, Walsh served as a groundskeeper and golf course superintendent at several Pittsburgh area golf courses. His work involved the regular application of various pesticides (primarily insecticides and fungicides) on the golf courses. Over this time, Walsh kept a detailed record of his activities regarding the pesticides he used, including a detailed log of the specific products and the dates of their applications. In addition, a coworker, Blaise Santoriello, testified with regard to Walsh's activities, including how the pesticides were applied, the protective gear they wore when doing so, what pesticides were used and in what concentrations. In the early years, gloves were the only protective gear that they used, although in later years they also wore overalls, rubber boots and masks. Eventually they began wearing disposable protective gear. Even with these protections, Santoriello explained, exposure to the dust from the pesticide products would occur while opening the bags and mixing the chemicals.

On October 5, 2008, Walsh was suffering from fever, chills, and a cough when he arrived at an emergency room. A bone marrow biopsy resulted in a diagnosis of Acute Myelogenous Leukemia ("AML"). Cytogenetic testing revealed significant chromosomal aberrations. On February 2, 2009, Walsh died. His treating oncologist, James Rossetti, D.O., later opined that Walsh's extensive exposure to pesticides raised a high degree of suspicion that said exposure played a significant role in the development of his AML.

Walsh's executor commenced this wrongful death and survival action against the manufacturers of various pesticides that he had applied during his career, asserting claims in strict products liability, negligence, and breach of warranty. Based upon a lack of expert testimony identifying various pesticides as substantial contributing factors in Walsh's death, the trial court granted summary judgment in favor of a large number of manufacturers. Appellants, the remaining manufacturers, manufacture fifteen pesticides products to which Walsh was exposed.

Three of the current Appellants, Bayer CropScience LP, Bayer Corporation and Bayer CropScience Holdings, Inc. (collectively "Bayer"), filed a *Frye* motion[1] to exclude the testimony of the Executor's expert witnesses, Nachman Brautbar, M.D ("Dr. Brautbar") and April Zambelli-Weiner, Ph.D. ("Dr. Zambelli-Weiner"). The remaining defendants either joined Bayer's *Frye* motion or filed their own. In these motions, the Appellants alleged that Drs. Brautbar and Zambelli-Weiner failed to apply methodologies generally accepted in the relevant scientific communities.

In his original expert report,[2] Dr. Brautbar explained that "[k]nowledgeable physicians approach the question whether a person's disease was caused by a particular chemical by considering two separate, but related, questions." Brautbar Initial Report, 2/17/2014, at 13. The first question is whether the chemical can cause "the particular

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[1] *See* Pa.R.C.P. 207.1 ("Motion to Exclude Expert Testimony Which Relies upon Novel Scientific Evidence").

[2] In his original expert report, Dr. Brautbar discussed the methodologies he employed and gave an overview of what the nine Bradford Hill factors entailed (discussed infra). In a supplemental expert report, Dr. Brautbar provided a thorough analysis of his observations and conclusions with respect to each factor. Brautbar Supplemental Report, 10/22/2015, at 3-13.

condition the person has" (general causation), and the second question is "whether a chemical that is capable of causing the condition that the person has actually caused the person's condition." *Id.* For general causation, Dr. Brautbar described the generally accepted methodology he employed as follows:

> (1) identify all relevant studies, (2) read and critically evaluate all the relevant studies, (3) evaluate all the data based upon recognized scientific factors (the Bradford Hill viewpoints) and other factors relevant to the chemical and the disease; (4) exercise best professional judgment in reaching a conclusion on the issue of whether a particular chemical or class of chemicals can cause a particular disease; and (5) explain the factual basis and the reasoning supporting the conclusion.

Id.

With respect to causality, Dr. Brautbar indicated that he utilized the "Bradford Hill criteria" or "viewpoints," a set of nine factors used to determine whether a recognized association is in fact a causal link. *Id.* at 13-15 (citing Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation*, Section of Occupational Medicine, at 295 (January 1965)). In his 1965 article,[3] Sir Bradford Hill indicated that his new methodology was necessary to decide whether an observed association between a potential toxin and a particular disease was in fact the outcome of an actual causal relationship.

> [M]ore often than not we are dependent upon our observation and enumeration of defined events for which we then seek antecedents. In other words, we see that the event B is associated with the environmental feature A, that, to take a specific example, some form of respiratory illness is associated with a dust in the environment. In what circumstances can we pass from this observed **association**

[3] Sir Bradford Hill's focus at the time was to determine whether there was a causal relationship between smoking and lung cancer.

> to a verdict of **causality**? Upon what basis should we proceed to do so?

Id. (emphasis in original).

After an association between agent and disease has been identified, the nine factors are evaluated to determine the strength of that association, with a strong association pointing to a causal relationship. Sir Bradford Hill explained the process as follows:

> Here then are nine different viewpoints from all of which we should study association before we cry causation. What I do not believe – and this has been suggested is that that we can usefully lay down some hard-and-fast rules of evidence that must be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for and against the cause-and-effect hypothesis and none can be required as a sine qua non. What they can do, with greater or less strength, is help us to make up our minds on the fundamental question – is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect.

Id. at 299.

The nine criteria are (1) consistency of the observed association, (2) strength of the observed association, (3) specificity of the observed association, (4) temporal relationship of the observed association, (5) biological gradient, (6) biological plausibility, (7) coherence, (8) experimental evidence from human populations, and (9) analogy. *Id.* at 295-99. According to Dr. Brautbar, these criteria are widely accepted in the relevant scientific community, including by scientific bodies (e.g., the World Health Organization) and in modern textbooks on epidemiology, occupational and environmental medicine, and toxicology. Brautbar Initial Report, 2/17/2014, at 15-16. Dr. Brautbar stresses that there is no formula or algorithm for assessing the factors, but rather it requires judgment and

scientific expertise to measure the weight and significance of each factor when conducting a particular evaluation. *Id.* at 16-17.

In his original expert report, Dr. Brautbar provided an overview of what the nine Bradford Hill factors entailed, and then a supplemental expert report filed after the reports of the Appellants' experts had been received. In the supplemental report, Dr. Brautbar provided a detailed analysis of his observations and conclusions with respect to each factor, including "the facts and studies that I rely on [to] provide evidence supportive of causality under each of the Bradford Hill factors… ." Brautbar Supplemental Report, 10/22/2015, at 2. In this supplemental report, he observed that all of the experts in the case agreed that the Bradford Hill factors was the appropriate methodology to assess causation in this case. *Id.* He explained that the differing conclusions of the Appellants' experts "is due to differences in professional judgment, rather than methodology," indicating that "different experts may reach differing conclusions based upon their best exercise of professional judgment, even though they may employ the same generally accepted methodology, they may rely on generally the same body of literature, and may base their opinion on the same facts relative to the patient and the workplace." *Id.*

Dr. Brautbar conducted his Bradford Hill factors analysis on the association between AML and pesticides. While conducting his analysis, he did not mention the pesticides manufactured by any of the Appellants or refer to any articles or studies relating to any specific pesticide or product. Having concluded that the Bradford Hill factors supported the existence of a causal link between AML and pesticides generally, he then acknowledged that because "some pesticides cause [AML] does not necessarily mean that all pesticides cause this disease." *Id.* He proceeded to conduct product-specific

analyses of each product manufactured by the Appellants, including detailed tables attached to his report identifying every exposure that Walsh had to each product (including by date and specific product) (hereinafter "Exhibit B"[4]) as well as the carcinogenic potential for the active ingredients in each product (hereinafter "Exhibit C"[5]). He did not purport to present direct evidence of a causal link between AML and the Appellants' specific products. Instead Dr. Brautbar opined that the causal link could be demonstrated indirectly. In particular, he identified studies that demonstrated that the active ingredients in these specific pesticides are genotoxic and thus cause chromosomal abnormalities. In what he refers to as the "fingerprint theory," he cited to studies showing that when exposure to pesticides or benzene causes AML, cytogenetic review identifies a unique set of chromosomal abnormalities (abnormalities of the fifth and seventh chromosomes), which in turn start the process to carcinogenicity. Brautbar Initial Report, 2/17/2014, at 22. According to Dr. Brautbar, this specific pattern of chromosomal abnormalities were identified in the cytogenetic testing performed on Walsh.

For specific causation, Dr. Brautbar utilized a differential diagnosis (or differential etiology) methodology, which he explained involves "ruling in all identifiable known causes of (and risk factors for) [the disease in question] and then ruling out those for which there is inadequate evidence." *Id.* at 61. According to Dr. Brautbar, "[t]he remaining

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[4] Exhibit B sets forth, in column form, the company and pesticide, toxicity per MSDS, Thomas Walsh exposure history per Complaint, pages of deposition, and a summary of testimony of co-worker (Santoriello).

[5] Exhibit C sets forth, in column form, the company, product, composition, EPA cancer classification, human cancer, animal carcinogen, and cytogenicity, cytotoxicity, genotoxicity and immunotoxicity.

cause(s) would then be deemed the probable cause(s) provided that substantial scientific and medical evidence exists for causality." *Id*.

Dr. Zambelli-Weiner conducted what she described as a critical review of "the published epidemiological literature on pesticide exposure and leukemia." Zambelli-Weiner Report, 7/18/2012, at 4. She indicated that in assessing the causal assessment, she employed a variety of methodologies, "including reviews, meth-analysis, weight-of-the-evidence analyses and application of the Bradford Hill criteria for causality." *Id.* at 5. She concluded that "exposure to organophosphate pesticide formulations, individually or in combination, is causally related to an increased risk of leukemia in humans exposed to them." *Id.* at 15.

The trial court did not conduct a *Frye* hearing, but rather ordered the parties to conduct depositions and file briefs. Upon review of these materials and after oral arguments by counsel, the trial court granted the Appellants' *Frye* motions by written opinion. It first concluded that Dr. Brautbar's expert report did not establish either general or specific causation for pesticides not containing benzene. Trial Court Opinion, 10/5/2016, at 2-13. With respect to pesticides containing benzene, the trial court determined that Dr. Brautbar's expert report demonstrated general causation, as it cited to numerous studies showing that exposure to benzene "at some level" may cause AML. *Id.* at 13-19. The trial court rejected Dr. Brautbar's specific causation analysis with regard to benzene products, however, because it concluded that the reports and studies he cited did not support the contention that low level exposures of benzene could cause AML. *Id.* at 13-17. The trial court also refused to credit Dr. Brautbar's alternative theory of specific

causation, namely the 'fingerprint theory" that Dr. Brautbar claimed resulted in no cases of idiopathic instances of AML (no known external cause). *Id.* at 18-19.

Because Dr. Brautbar's expert report did not establish specific causation for any of the Appellants' products, the trial court decided that it was not necessary to consider Dr. Zambelli-Weiner's expert report (which was offered only for general causation purposes). *Id.* at 19. The trial court noted that it did not consider Dr. Zambelli-Weiner's "pesticides as a class" opinion to be in accordance with generally accepted scientific methodology "because it fails to account for variations in composition of the universe of chemicals, compounds, or the like that might be considered a pesticide." *Id.* The trial court did not cite to any authority or expert testimony of record in support of this conclusion.

In light of the trial court's grant of the Appellants' *Frye* motions, the parties stipulated to the entry of summary judgment "in favor of all remaining defendants and against [Walsh] on all of [Walsh's] remaining claims, … with all rights of appeal preserved." Stipulated Order of Court, 19/14/2016.

The Executor then appealed to the Superior Court and the trial court issued a Pa.R.A.P. 1925(a) opinion. The Superior Court reversed the trial court's grant of the Appellants' *Frye* motions. *Walsh v. BASF Corp.*, 191 A.3d 838 (Pa. Super. 2018), *appeal granted*, 203 A.3d 976 (Pa. 2019). It began by denying the Executor's contention that the causal relationship "has crossed the threshold from novel science to general acceptance." *Id.* at 844. Despite acknowledging that there are more than 700 scholarly articles and studies examining this causal relationship, the Superior Court recognized that in *Betz v. Pneumo Abex LLC*, 44 A.3d 27 (Pa. 2012), this Court indicated that "a reasonably broad

meaning should be ascribed to the term 'novel,'" and that application of the *Frye* standard is necessary when a trial court has "articulable grounds to believe that an expert has not applied generally accepted scientific methodology in a conventional fashion in reaching his conclusions." *Id.* (citing *Betz*, 44 A.3d at 47). Because some of Appellants' experts had opined that the Executor's experts had not applied generally accepted methodologies in a conventional way, the Superior Court concluded that the trial court did not abuse its discretion in conducting a *Frye* inquiry. *Id.*

However, the Superior Court held that the trial court, by making itself the arbiter of what research could be scientifically relied upon to support an expert's opinion, had overstepped its "gatekeeper" function because that is "not the proper role of the trial court in a *Frye* inquiry." *Id.* at 844. The Superior Court cited to this Court's decision in *Commonwealth v. Topa*, 369 A.2d 1277 (Pa. 1977), in which we indicated that we adopted the *Frye* test to avoid having judges try to understand the complexities of modern science, as it is better to allow the scientists to do that to ensure reliability. *Id.* at 842-43 (citing *Topa*, 369 A.2d at 1282).

The Superior Court further rejected the trial court's determination that the research relied upon by Dr. Brautbar was not scientifically acceptable because, on some occasions, the conclusion of the study's author were contrary to those of Dr. Brautbar. *Id.* at 843. The court cited to a dissent by then-Chief Justice Castille in *Blum v. Merrell Dow Pharma., Inc.*, 764 A.2d 1 (Pa. 2000), in which he noted that limiting an expert testifying to the conclusions of other scientists would conclusively set in stone the views of the first researcher. *Walsh*, 191 A.3d at 846 (citing *Blum*, 764 A.2d at 15 (Castille, J.,

dissenting)). Instead, any conclusion reached by application of generally acceptable methodologies meets the *Frye* test.

The Appellants argued that generally accepted methodologies do not permit a scientist to extrapolate from studies involving harm from a broad product class (pesticides) to a specific product (Appellant's chemicals) causing a specific harm (AML). In other words, the Appellants indicated that Dr. Brautbar needed to rely on studies identifying a causal link between their specific product and AML. The Appellants likewise insisted that it was inappropriate for Dr. Brautbar to rely upon animal studies or in vitro (test tube) experiments instead of epidemiology studies involving humans.

As to the first point, the Superior Court held that an expert need not rely on studies that mirror the exact facts under consideration. *Id.* at 848. It is sufficient if the synthesis of various legitimate studies reasonably permits the conclusion reached by the expert. *Id.* The absence of a treatise or study directly on point goes to the weight, not the admissibility, of expert opinion. *Id.* An expert's opinion will satisfy *Frye* when it is deduced from generally acceptable scientific principles and supported by studies or literature, even where the expert could not point to one study involving precisely parallel circumstances. *Id.* The Superior Court disagreed that studies of Appellant's particular products were required, as the EPA regularly conducts studies on the cumulative risk of broad classes of pesticides that share similar "mechanisms of toxicity or act the same way in the body." *Id.* at 847. Many of the articles/studies by the Executor's experts looked at multiple pesticide exposures in agricultural settings, based upon the notion that this approach presents a better picture of occupational exposure to various pesticides (which are typically used in combination rather than singularly). *Id.* Zambelli-Weiner's expert report

indicated that most epidemiological studies are conducted on exposures to classes of pesticides because they are "additive, cumulative, and synergetic." *Id.*

As to the second point, the Superior Court noted that scientists routinely conduct and rely upon animal studies and/or in vitro testing. *Id.* at 847. Dr. Brautbar did not rely exclusively on such studies. *Id.* Dr. Brautbar also relied upon human studies of pesticide exposure by golf course superintendents (like Walsh), farmers, and other pesticide applicators subject to occupational pesticides. *Id.* According to the court, all of these studies, in the aggregate, support a causal link between pesticide exposure and leukemia (including AML).

Finally, the Superior Court responded to the trial court's rejection of Dr. Brautbar's opinion that medical science, in the form of cytogenetic studies of chromosomal aberrations, was proof of a causal link resulting in AML. The trial court indicated that these studies were not conclusive but the Superior Court disagreed, indicating that "we find the existence of these studies, together with the differential etiology methodology employed by Dr. Brautbar, sufficient to pass muster under *Frye*. *Id.* at 848.

In dissent, Judge Bender held that that the trial court's review of the studies relied upon by Plaintiff's experts was "necessary to prevent experts from `evad[ing] a reasoned *Frye* inquiry by making reference to accepted methods in the abstract.'" *Id.* at 849 (Bender, J., dissenting). According to Judge Bender, "more particularity is necessary" than the pesticide class methodology deemed sufficient by the majority. *Id*. at 850.

On appeal, the Appellants raise three issues:

I. Did the Superior Court majority commit reversible error in concluding that, when evaluating scientific evidence under the Frye standard, trial courts are not permitted to act as "gatekeepers" to ensure the relevance and reliability

of scientific studies offered by experts to support their opinions by scrutinizing whether those studies actually support their opinions?

II. Did the Superior Court majority commit reversible error in concluding that trial courts may not review experts' opinions extrapolating from a broad class of products and injuries to a specific product and injury, thereby eliminating plaintiff's burden to show product-specific causation of plaintiff's specific injury?

III. Did the Superior Court majority commit reversible error in concluding that the trial court erred without explaining how it abused its discretion because of manifest unreasonableness, partiality, prejudice, bias, ill-will or such lack of support from the evidence or the record so as to be clearly erroneous?

Walsh v. BASF Corp., 203 A.3d 976 (Pa. 2019). Although technically the trial court granted summary judgment by consent of the parties, its ruling was based upon its interlocutory decision on the Appellants' *Frye* motions. The appropriate appellate standard of review is typically the one pertaining to the underlying ruling. *See Gallagher v. PLCB,* 883 A.2d 550, 559 n.11 (Pa. 2005). When reviewing a trial court's grant or denial of a *Frye* motion, an abuse of discretion standard applies. *Betz*, 44 A.3d at 54. Accordingly, we will apply an abuse of discretion standard in our review of the trial court's grant of the Appellants' *Frye* motions.

We begin our discussion with Rule 702 of the Pennsylvania Rules of Evidence. Rule 702, entitled "Testimony by experts," which controls the admissibility of expert testimony on scientific knowledge, states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge is beyond that possessed by the average layperson; (b) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; and (c) **the expert's methodology is generally accepted in the relevant field**.

Pa.R.E. 702 (emphasis added).

The requirement that the expert's methodology be generally accepted is commonly referred to as the *Frye* test. First announced in *Frye v. United States*, 293 F. at 1013, it was adopted by this Court in Pennsylvania in *Topa*. In *Grady v. Frito Lay, Inc.*, 839 A.2d 1038, 1047 (Pa. 2003), we clarified that the *Frye* rule "applies to an expert's method, not his conclusions." As artfully stated by former Chief Justice Cappy,

> The *Frye* standard is limited to an inquiry into whether the **methodologies** by which the scientist has reached her conclusions have been generally accepted in the scientific community... . It restricts the scientific evidence which may be admitted as it ensures that the proffered evidence results from scientific research which has been conducted in a fashion that is generally recognized as being sound, and is not the fanciful creations of a renegade researcher. Yet, such a standard is not senselessly restrictive for it allows a scientist to testify as to new conclusions which have emerged during the course of properly conducted research.

Blum, 764 A.2d at 9 (Cappy, C.J., dissenting) (emphasis in original). The proponent of the admission of expert scientific evidence bears the burden of establishing all of the elements supporting its admission, including the general acceptance of the methodology employed in the relevant scientific community. *Grady*, 839 A.2d at 1045; *Betz*, 44 A.3d at 54. While the methodologies employed by the expert must be generally accepted, the conclusions reached from those applications need not also be generally accepted. *Trach v. Fellin*, 817 A.2d 1102, 1112 (Pa. Super. 2003) (en banc).

The Court in *Grady* made clear that whether a methodology is generally accepted in the relevant scientific community is a determination that has to be made based on the testimony of the scientists in that community, not upon any scientific expertise of judges.

> One of the primary reasons we embraced the *Frye* test in *Topa* was its assurance that judges would be guided by

> scientists when assessing the reliability of a scientific method. *See Topa*, 369 A.2d at 1281 (quoting *United States v. Addison*, 498 F.2d 741, 744 (D.C.Cir. 1974)). Given the ever-increasing complexity of scientific advances, this assurance is at least as compelling today as it was in 1977, when we decided that case. We believe now, as we did then, that requiring judges to pay deference to the conclusions of those who are in the best position to evaluate the merits of scientific theory and technique when ruling on the admissibility of scientific proof, as the *Frye* rule requires, is the better way of insuring that only reliable expert scientific evidence is admitted at trial.

Grady, 839 A.2d at 1044–45; *see also id.* at 1045 ("This does not mean, however, that the proponent must prove that the scientific community has also generally accepted the expert's conclusion. … This, in our view, is the sensible approach, for it imposes appropriate restrictions on the admission of scientific evidence, without stifling creativity and innovative thought.").[6]

Relatedly, with respect to causation issues, the Superior Court has offered the following:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by

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[6] In *Betz*, this Court described the trial court's role in a *Frye* hearing as deciding whether "an expert witness has … applied accepted scientific methodology in a conventional way in reaching his or her conclusions." 44 A.3d at 53. As noted by the concurring Justice, this language could be viewed as interjecting an element of the *Daubert* standard into our otherwise steadfast adherence to *Frye*'s teaching that the expert's methodology be "generally accepted in the relevant field." Concurring Op. at 15 n.13. The dissenting Justice outright disagrees with the notion that the "conventional fashion" language was used in *Betz* to redefine *Frye*'s general acceptance standard. Instead, the dissenting Justice indicates that this terminology was used only to identify novel science for the purpose of determining whether to conduct a *Frye* hearing. Dissenting Op. at 14-16.

Accepting both the concurring Justice's view that the phraseology may be confusing and the dissenting Justice's opinion that its use was not intended to modify the *Frye* general acceptance standard, we will not use the "conventional fashion" language in our discussion. Here, the novelty of the science has been conceded by Appellee, who did not appeal the Superior Court's determination that the science was novel.

> the attempt to link low-level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, **if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony.**

Trach, 817 A.2d at 1117 (emphasis added) (quoting *Ferebee v.* Chevron *Chemical Co.*, 736 A.2d 1529, 1534 (D.C. Cir. 1984)).

Issue One: Did the Superior Court majority commit reversible error in concluding that, when evaluating scientific evidence under the Frye standard, trial courts are not permitted to act as "gatekeepers" to ensure the relevance and reliability of scientific studies offered by experts to support their opinions by scrutinizing whether those studies actually support their opinions?

For their first issue on appeal, the Appellants contend that the Superior Court erred in ruling that the trial court had improperly exceeded its boundaries by reviewing in detail the studies that Dr. Brautbar relied upon in reaching his expert opinions. The Appellants posit that the Superior Court improperly held that in *Frye* proceedings trial courts are not "gatekeepers," as that is precisely the role that they play. Appellants' Brief at 21 (citing *Blum ex rel. Blum v. Merrell Dow Pharmeceuticals, Inc.*, 705 A.2d 1314, 1322 (Pa. Super. 1997) ("[T]he judge as gatekeeper decides whether the expert is offering sufficiently reliable, solid, trustworthy evidence.")), *affirmed*, 764 A.2d 1 (Pa. 2000). According to the Appellants, in past cases this Court has approved of careful review of the studies and evidence relied upon by an expert to assess relevance and reliability. Appellants' Reply Brief at 5-8 (citing, e.g., *Betz).*

In contrast, the Executor supports the Superior Court's contention that trial courts are not "gatekeepers." The Executor claims that the Superior Court did not rule that a trial court may not review studies or other evidence relied upon by an expert. Instead,

the Executor contends that rather than merely reviewing the studies cited by Dr. Brautbar, the trial court made a number of bald assertions regarding the relevance and validity of said studies to Dr. Brautbar's proposed scientific opinions. Executor's Brief at 4. The Executor insists that the trial court, by analyzing the scientific literature on its own, "delved into an area beyond the training and experience of judges and lawyers and substituted its analysis of the scientific literature for the analysis that was conducted by [Executor's] experts." *Id.* at 7.

Whether we refer to the role of the trial court in a *Frye* contest as that of a "gatekeeper" is not consequential. What is of consequence is the role that the trial court plays during *Frye* proceedings. A careful review of our prior *Frye* decisions makes clear that it is the trial court's proper function to ensure that the expert has applied a generally accepted scientific methodology to reach his or her scientific conclusions. To fulfill this function, the trial court must be guided by scientists in the relevant field, including the experts retained by the parties in the case and any other evidence of general acceptance presented by the parties (e.g., textbooks). Conversely, trial courts may not question the merits of the expert's scientific theories, techniques or conclusions, and it is no part of the trial court's function to assess whether it considers those theories, techniques and/or conclusions to be accurate or reliable based upon the available facts and data. As is plainly set forth in Rule 702(c), the trial court's role is strictly limited to determining whether "the expert's methodology is generally accepted in the relevant field." Pa.R.E. 702(c). The trial court may consider only whether the expert applied methodologies generally accepted in the relevant field, and may not go further to attempt to determine whether it

agrees with the expert's application of those methodologies or whether the expert's conclusions have sufficient factual support.[7] Those are questions for the jury to decide.

Judges typically have no specialized training that qualifies them to weigh in on the expert's resolution of the highly complex issues involved in the determination of the causality of human disease resulting from exposure to specific toxins. By requiring the scientists addressing those issues to utilize generally accepted methodologies, the trial court conducting a *Frye* hearing ensures that the jury receives scientific opinion that is the result of sound research, while simultaneously leaving sufficient flexibility for new research to arrive at new conclusions previously uncredited.

Based upon our review, we must agree with the Superior Court's assessment that the trial court's *Frye* inquiry was at times "overly expansive." *Walsh*, 191 A.3d at 844. For example, the trial court rejected as scientifically unacceptable "animal studies, test-tube studies and studies that include significant limiting language as to the applicability of their results to causation theories."[8] Trial Court Opinion, 10/5/2016, at 12-13. According

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[7] To the extent that Pennsylvania trial courts conduct an "essential review for reliability," Dissenting Op. at 11, that review may consist only of establishing that the expert utilized generally accepted methodologies in reaching his or her scientific conclusions. Under *Frye*, requiring that an expert employ generally accepted methodologies is, in and of itself, the means by which Pennsylvania courts ensure that only reliable scientific evidence is presented to juries. *See, e.g.*, *Topa*, 369 A.2d at 1282 ("The requirement of general acceptance in the scientific community assures that those most qualified to assess the general validity of a scientific method will have the determinative voice."); *Grady*, 839 A.2d at 1045 ("We believe now, as we did then, that requiring judges to pay deference to the conclusions of those who are in the best position to evaluate the merits of scientific theory and technique when ruling on the admissibility of scientific proof, as the *Frye* rule requires, is the better way of insuring that only reliable expert scientific evidence is admitted at trial.").

[8] The Appellants point out that this Court in *Betz* discounted the usefulness of these types of evidence in a substantial cause analysis. *Betz*, 44 A.3d at 55. That assessment was, however, obviously based upon the evidence of record (including expert deposition

to the trial court, it is not generally accepted methodology "to select portions of studies that favor a certain outcome while ignoring direct statements against that outcome within the same article." *Id.* In so ruling, however, the trial court did so unilaterally, without citation to any authority or to the voluminous expert deposition testimony in the certified record. Whether it was in accordance with generally accepted methodology to rely upon animal and/or test tube studies of the sorts cited on Dr. Brautbar's Exhibit C (evaluating the genotoxicity of the active ingredients in the Appellants' products) constituted a scientific judgment that must be guided by the experts, not a trial court. Similarly, whether Dr. Brautbar could rely upon articles containing limiting language would depend upon the precise nature of that limiting language and the purpose for which Dr. Brautbar was relying upon it. Again, it was not the province of the trial court, but rather the scientists (including Dr. Brautbar), to guide this decision. The trial court's role was limited to determining whether Dr. Brautbar reached his scientific conclusions by applying generally accepted scientific methodologies.

The trial court likewise found it unacceptable for Dr. Brautbar to rely on studies that did not reach the same ultimate conclusion reached by Dr. Brautbar, rejecting studies that did not identify a direct causal link between AML and a particular pesticide manufactured by one of the Appellants. The trial court acknowledged that Dr. Brautbar's opinion relied upon an indirect link between pesticides and AML, specifically that pesticide exposures result in specific chromosomal abnormalities (abnormalities of the fifth and seventh

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testimony) in that case, and the manner in which the expert was attempting to use such studies when formulating his conclusions. In baldly rejecting "animal studies, test-tube studies and studies that include significant limiting language," the trial court did not refer to the certified record in this case or to any other authority in support of its pronouncement.

chromosomes), which in turn start the process to carcinogenicity that leads to leukemia (including AML). Brautbar Initial Report, 2/17/2014, at 22. After reviewing the studies Dr. Brautbar cited in support of his conclusions, however, the trial court rejected, as unsupported, Dr. Brautbar's scientific **conclusion** that "[c]hromosomal changes are like fingerprints of prior exposure" to certain types of chemicals, including pesticides and/or benzene. *Id.* at 21.

Dr. Brautbar's conclusion that specific patterns of chromosomal aberrations are like "fingerprints" was an important component in his product specific analyses by demonstrating that Walsh's exposure to pesticides and benzene was a substantial contributing cause of his AML, as per the detailed information in Exhibits B and C of his report. It was also important to his differential diagnosis, as it is his contention that "fingerprints" in chromosomal aberrations excluded a finding that Walsh's' AML was idiopathic (without any known external cause). The trial court noted that Dr. Brautbar had relied upon (among others) a study by Cuneo that provided some support for the chromosomal aberrations theory based upon a comparison of individuals with AML divided into two groups (those exposed to pesticides and those not exposed). Cuneo concluded that "patients exposed to pesticides had the same recurring chromosomal aberrations and cytological features, which were different from those found in the unexposed group." Brautbar Initial Report. 2/17/2014, at 24 (citing Ontario College of Family Physicians, Leukemia (Chapter 5), Pesticides Literature Review (April 23, 2004), 49-50) (reviewing Cuneo, A., et al., *Morphologic, Immunologic and Cytogenetic Studies in Acute Myeloid Leukemia Following Occupational Exposure to Pesticides and Organic Solvents*, Leuk Res. 16:789-796 (1992))).

The trial court, however, noted that Cuneo's study did not show that individuals with AML in the exposed group **always** showed chromosomal aberrations to the fifth and seventh chromosomes, as the cytogenetic results of a few members of the exposed group did not demonstrate the identified pattern of aberrations. Trial Court Opinion, 10/5/2016, at 18-19. According to the trial court, this proved that there was no "fingerprint" of AML caused by exposure to pesticides and/or benzene. *Id.* In reaching this conclusion, the trial court did not consider Dr. Brautbar's deposition testimony, in which he explained at some length that Cuneo had used an older methodology for the identification of members of the exposed and unexposed groups and that the use of a newer methodology in fact demonstrates a chromosomal fingerprint in Cuneo's exposed group. Brautbar Deposition, 5/13/2014, at 364-79.

Importantly, the trial court's rejection of Dr. Brautbar's "fingerprint" conclusion was based solely upon its own analysis of the scientific studies proffered by Dr. Brautbar and not on any review of the methodology that Dr. Brautbar was utilizing to reach his conclusion.[9] A focus on his methodology would have included consideration of both Dr.

[9] The Appellants contend that in past cases this Court has approved of trial courts conducting their own intensely granular reviews of the scientific evidence offered by experts in support of their opinions. The Appellants argue that in *Betz*, the Court recognized that the trial court had considered "the testimony of the witnesses, voluminous scientific literature, and numerous legal authorities proffered in support of the plaintiffs' and defendants' respective positions." *Betz*, 44 A.3d at 39 (citing *In re Toxic Substance Cases*, 2006 WL 2404008, at *2 (C.P.Allegheny, Aug. 17, 2006)). In so doing, however, and in contrast to the trial court in the case before us, this Court emphasized that the trial court's systemic review of the evidence was for the express purpose of deciding whether the expert witness had utilized a generally accepted **methodology**. *Id.* at 39 ("Focusing upon **methodology**, Judge Colville found no support for the any-exposure theory of specific causation in any of the sources upon which Dr. Maddox relied.") (emphasis added); *id.* at 40 ("Rather, [the trial court] agreed with the defendants' experts that Dr. Maddox's **methodology** was plagued by unwarranted liberties and logical errors."

Brautbar's deposition testimony as well as that of the Appellants' experts. Dr. Marshall Lichtman, for example, testified at his deposition that up to 85% of AML cases are idiopathic and that about half of them have no distinct pattern of chromosomal aberrations. Lichtman Deposition at 28. Dr. Lichtman further testified that in comparison to the Cuneo study, in which 21 patients were in the exposed group, Dr. Brautbar had not considered at least four larger subsequent studies (with more than 5,500 patients) which found cytogenetic abnormalities are not present in about half of de novo AML cases, and that as a result one cannot use the appearance of chromosomal abnormalities to reach the conclusion that the AML case must have been externally caused (e.g., by exposure to pesticides or benzene). *Id.* at 49-50. According to Dr. Lichtman, Dr. Brautbar did not follow a generally accepted scientific methodology by relying only on those studies that supported his conclusions while ignoring much larger studies that did not do so. *Id.*

In their *Frye* motions filed in the trial court, the Appellants raised this issue – whether Dr. Brautbar applied a generally accepted methodology to arrive at his cytogenetic "fingerprint" conclusion. *See* Defendants' Joint Brief in Support of Motions to Exclude Expert Testimony of April Zambelli-Weiner and Nachman Brautbar, 3/9/2016, at 2-5. The trial court issued no ruling on the issue. The Appellants also questioned whether Dr. Brautbar and/or Dr. Zambelli-Weiner utilized a generally accepted methodology when they applied the Bradford Hill criteria to establish causation to "pesticides-as-a-class" rather than to their individual products, by applying certain of the Bradford Hill factors

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(emphasis added); *id.* at 53 ("[The trial court] spent considerable time listening to the attorneys' arguments but was unable to discern a coherent **methodology** supporting the notion that every single fiber from among, potentially, millions is substantially causative of disease.") (emphasis added).

contrary to the ways in which Sir Bradford Hill intended for them to be applied (and ignoring others entirely), and by failing to identify any epidemiological studies demonstrating a causal association between AML and their specific products before engaging in the Bradford Hill methodology at all. *Id.* The Appellants contested Dr. Brautbar's methodology of opining on specific causation without first establishing the specific dose at which their products could cause AML. *Id.* The Appellants contended that Drs. Brautbar and Zambelli-Weiner did not follow a generally accepted methodology by "cherry-picking" studies that supported their conclusions while ignoring other studies that did not. *Id.* Finally, the Appellants contested Dr. Brautbar's application of the differential diagnosis methodology when he failed to rule out a known cause of AML (obesity). *Id.*

The trial court issued no rulings on any of these *Frye* challenges. To the contrary, in its initial opinion granting the Appellants' *Frye* motions, the trial court did not even mention the Bradford Hill criteria or indicate that the Executor's experts (and at least one of the Appellants' experts) were employing this methodology. In its subsequent Rule 1925(a) opinion, the trial court merely indicated that Dr. Brautbar's use of the Bradford Hill methodology required reliance upon peer-reviewed research, which it had already concluded "did not stand for the conclusions that Dr. Brautbar cited them for." Rule 1925(a) Opinion, 12/22/2016, at 5. By questioning the judgment of the Executor's experts and the reliability of their scientific conclusions, rather than focusing on whether the Executor satisfied his burden of proof that Drs. Zambelli-Weiner and Brautbar formed their opinions by application of methodologies that are generally accepted in the relevant fields of study, the trial court abused its discretion. Accordingly, we agree with the

Superior Court's decision to vacate the trial court's orders granting the Appellants' *Frye* motions and entering summary judgment. On remand, the Appellants should be afforded the opportunity to renew their *Frye* motions so that the relevant issues can be addressed.

Issue Two: Did the Superior Court majority commit reversible error in concluding that trial courts may not review experts' opinions extrapolating from a broad class of products and injuries to a specific product and injury, thereby eliminating plaintiff's burden to show product-specific causation of plaintiff's specific injury?

For their second issue on appeal, the Appellants argue that the Superior Court held that experts can satisfy their burden under the *Frye* test by and through the unrestricted use of extrapolation. The Appellants insist that the Superior Court held that establishing a causal link between cancer and long-term exposure to "pesticides-as-a-class" is sufficient to support a causation decision regarding exposure to the **specific** pesticide products at issue in the case. The Appellants contend that under the Superior Court's analysis, if an expert can cite to literature suggesting that a class of products may cause a disease, then that expert has met his or her burden under *Frye* to opine that any particular product in that class caused the disease, regardless of the diversity between the various types of products within that class. According to the Appellants, the Superior Court's ruling ignores this Court's ruling in *Betz*, which established strong limitations on the use of extrapolation in substantial cause analyses and effectively eliminates the plaintiff's the burden to show product-specification.

The Appellants have misread the Superior Court's opinion, as it does not in any respect bless the unfettered use of extrapolation in a substantial cause analysis and it did not eliminate a plaintiff's burden to show product-specification. To the contrary, the

Superior Court's principal focus was directed to the trial court's rejection of studies cited by Dr. Brautbar based upon its own conclusion that his reliance on them was not scientifically acceptable, either because the study did not identify a direct causal link between a particular Appellant's product and AML or because it reached a conclusion contrary to that ultimately reached by Dr. Brautbar. *Walsh*, 191 A.3d at 845-46. The trial court, in reviewing and analyzing the cited scientific articles, had "impermissibly set himself up 'as a super expert in the field of medicine,'" and had thus added an extra "layer to the generally accepted methodology requirement" that is not any part of a proper *Frye* analysis. *Id.* In response, the Superior Court properly indicated that the "absence of a treatise or study directly on point goes to the weight, not to the admissibility, of expert testimony," *id.* at 847, and further stated that an expert is not required to parrot the conclusions of study authors." *Id.* at 846. The Superior Court likewise rejected any notion that a proper *Frye* causal analysis must include an epidemiological study demonstrating an increased incidence of AML after substantial exposures to their specific products (or the active ingredients in their specific products). *Id.* at 847-48 ("For purposes of *Frye*, an expert need not rely on studies that mirror the exact facts under consideration.").

In *Trach*, the Superior Court described extrapolation as a logical method used "to estimate the value of a variable outside its tabulated or observed range" or "to infer (that which is not known) from that which is known." *Trach*, 817 A.2d at 1114-16 (citing *Donaldson v. Central Illinois Public Service Co.*, 767 N.E.2d 314, 328–329 (Ill. 2002) ("Extrapolation is commonly used by scientists in certain limited instances ..., for example, when the medical inquiry is new or the opportunities to examine a specific cause and effect relationship are limited; when the number of cases limits study of the disease; or

… when ethical considerations prevent exposing individuals to a toxic substance for research purposes.")). Given the breadth of these definitions of the term, except in those rare circumstances in which a perfectly comparable study supports a direct causal relationship between a particular agent and a disease, virtually every expert opinion on substantial causation will likely contain instances of the use of extrapolation. The Executor here does not contend that Drs. Zambelli-Weiner and Brautbar did not engage in the use of any extrapolation in formulating the opinions set forth in their expert reports. To the contrary, at his deposition Dr. Brautbar forthrightly admitted to his use of extrapolation in at least one respect, namely that "[e]xtrapolation from animal studies, extrapolation from cell studies, extrapolation from human cell studies to disease causation" are part of "the "mechanistic aspects to understanding causation of disease. Brautbar Deposition, 5/13/2014, at 30-31).

Importantly for present purposes, however, our review of the expert reports of Drs. Zambelli-Weiner and Brautbar does not reflect that either of them used extrapolation in the manner now complained of by Appellants. Specifically, while both experts employed the Bradford Hill criteria to establish a causal link between cancer (or AML) and long-term exposure to pesticides, neither expert opined that this link wholly constituted product-specific causation between cancer and long-term exposure to the Appellants' specific pesticide products. In her expert report, Dr. Zambelli-Weiner offered no opinions with regard to any of the Appellants' specific products.[10] To the contrary, at her deposition

[10] Dr. Zambelli-Weiner's expert report sets forth three opinions:

she expressly refused to answer questions about whether any of the Appellants' specific products cause cancer/AML. Zambelli-Weiner Deposition, 9/23/2014, at 107-08; ("I was not charged with evaluating the association of any particular product ... with leukemia."); *Id.*, 9/24/2014, at 355 ("I wasn't tasked with studying chlorpyrifos specifically.").

With respect to the Appellants' *Frye* motions, we note that the trial court issued no ruling with respect to whether Dr. Zambelli-Weiner's failure to opine on whether the Appellants' specific products may cause leukemia precludes her use as an expert on general causation at trial,[11] and the Superior Court likewise did not address this issue. As a result the Superior Court's opinion, contrary to the assertions of Appellants, did not eliminate the plaintiff's burden to show product-specification. *See Rost v. Ford Motor Co.,*

> 1. Mr. Walsh had cumulative lifetime exposure days to pesticides consistent with exposure levels associated with increased risk of leukemia, and AML specifically, in published peer-reviewed literature.
>
> 2. It is my opinion, to a reasonable degree of medical certainty, that exposure to pesticide formulations, individually or in combination, is causally related to an increased risk of cancer in humans exposed to them.
>
> 3. It is my opinion, to a reasonable degree of scientific certainty, that exposure to organophosphate pesticide formulations, individually or in combination, is causally related to an increased risk of leukemia in humans exposed to them.

Zambelli-Weiner Report, 7/18/2012, at 13-15.

[11] The trial court stated that "I find that Dr. Zambelli-Weiner's general causation opinion regarding pesticides as a class is not in accordance with generally accepted scientific methodology because it fails to account for variations in composition of the universe of chemicals, compounds, or the like that might be considered a "pesticide." Trial Court Opinion, 10/5/2016, at 19. The trial court offered this observation as its own opinion, however, as it was not accompanied by citation to any scientific authority in the record in its support. Moreover, the remark must be considered to be mere dicta, as the trial court offered it only after having rejected Dr. Brautbar's opinion on specific causation opinions. *Id.* ("Because Dr. Brautbar's specific causation opinions are not formed using generally accepted scientific methodology, the viability of Dr. Zambelli-Weiner's general causation opinions is not material.").

151 A.3d 1032, 1044 (Pa. 2016) (Pennsylvania law requires that "to create a jury question, a plaintiff must adduce evidence that exposure to defendant's [product] was sufficient … to support a jury's finding that defendant's product was substantially causative of the disease.").

As indicated, Dr. Brautbar also applied the Bradford Hill criteria to establish a causal link between AML and long-term exposure to pesticides. He did not extrapolate from this finding that because pesticides increase the risk of contracting AML that Appellants' specific products likewise increase this risk. To the contrary, he disclaimed any use of this type of extrapolation, stating in his initial expert report "that some pesticides cause [AML] does not necessarily mean that all pesticides cause this disease." Brautbar Initial Report, 2/17/2014, at 18. He then proceeded to conduct product-specific analyses of each product manufactured by the Appellants, evaluating the chemical components of each of the pesticides individually and concluding that each of them contained chemicals that were genotoxic or caused DNA damage, and thus are carcinogenic. *Id.* at 21-23 and Exhibits B and C.

The Superior Court neither blessed the indiscriminate use of extrapolation nor adopted the Appellants' contention that its opinion may fairly be read to hold that establishing a causal link between cancer and long-term exposure to pesticides is sufficient to support a causation decision regarding exposure to a defendant's specific product; rather, the Superior Court properly indicated that an expert need not rely on studies mirroring the exact facts under consideration, as a synthesis of various legitimate studies which reasonably permits experts' conclusions may be sufficient for purposes of Frye. *Walsh*, 191 A.3d at 847-48. In our decision in *Rost*, this Court reaffirmed that the

plaintiff has a burden to show product-specification. *See Rost,* 151 A.3d at 1044. The Superior Court's opinion may not be fairly read to alter that burden in any respect.

Issue Three: Did the Superior Court majority commit reversible error in concluding that the trial court erred without explaining how it abused its discretion because of manifest unreasonableness, partiality, prejudice, bias, ill-will or such lack of support from the evidence or the record so as to be clearly erroneous?

The Appellants argue that although the Superior Court found that the trial court erred, "it never actually stated that he abused his discretion." Appellants' Brief at 59. The Appellants insist that the Superior Court failed to identify how the trial court erred and further allege that the Superior Court, rather than applying the abuse of discretion standard, instead substituted its own judgment for that of the trial court. *Id.*

We disagree. It is unnecessary for an appellate court to use any "magic language" when ruling that a lower court abused its discretion. It is enough for the appellate court to explain how the lower court abused its discretion. In our view, the Superior Court plainly set forth numerous abuses of discretion by the trial court, including its review of the scientific literature at a granular level to make its own bald judgments about which studies relied upon by Dr. Brautbar were scientifically acceptable, relevant and/or supportive of his conclusions. *Walsh*, 191 A.3d at 844-45. As the Superior Court correctly recognized, "[t]hat is not the proper role of the trial court in a *Frye* inquiry." *Id.* at 844.

As such, the Superior Court found the trial court's consideration of the Appellants' *Frye* motions to be flawed in multiple respects and vacated the trial court's decision on that basis. We thus conclude that the Superior Court properly applied its standard of review.

The order of the Superior Court is affirmed. On remand to the trial court, the Appellants should be afforded the opportunity to renew their *Frye* motions for the reasons addressed in this Opinion.

Justices Dougherty, Wecht and Mundy join the opinion.

Justice Wecht files a concurring opinion.

Justice Baer files a concurring and dissenting opinion.

Chief Justice Saylor files a dissenting opinion in which Justice Todd joins.