

PITTSBURGH LEGAL JOURNAL

OPINIONS

ALLEGHENY COUNTY COURT OF COMMON PLEAS

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. Bio-Sciences 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., Ignelzi, J.Page 7
Frye—General Causation—Specific Causation—Toxic Tort—Expert Reports—Rule of Professional Conduct 3.2

Plaintiff's estate brought a wrongful death suit alleging that his exposure to pesticides over the course of thirty years caused him to develop acute myelogenous leukemia. Plaintiff appealed trial court order striking expert reports and case was remanded back to the trial court. On remand, trial court concluded that, even though the motions to exclude relied on Frye and its progeny, that the basis for motions was not the methodology of the experts' analyses but rather the experts' conclusions. Because expert opinions and conclusions go to the weight of the opinion, the trial court denied the motions. The trial court advised litigants in Allegheny County to review the Supreme Court case of Walsh v. BASF Corp., 151 A.3d 1032 and Rule of Professional Conduct 3.2 before filing a motion to exclude expert opinions. Lastly, the trial court cautioned litigants that experts must clearly define the methodology employed and Frye motions must clearly define the objections to the applied methodology.

**In the Interest of: K.T., a minor child,
 Appeal of: Allegheny County Children Youth and Family Services and Child's Legal Counsel, Regan, J.Page 20**
Involuntary Termination of Parental Rights—Standard of Appellate Review

- *When reviewing denial of petition to terminate parental rights, appellate courts must apply abuse of discretion standard.*
- *Involuntary Termination of Parental Rights – Statutory ground under 23 Pa. C.S. §2511(a) must be proven by clear and convincing evidence.*
- *Involuntary Termination of Parental Rights – Bifurcated analysis is required, with first focus on conduct of parent.*
- *Involuntary Termination of Parental Rights – Once statutory grounds for termination are proven under 23 Pa. C.S. §2511(a), second focus under 23 Pa. C.S. §2511(b) is on needs and welfare of child, on case-by-case basis.*
- *Involuntary Termination of Parental Rights – Where Mother has continuing issues with substance abuse, has diagnoses of several mood and personality disorders and experiences issues with focus and stress, has a history of criminal violations and is unable to understand the role of drugs in her life, statutory grounds for termination of parental rights have been established under 23 Pa. C.S. rights have been established under 23 Pa. C.S. §2511(a)(2), (5) and (8).*
- *Involuntary Termination of Parental Rights – Where evidence proved that Child had emotional bond with Mother, was eager to spend time with mother and reluctant to leave, and there had been no significant period of time when Mother and Child were not in contact, held that permanently severing that bond would have detrimental impact on Child and evidence failed to demonstrate that termination of parental rights would meet needs and welfare of child; rather, it would adversely affect Child.*

PLJ

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OPINIONS

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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. Bio-Sciences 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.**

Frye—General Causation—Specific Causation—Toxic Tort—Expert Reports—Rule of Professional Conduct 3.2

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No. GD 10-018588. In the Court of Common Pleas of Allegheny County, Pennsylvania, Civil Division.
Ignelzi, J.—November 15, 2021.

MEMORANDUM OPINION AND ORDER OF COURT

Re: Defendants' Motions to Exclude Plaintiff's Causation Experts and Motions for Summary Judgment

AND NOW, to-wit, this 12th day of October, 2021; upon receipt and review of: Defendants BASF Corporation's ("BASF"); Bayer Cropscience LP's, Bayer Corporation's, and Bayer Cropscience Holding Inc.'s ("Bayer"); Deere & Company's ("Deere"); Monsanto Company's ("Monsanto"); and Syngenta Crop Protection, Inc.'s ("Syngenta") respective Renewed Motions to Exclude Plaintiff's Causation Experts and Motions for Summary Judgment; Plaintiff's pre-remand Reply Brief in Opposition to Motions to Exclude Expert Witness Testimony ("Pltf. Brf. Opp.", ECF 301); the parties' incorporated pre-remand motions and responses², associated pleadings, exhibits, and the record herein; applicable Pennsylvania caselaw governing toxic tort causation and methodology including Walsh Est. of Walsh v. BASF Corporation, 234 A.3d 446 (Pa. 2020); Rost v. Ford Motor Company, 151 A.3d 1032 (Pa. 2016), and Betz v. Pneumo Abex LLC, 44 A.3d 27 (Pa. 2012); and application of the Frye³ Test per Pa.R.Civ.P. 207.1; this Court submits the following Memorandum Opinion and enters the attached Order of Court.

I. Procedural Summary

On July 21, 2020, the Pennsylvania Supreme Court issued an Opinion and Order remanding this case with instructions to evaluate Defendants' renewed Frye motions pursuant to standards prescribed in the Opinion at Walsh Est. of Walsh v. BASF Corp., 14 WAP 2019, 234 A.3d 446 (Pa. 2020) (appeal from the Order of the Superior Court entered June 20, 2018 at No. 1661 WDA 2016 vacating and remanding the Order of the Court of Common Pleas of Allegheny County entered October 14, 2016 at No. GD 10-018588, Wettick, J.). This Court was assigned the case upon remand.⁴

II. Factual Background

Richard Thomas Walsh, ("Plaintiff") is the Executor of Thomas J. Walsh's ("Patient Walsh") estate. Plaintiff brings this toxic tort suit seeking relief in five main causes of action: negligence, strict liability, breach of warranty, wrongful death, and a survival claim. (Pltf. Cmplt., ECF 1 at ¶¶23-46).

Our Supreme Court summarized the underlying facts as follows: For nearly forty years, Patient 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, Patient 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. On October 5, 2008, he presented at the emergency room suffering from fever, chills, and a cough. After a bone marrow biopsy, Walsh was diagnosed with Acute Myelogenous Leukemia ("AML"). Further Cytogenic testing revealed significant chromosomal aberrations. Walsh died on February 2, 2009. His treating oncologist, James Rosetti, D.O., opined that Walsh's extensive exposure to pesticides led to a suspicion that said exposure played a significant role in his development of AML. See Walsh, 234 A.3d at 450 (Pa. 2020).

Plaintiff alleges that the decedent, Patient Walsh, developed AML from exposure to Defendants' products as a result of his thirty-eight-year employment as a superintendent and groundskeeper at several golf courses. (Pltf. Cmplt., ECF 1 at ¶8). Plaintiff asserts that throughout the course of Patient Walsh's employment, pesticides came in contact with his skin, eyes, nose, lungs, mouth and gastrointestinal system. (See Pltf. Cmplt., ECF 1 at ¶¶13-14; Pltf. Brf. Opp., ECF 278 at Exhibit 8 citing to the deposition of Patient Walsh's co-worker Blaise Santoriello; and Id. at Exhibit 9 citing to Patient Walsh's handwritten notes and calendar summarizing products used on specific dates). Patient Walsh's calendar logs, in conjunction with Santoriello's testimony, are proffered to establish that Patient Walsh worked with and was exposed to Defendants' products.

III. Experts

In support of Defendants' Motions to Exclude Plaintiff's Causation Experts, Defendants have presented the expert reports of: David H. Garabrant, M.D., Ph.D., ("Garabrant"), epidemiology; Michael Greenberg, M.D., M.P.H., ("Greenberg"), toxicology; Marshall A. Lichtman, M.D., ("Lichtman"), hematology; Scott D. Phillips, M.D., ("Phillips"), toxicology; and John H. Ross, Ph.D., ("Ross"), comparative pharmacology and toxicology. Defendants' Motions to Exclude Expert Testimony challenges the general

acceptance of the methodology used by Plaintiff's experts to draw a causal link between pesticides and Patient Walsh's AML.⁵

In support of their objections, Defendants maintain the proposition that "the proponent of novel scientific evidence must establish that the methodology used by the expert is generally accepted in a relevant scientific field," and assert that Plaintiff's experts fail to demonstrate the general acceptance of their methodology. (Bayer Renewed Mtn. Excl., ECF 357 at ¶¶ 4-5 and Brief in Support, ECF 365 at p. 12).

Defendants assert that the Plaintiff has failed to provide evidence that Patient Walsh was exposed to a dose of any of their respective products that could have been a substantial contributing cause of his AML; that Plaintiff's experts have not identified the dose required for any product to cause AML; and have not identified the dose specific response that was experienced by Patient Walsh. (See e.g., Bayer Renewed Mtn. Excl., ECF 357, p. 4, ¶¶12-13 and Bayer Mtn. Excl., ECF 218 at ¶4).⁶

In contrast to Defendants' experts, Plaintiff's experts assert that a causal link exists between pesticide exposure and Walsh's AML. Plaintiff's experts are Nachman Brautbar, M.D., ("Brautbar"), toxicology, internal medicine, occupational medicine, and nephrology; and April Zambelli-Weiner, Ph.D. ("Zambelli-Weiner"), epidemiology. Plaintiff's experts have submitted the following expert reports: Zambelli-Weiner Report, dated July 18, 2012; Brautbar Report, dated February 19, 2014; and Brautbar Rebuttal Report, dated October 27, 2015. Through their reports, Plaintiff asserts that the pesticides contained carcinogens, to which Walsh was exposed, thereby causing his AML. (Brautbar Report dated February 19, 2014, at page 22, contained in Pltf. Brf. Opp., ECF 278 at Exhibit 7).

At present, 13 pesticide products remain at issue. (See Bayer Renewed Motion and Brief (filed under seal), ECF 365 at pp. 5-6 ("Plaintiff's pending claims now involve the following 13 pesticide products, which include a wide variety of chemically and functionally different insecticides, fungicides and herbicides[.]" See also Chart, *id.* at p. 6 identifying the 13 products)).

The following pesticides are purported to have a causal link to Patient Walsh's AML:

- BASF (1 product): Touche®;
- Bayer (4 products): Bayleton®, Chipco® 26019/26GT Flo, Dylox®, and Sevin®;
- Deere (1 product): Manicure®;
- Monsanto (1 product): Roundup®;
- Sygenta (6 products): Banner/Banner Maxx®, Daconil®, Heritage®, Medallion®, Sentinel®, and Subdue®.

See (Chart in Bayer Renewed Mtn. Excl., ECF 365 at p.6 (under seal)).

The issue before this Court is whether Plaintiff has proffered sufficient evidence that its experts used generally accepted methodologies within the relevant scientific communities, pursuant to Pa.R.Civ.P. 207.1 and the Frye standard, in reaching their respective conclusions.

Upon remand and review, this Court discerns Plaintiff's experts' proffered methodological framework as follows⁷:

The Plaintiff claims that studies show an association between pesticide exposure and chromosomal aberrations which cause AML. Plaintiff's experts purport to establish that chromosomal changes are caused by the existence of carcinogenic active chemicals found in pesticides. Next, Plaintiff specifically claims these carcinogenic chemicals are found in Defendants' products. Thereafter, to determine the cause of Patient Walsh's AML, Plaintiff's experts purport to review the causes and risk factors for the chromosomal aberrations. Upon ruling out alternative causes, Plaintiff then asserts that record evidence establishes Patient Walsh's extensive historical exposure to Defendants' products caused his disease.

In summary, Plaintiff infers and extrapolates that because long term exposure to carcinogenic chemicals found in Defendants' products have been shown to cause chromosomal aberrations and all other applicable causes and risk factors have been ruled out based on the evidence, then exposure to Defendants' products caused Patient Walsh's chromosomal aberrations and therefore his AML.

IV. Legal Standard

A review of our Supreme Court's application of the Frye Test over the past twenty-five years, which includes Pa.R.Civ.P. 207.1 and Walsh, Rost, and Betz, *supra*, confirms the well-settled proposition that the Frye Test only applies when a party seeks to introduce novel scientific evidence. Frye does not apply every time science enters the courtroom. See also, Trach v. Fellin, 817 A.2d 1102 (Pa. Super 2003).

Our Supreme Court reaffirmed the proper application of Frye to novel scientific evidence when it adopted Pa.R.Civ.P. 207.1, "Motion to Exclude Expert Testimony Which Relies upon Novel Scientific Evidence." Pa.R.Civ.P. 207.1, 42 Pa.C.S.A., adopted 2001, January 22, 2001, effective July 1, 2001. As the explanatory comment to that Rule states, "The purpose of Rule 207.1 is to provide the procedure for pre-trial motions concerning the admissibility of expert testimony which relies upon novel scientific evidence." *Id.*, Explanatory Comment—2001 (emphasis added).

In examining Defendants' Frye Motions, this Court will not part with evaluating the totality of Plaintiff's expert reports with regard to causation in order to determine whether Plaintiff's experts, Drs. Brautbar and/or Zambelli-Weiner, proffer expert testimony which relies upon novel scientific evidence for purposes of the methodology employed in reaching their expert conclusions. See Pa.R.C.P. 207.1 and Walsh v. BASF, *supra*.

The requirement that the expert's methodology be generally accepted is commonly referred to as the Frye test [T]he Frye rule applies to an expert's method, not his conclusions 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.

Walsh v. BASF, 234 A.3d at 456 (quoting Blum ex rel. Blum v. Merrell Dow Pharm., Inc., 764 A.2d at 9 (Cappy, C.J., dissenting) (emphasis in original). Whether a methodology is generally accepted is a determination that must be based upon the testimony of scientists in the relevant scientific community, not upon any scientific expertise of a judge. See Pa.R.E. 702(c).

In reviewing a Frye motion, trial courts may not assess the merits of the expert's scientific theories, techniques, or conclusions. Walsh, 234 A.3d at 458. The trial court may only consider whether the expert applied methodology generally accepted in the relevant scientific community, and may not go further to attempt to determine whether it agrees with the expert's application or

whether the expert's conclusions have sufficient factual background support. Walsh, 234 A.3d at 457. Those issues are a question of fact for the jury. *Id.*

After evaluation of Defendants' Frye Motions pursuant to the standards set forth herein, this Court will then apply the well-established legal standard for Defendants' accompanying Motions for Summary Judgment pursuant to Pa. R.Civ.P. 1035.2 and in reviewing the record, shall construe the record in the light most favorable to the non-moving party, and doubts regarding the existence of a genuine issue of material fact resolved in the favor of the non-moving party. *Young v. Commonwealth of Pa.*, Dept of Transp., 744 A.2d 1276, 1277 (Pa. 2000).

V. Discussion

As referenced above and per directive of our Supreme Court, Defendants renewed their Frye Motions. (See Bayer - ECFs 357, 365; Monsanto - ECFs 358-359; BASF - 361-362; Deere - 362-363; and Sygenta - 366-367). Defendants incorporated the arguments set forth in their pre-remand Frye Motions. This Court also takes judicial notice, *inter alia*, of Plaintiff's pre-remand Brief in Opposition to Defendants' Frye Motions (ECF 278 filed March 9, 2016) and Reply Brief in Opposition (ECF 301 filed April 18, 2016) and incorporates those arguments for consideration herein. As a framework, this Court addresses the remaining issues raised by our Supreme Court in Walsh, 234 A.2d at 461 and the respective positions of the parties pursuant to the Renewed Motions and Responses.

A. Whether Dr. Brautbar and/or Dr. Zambelli-Weiner utilized a generally accepted methodology when they applied the Bradford Hill Criteria to establish the causation of certain chemicals, and by applying certain of the Bradford Hill factors contrary to the ways in which Sir Bradford Hill intended for them to be applied. (Walsh, 234 A.3d at 461).

Whether a methodology is generally accepted is a determination that must be based upon the testimony of scientist in the relevant scientific community, not upon any scientific expertise of a judge. See Pa.R.E. 702(c).

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

Walsh, 234 A.3d 446, 457 (Pa. 2020) (quoting *Ferebee v. Chevron Chemical Co.*, 736 A.2d 1529, 1534 (D.C. Cir. 1984)). In reviewing a Frye motion, trial courts may not assess the merits of the expert's scientific theories, techniques, or conclusions. Walsh, 234 A.3d at 458. The trial court may only consider whether the expert applied methodology generally accepted in the relevant scientific community, and may not go further to attempt to determine whether it agrees with the expert's application or whether the expert's conclusions have sufficient factual background support. Walsh, 234 A.3d at 457. Those issues are a question of fact for the jury. *Id.*

Following our Supreme Court's directives, this Court sets out to determine whether the Bradford Hill Criteria⁸ is a reliable method within the relevant scientific community to demonstrate a causal link between chemical and disease. As stated in Defense Expert Greenberg's Report at page 11, the Bradford Hill Methodology is "the most useful and widely applied methodology or process for evaluating data for evidence of their specific or general causation."

Both Plaintiff's and Defendants' Experts agree that the nine Bradford Hill criteria (viewpoints), include assessing the: (a) strength of the association; (b) consistency of the association; (c) specificity of association; (d) temporal relationship of the association; (e) biological gradient observed; (f) biological plausibility; (g) coherence; and (h) experimental or intervention effects. (See Greenberg Report at p. 11; Garabrant Report at p. 8; Phillips Report at pp. 9-10; and Brautbar Report at pp. 13-15).

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. Additionally, the Frye test protects both parties by assuring that a minimal reserve of experts exists who can critically examine the validity of a scientific determination in a particular case. Since scientific proof may in some instances assume a posture of mystic infallibility in the eyes of a jury of laymen, the ability to produce rebuttal experts, equally conversant with the mechanics and methods of a particular technique, may prove to be essential.

Walsh, 234 A.3d at 467 (Wecht, J., concurring) (quoting *United States v. Addison*, 498 F.2d 741, 744-45 (D.C. Cir. 1974) (emphasis added)).

Plaintiff posits that Bradford Hill is the proper methodology to determine an association between chemical and disease. (Pltf. Brf. Opp., ECF 301 at p. 6). In response, Defendants do not argue that Bradford Hill is an improper methodology; but rather assert that Plaintiff's Experts Brautbar and Zambelli-Weiner improperly employed their professional judgment in applying the Bradford Hill methodology to reach their conclusions. (ECF 301 at p. 8). Fundamentally, Defendants' argument is not supported under Frye⁹ in ruling out novel science; nor is the Defendants' argument supported as per the guidance provided by our Supreme Court in Walsh, 234 A.3d 446, *infra*.

To the extent that Defendants object, their objections are to Plaintiff's Experts' application and conclusions. Defense Experts Garabrant, Greenberg, and Phillips allege that Plaintiff's Experts' application of the Bradford Hill criteria was improper, but admit that Bradford Hill is the proper test to prove causation. (Greenberg Report at p. 11; Garabrant Report at p. 8; and Phillips Report at pp. 9-10). Certainly, Defendants may attack the techniques and application implored by Plaintiff's Experts through cross examination, but not as a part of their Frye Motion challenge to exclude Plaintiff's Experts from testifying. As such, The Bradford Hill criteria is a proper methodology employed in the relevant scientific communities of epidemiology and forensic pathology.

Underlying the use of the Bradford Hill Methodology, the Defendants' Experts specifically criticize the studies used by Plaintiff's Experts to reach their conclusions. (Garabrant Report at pp. 12-14; and Greenberg Report at pp. 15-23). Defendants argue that Plaintiff's Experts, Drs. Brautbar and Zambelli-Weiner, improperly applied Bradford Hill by "cherry-picking" data¹⁰ and ignoring certain studies. (Bayer Brf. Support Mtn. Excl. (under seal), ECF 365 at p. 28). However, Defendants' Experts also engaged in the same practice whereas the Plaintiff equally asserts that Defendants' Experts failed to address the Plaintiff's studies when forming their respective conclusions. (Pltf. Brf. Opp., ECF 301 at pp. 16-24 citing Dr. Phillips Depo. at 80 (only considered 16 studies in his analysis); and see also, Dr. Garabrant Depo. at 126-134 (failing to comment on studies used by Plaintiff's Experts in forming his conclusion)).

Notwithstanding each party's "cherry-picking" critique of the other in reviewing studies purporting to show an association between chemical and disease; the record indicates Dr. Zambelli-Weiner conducted a PubMed¹¹ search containing the keywords: "pesticide," in combination with "cancer," "leukemia," "acute myelogenous leukemia," "acute myeloid leukemia," "acute non-lymphocytic leukemia," and "AML." (Pltf. Brf. Opp. ECF 278 at p. 48). Dr. Zambelli-Weiner identified certain intrinsic challenges in studying the relationship between occupational exposure to pesticides and leukemia. (Id. at 46). These challenges were due to the rarity of leukemia and more specifically the subtype AML. (Id.) Dr. Zambelli-Weiner reviewed all 165 papers yielded by the PubMed search. (Id. at 49). She then applied her professional judgment in evaluating the studies for potential bias and part of that evaluation included: design of the study; exposure assessment; and measurement of bias. (Id. at 47-48). Dr. Zambelli-Weiner specifically looked for studies of long-term occupational exposure to pesticides, which were similar to Patient Walsh's exposure. (Id.).

This Court finds nothing "renegade" about Dr. Zambelli-Weiner's methodology. It is not the role of this Court to question an expert's exercise of professional judgment or to determine which studies, or the weight given a study, an expert must use or employ in forming their opinions on medical causation provided that the opinion is based upon an accepted methodology in the relevant scientific community supported by proffered facts of record.

Finally, Defendants also criticize Plaintiff's Experts' decision to only use six of the nine Bradford Hill criteria. (Garabrant Report at pp. 12-14; and Greenberg Report at pp. 15-23). However, as cited by Defendants' Experts, "[i]t is not necessary to simultaneously meet and fully satisfy all nine considerations." (Greenberg Report at p. 11). Not one of these criteria is determinative, and satisfying all criteria does not itself prove causation. (Garabrant Report at p. 8). As agreed by Defendant's Experts, these factors inform scientists of the extent to which a causal interpretation of evidence is supported. (Garabrant Report at p. 8).

As stated by Sir Austin Bradford Hill:

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 we can usefully lay down some hard-and-fast rules of evidence that must be observed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or 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 to 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?

Hill AB. The Environment and Disease: Association or Causation? *Proc. Royal Soc. Med.* 1965; 58:295-300 at 299.

A challenge to scientific methodology for purposes of determining novel science cannot be based upon disagreements with an opposing expert's conclusions. It is not uncommon for trials to be "battles of the experts" based upon differing conclusions reached by differing experts in their respective and relevant fields of expertise employing proper methodology. Utilization of the Bradford Hill viewpoints is a generally accepted method in the relevant scientific community, and Defendants are able to produce rebuttal witnesses equally conversant with the mechanics and methods of the technique employed. At this juncture, this Court intentionally does not provide an imprimatur as to any application or conclusions reached by any expert in employing the Bradford Hill methodology.

As set forth above, there is no evidence or expert testimony demonstrating that use of the Bradford Hill viewpoints is an improper methodology or is utilized as a novel science to establish causation. To the contrary, Bradford Hill is a proper method used by both Plaintiff's and Defendants' Experts. This Court acknowledges that Defendants' Experts have proffered opinions challenging the Plaintiff's application of the Bradford Hill methodology. These challenges are appropriately permissible through cross-examination at trial. This Court finds Defendants' objections to exclude Plaintiff's Expert testimony — based upon application of the Bradford Hill criteria and the studies cited by Plaintiff's Experts — goes to the weight and credibility of the expert testimony at the time of trial, not admissibility in the first instance. Defendants' Frye Motions are denied as to Plaintiff's Experts' use of the Bradford Hill methodology.

B. Whether Dr. Brautbar applied a generally accepted methodology to arrive at his cytogenetic¹² "fingerprint" conclusion. (Walsh, 234 A.3d at 461).

As stated by our Supreme Court:

In their Frye motions filed in the trial court, the Appellants [Defendants herein] 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.

See Walsh, 234 A.3d at 461.

Nachman Brautbar, M.D. has been proffered as Plaintiff's causation expert in application of the cytogenetic fingerprint methodology. As presented by Dr. Brautbar:

The use of genotoxicity data to predict carcinogenicity is founded on the principle that genetic alteration are found in all cancers. Genotoxicity is the ability of chemicals to change the genetic material in a way that allows alterations to be transmitted during cell division. Genetic alterations can occur through via differing mechanisms including gene mutations, insertions, deletions, translocations, or amplification. Mutagenicity is a specific category of genotoxicity. It is an accepted scientific principle that evidence of mutagenesis provides mechanistic support for potential carcinogenicity in humans. Mutagenesis includes the ability to cause changes in the structure of genetic material. It also can cause changes in the amount of genetic material. These changes can lead to heritable alterations in genetic function. Three types of genetic damage can be caused by mutations. These include: A) changes in chromosome number B) gene mutations in the form of deletions, insertions or point mutations that may impact genes adversely, and C) structural changes in the chromosomes. It is generally accepted in the scientific community that that any exposure to a genotoxic carcinogen is capable of causing a change in genetic material such as DNA that begins the process of carcinogenesis in humans. As a result, any exposure to a genetic carcinogen may increase the risk of cancer in humans.

(Brautbar Report dated February 17, 2014, p. 20)(filed under seal). Dr. Brautbar asserts that chromosomal aberrations in lymphocytes provide cytogenetic biomarkers (“fingerprints”). As expressed, “[c]hromosomal changes are like fingerprints of prior exposure [to carcinogens].” (Id. at p. 21).

1. General Causation

To establish general causation, Plaintiff’s experts utilize the Bradford Hill Criteria to demonstrate the existence of a causal association among certain pesticides and the chromosomal aberrations which can cause AML. In his report, Dr. Brautbar asserts that these chromosomal changes are cytogenetic fingerprints of a leukemia caused by pesticides and/or benzene. (Pltf. Brf. Opp. at p. 7, see also Brautbar Report, dated February 19, 2014, at p. 12, ECF 278 at Exhibit 7). Dr. Brautbar asserts that these chromosomal changes only occur under certain circumstances. (Brautbar Report at p. 61).

Dr. Brautbar’s cytogenetic methodology to establish general causation employs “several well-conducted epidemiological studies [that] show that increased chromosomal aberrations in peripheral blood lymphocytes increase the risk of cancer in humans.” (Brautbar Report at p. 20). In support of his cytogenetic methodology, Dr. Brautbar cites nine epidemiological studies (Id. at 20-21)¹³ to assert “research show pesticides as causative of myelodysplastic syndrome, which is a pre-leukemic stage, in exposed individuals.” (Id. at 21). Dr. Brautbar asserts that “cytogenetic studies allow us to examine whether there was a history of radiation exposure, heavy cigarette smoke which contains benzene, or whether the individual was exposed to pesticides and/or benzene.” (Id. at 21).

As defined by our Pennsylvania Supreme Court:

[E]pidemiological evidence is clearly relevant and useful in demonstrating general causation. Epidemiology deals with, inter alia, the identification of potentially causative associations in various populations between possible causative agents and the resulting incidence of particular diseases and seeks to generalize those results. In so doing, epidemiology may provide “useful information as to whether there is a relationship between an agent and a disease and, when properly interpreted, can provide insight into whether the agent can cause the disease.” See, e.g., *Blum by Blum v. Merrell Dow Pharm., Inc.*, 705 A.2d 1314, 1323–24 (Pa. Super. 1997), *aff’d sub nom. Blum ex rel. Blum v. Merrell Dow Pharm., Inc.*, 564 Pa. 3, 764 A.2d 1 (2000), and abrogated on other grounds by *Trach v. Fellin*, 817 A.2d 1102 (Pa. Super. 2003). Given its focus on identifying generalized causal relationships between potential causative agents and the resulting incidence of disease, epidemiology’s focus on statistical analysis may be uniquely suited to illuminate whether there is a general causal relationship between types of cancer and Group 1 carcinogens.

City of Philadelphia v. Workers’ Compensation Appeal Board, 195 A.3d 197, 208-209 (Pa. 2018) (internal footnote omitted).¹⁴

Dr. Brautbar’s Report states that he undertook to review, inter alia: Patient Walsh’s medical records; Patient Walsh’s West Penn Hospital Cytogenetic Results¹⁵; and Dr. Zambelli-Weiner’s July 18, 2012 Report, entitled “Review of Leukemia and Occupational Pesticide Exposure.” (See Brautbar Report, pp. 7-8). Dr. Brautbar states he relied on the Report of April Zambelli-Weiner, Ph.D., M.P.H (epidemiology), “which gathered epidemiological literature to present time and further documents that occupational pesticide exposure is a cause of leukemia both for the active ingredients present in the pesticides and for petroleum solvents as a component of the formulation.” (Id. at p.19).

Dr. Zambelli-Weiner’s methodology identified “18 studies that examined the relationship between occupational pesticide exposures and leukemia.” (Zambelli-Weiner Report, p. 5). Dr. Zambelli-Weiner stated that her “causal assessment is based on my expertise as an epidemiologist in weighing the totality of the epidemiologic evidence as well as my consideration – but not strict application – of the Bradford Hill criteria as a guide for making causal inference from a body of literature.” (Id.).¹⁶ Dr. Zambelli-Weiner asserted “[i]t should be noted that Hill’s criteria do not require statistical significance.” (Id.). Dr. Zambelli-Weiner’s methodology included a PubMed literature search for leukemia and pesticide studies in humans. (See footnote 11 re: PubMed, *infra*). Her search yielded 165 papers. Of those 165 papers, Dr. Zambelli-Weiner identified 8 occupational studies¹⁷ of pesticide exposure that demonstrate “an increased risk of, or rate of death from leukemia, and AML specifically, from exposure to pesticides.” (Id. at p. 6). Dr. Zambelli-Weiner’s methodology then identified the association between organophosphate pesticide (OP) exposure and leukemia risk. She referenced four pesticides: Diazinon, Fonofos, Terbufos, and Crotoxyphos. (Id. at p. 10, see also Table 2, p. 11). Dr. Zambelli-Weiner also examined five studies related to the association of benzene exposure with increased risk of leukemia. (Id. at p. 11-12, n.32-36) (Dr. Zambelli-Weiner stating, “a comprehensive review of the evidence supporting an association between solvent exposure and leukemia, and AML specifically, is beyond the scope of this report.”). (Id. at p. 12).

In addition to his review of Zambelli-Weiner’s Report, Brautbar’s Report incorporates an Exhibit A -- Literature Index consisting of 25 pages (including 446 science-related references); Exhibit B -- Table 1 consisting of 9 pages (pesticides, Patient Walsh’s exposure, and witness testimony summary); and Exhibit C -- Table 2 consisting of 39 pages (components of each pesticide and carcinogenic potential of each chemical in those pesticides). Dr. Brautbar’s 446 referenced endnotes incorporate published scientific studies and reports related to chromosome patterns, cytogenetics, genotoxicity, cytogenotoxicity, and chromosomal aberrations along with references to scientific reports, studies, and other data related to general causation of pesticides and particular chemicals, including benzene, to carcinogenic risk and Acute Myeloid Leukemia.

Our Pennsylvania Supreme Court has affirmed that an expert need not rely on studies mirroring the exact facts under consideration but a synthesis of various legitimate studies which reasonably permits experts’ conclusions may be sufficient for purposes of *Frye*. *Walsh*, 234 A.3d at 464 (emphasis added).

This Court does not find the methodology employed by either Dr. Zambelli-Weiner and/or Dr. Brautbar as related to general causation to be a novel foundation for Dr. Brautbar’s application of the Cytogenetic Fingerprint Methodology as discussed below.

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.

Walsh, 234 A.2d at 463 (footnote omitted).

As determined by our Supreme Court, it is clear that Dr Zambelli-Weiner’s testimony only relates to general causation and not to specific causation as to any of Defendants’ products. As such, this Court examines specific causation as related by Dr. Brautbar.

2. Specific Causation

In his report, Dr. Brautbar asserts that the chromosomal changes found in Patient Walsh are cytogenetic fingerprints of a leukemia caused by pesticides and/or benzene. (Pltf. Brf. Opp. at p. 7 and Brautbar Report at p. 12, ECF 278 at Exhibit 7).

Upon review, at present a total of thirteen products are identified as subject to Plaintiff's claims.¹⁸ Brautbar's Report at Exhibits B and C presents a binary delineation of specific products purported to cause disease. Exhibit B identifies, inter alia, benzene-related chemicals in certain Defendant products.¹⁹ Exhibit C identifies carcinogen-related chemicals in certain Defendant products. To reiterate, this Court makes no findings nor ascribes any weight to the specific chemicals identified, and the applications or conclusions contained, inferred, or extrapolated from Exhibits B and C. Per Walsh, *infra*, this Court is constrained but to confirm a proffered basis for Dr. Brautbar's methodology as to its general acceptance in the relevant scientific community per the Frye Test and the standards set forth in Rost, Betz, and Trach, *infra*.

Of the thirteen products, it is noted that a purported benzene-related chemical is found in seven of the thirteen. (Brautbar Report at Exhibit B).²⁰ Of the six remaining products that do not contain a benzene-related chemical, Dr. Brautbar references studies proffered to support his opinion about the carcinogenicity of active chemicals found in the remaining six products purporting to cause chromosomal aberrations consistent with AML. (Brautbar Report at Exhibit C).²¹

In conjunction with the above product-specific analysis, Dr. Brautbar employs a cytogenetic "fingerprint" methodology in conjunction with the patient's history to determine the specific cause of Patient Walsh's AML. (See Certification of Death, dated February 3, 2009, with cause of death due to consequence of "Acute Myelogenous Leukemia", ECF 278 at Ex. 2). As referenced herein, Patient Walsh had bone marrow aspirations on four dates for collection of specimens for cytogenetic analysis.

The Cytogenetic Results for each date revealed a complex karyotype.²² Each report identified the unique profile of chromosomal abnormalities with reports stating, "[a]ll of these abnormalities are common in patients with AML and/or MDS²³." All reports stated that each of the findings were "reported in secondary leukemia, and the loss of p53 [gene region on chromosome #17] is associated with poor prognosis."

The first Cytogenetic Results report of 10/23/2008 identified deletion of chromosome 5q and 20q, and "[t]he results for chromosome #7 were normal." The second Cytogenetic Results report of 10/29/2008 identified the deletion of both chromosome 5q and 7q.²⁴

The third and fourth Cytogenetic Results reports added "secondary leukemia", along with AML and MDS as being common diagnosis of patients with deletions of 5q, 7q, and 20q.

Based upon the Cytogenetic Results reports, Patient Walsh's attending hematologist at West Penn Hospital, James Rossetti, D.O., opined:

As was mentioned earlier in this report, the abnormalities representing chromosomes 5, 7 and 20 are frequently seen in secondary leukemias. Such leukemias may arise from a myelodysplastic²⁵ state with such syndromes being linked to chemical exposure. Myelodysplasia was potentially present in Mr. Walsh given the persistent dyspoietic²⁶ features within the marrow following initial induction. Such leukemias may also be the direct result of toxic exposure which may be occupational, accidental or iatrogenic²⁷. While I am not a toxicologist, a large part of my practice does focus on treatment of the myelodysplastic syndromes and myeloid malignancies. It is well known that various chemical exposures are risk factors for these diseases. While experts in the area of toxicology are likely providing additional reports, I have also reviewed various chemicals to which Mr. Walsh was exposed. Given his clinical and pathological presentation, I do suspect that his occupational exposure related to various agents utilized for maintenance of golf courses over the years may indeed be a primary contributor to the development of his disease. As I have stated previously, both the complex karyotype and the dyspoietic features of post induction marrow specimens not only portend a high risk but strongly suggest a secondary or exposure related type of leukemia with an associated poor prognosis. In closing, the extensive chemical exposure to Mr. Walsh over the years accompanied by the high risk karyotype and dyspoietic features associated with his disease raise a high degree of suspicion that such exposure played a significant role in the development of his disease.

(Rossetti Report dated July 19, 2012, at p. 4 (footnote added) (emphasis added), attached as Exhibit 2 of Plaintiff's Brief in Opposition, ECF 278).

In furtherance of Dr. Rosetti's opinion of specific causation and the generally accepted use of Cytogenetic Fingerprint Methodology applied in the relevant scientific community of cytogenetics, the deposition of Richard Thomas Walsh (Patient Walsh's son) disclosed:

Q: So I understand your testimony, Dr. Rossetti told you that it was Dr. Rossetti's opinion or belief that your father's AML was caused by exposure to pesticides; is that correct?

A: Yes.

Q: Can you recall anything else specifically that Dr. Rossetti said with regard to that subject, that is the pesticides causing your father's AML?

A: The one thing that sticks out in my mind is that dad's DNA was abnormal. His chromosomes were altered, which Rossetti told me is an indication of environmental or toxic exposure to some form of chemicals.

Q: Do you recall anything more specific about what the abnormality of your father's DNA was either based on what Dr. Rossetti told you or some other information?

A: I believe it was chromosomes 5, 7 and 13; and that's just from trying to recall from memory; but I know for a fact he had told me that his DNA was abnormal and because of the certain chromosomes it was an indicator that it was environmental exposure.

And then when he had his second consolidation dose of -- when he said his induction dose of chemo, the first one, the leukemia went into remission; but the DNA didn't change, which was even more of an indication to Rossetti -- and he could put this in medical terms -- I'm just trying to remember what he told me -- that it was just the way the DNA was set up and manipulated and the abnormalities was an indication.

Q: Do you recall anything else that Dr. Rossetti told you with regard to pesticides as a cause a possible cause of your father's AML?

A: No. You would have to ask him. I don't --

(Richard Thomas Walsh Depo., 12/6/2011, p. 25, l. 14 - p. 26, l. 24 at ECF 278, Ex. 6). (emphasis added).

Based upon the above foundation, Dr. Brautbar employed the method of differential diagnosis²⁸ to reach his conclusions. This methodology was used in conjunction with Patient Walsh's chromosomal markers as revealed in the four Cytogenetic Results reports along with the epidemiological analysis Drs. Brautbar and Zambelli-Weiner have proffered. Dr. Brautbar's Report at pages 60-63 addresses his differential diagnosis as related to Patient Walsh.

In determining whether Mr. Walsh's leukemia was caused by his occupational exposure to organic solvents and pesticides, I employ the generally accepted methodology commonly known as a differential diagnosis, but in the medico-legal context perhaps more accurately described as a differential etiology. This methodology first involves ruling in all identifiable known causes of (and risk factors for) acute myelogenous leukemia and then ruling out those for which there is inadequate evidence. The remaining cause(s) would then be deemed the probable cause(s) provided that substantial scientific and medical evidence exists for causality. If substantial scientific and medical evidence does not exist for causality, the determination would be that the cause of the patient's disease remains unknown.

(Brautbar Report, p. 61). Dr. Brautbar's differential diagnosis (differential etiologic analysis) ruled out: antecedent hematologic disorders; congenital disorders; familial syndromes; viral infections; chemotherapeutic and cytotoxic agents; ionizing and non-ionizing radiation; cigarette smoking and secondhand tobacco smoke; and exposure to benzene, pesticides, and other industrial chemicals from prior occupational sources. (Id. at pp. 62-63) (emphasis added).

In support of his methodology for specific causation, Dr. Brautbar employed differential diagnosis by "ruling in all identifiable and known causes (and risk factors for) acute myelogenous leukemia and then ruling out those for which there is inadequate evidence." (Brautbar Report at p. 61). Upon considering and dismissing other potential causes and factors, Dr. Brautbar opined "with a degree of medical certainty, that each of the pesticides listed in Exhibit C was a substantial contributing factor in causing Mr. Wal[sh]'s acute myeloid leukemia, which in turn caused his death." (Id. at 64).

There is nothing scientifically novel about using differential diagnosis to make scientific/medical conclusions about causation. Differential diagnosis is a generally accepted methodology. See *Cummins v. Rosa*, 846 A.2d 148, 151 (Pa. Super. 2004) (Frye did not apply where the methodology employed by the plaintiffs' medical experts was generally accepted among the medical community for diagnosis and treatment; plaintiffs' experts analyzed plaintiff-wife's medical records and relied upon their personal expertise to reach a conclusion regarding the source of her injuries).²⁹

This Court notes that the Defendants assert that Dr. Brautbar misapplied his use of the differential diagnosis methodology to conclude that Patient Walsh's AML was caused by exposure to pesticides. (Bayer Brief Support Renewed Motion, ECF 365 at p. 11-12) (emphasis added). The Defendants posit:

First, he [Dr. Brautbar] purports to rule in exposure to pesticides at unknown levels as a potential cause of Mr. Walsh's AML without evidence that such general causation has been established using a generally accepted scientific methodology. Second, he has failed to rule out -- or, in fact, even consider -- one obvious potential cause of Mr. Walsh's AML, namely, Mr. Walsh's obesity, while also ignoring established medical science that most cases of AML (including a large percentage that share Mr. Walsh's cytogenetic "fingerprint") are de novo (idiopathic) AML, with no identifiable cause.

(Id.)

This Court acknowledges that Defendants challenge the manner in which Dr. Brautbar applied the differential diagnosis method. As addressed herein, the issue of application of a method to reach a conclusion is subject to scrutiny at trial and the issue of general causation has been addressed in Discussion – Section B(1) – General Causation, *infra*.

As to Dr. Brautbar's alleged failure to address obesity and the existence of de novo AML as potential causes of Patient Walsh's AML; this Court concludes that any alleged absence of factors involves the application of the differential diagnosis methodology. Moreover, at deposition Dr. Brautbar discusses de novo AML and obesity. (See e.g., Brautbar Dep. 5/13/2014, pp. 24-26 and 5/14/2014, pp. 322-323 (re: de novo / idiopathic AML); and 5/14/2014, pp. 347-350 (re: obesity)). As such, this Court finds the differential diagnosis factors to be issues related to the weight and credibility of Dr. Brautbar's application of the method and his conclusions. Per our Supreme Court, this trial court is constrained to evaluate an expert's conclusions provided that the causation expert has used a generally accepted methodology in the relevant scientific community. This Court finds that the differential diagnosis methodology is generally accepted in the medical community at large. Any alleged failure to apply the methodology based upon the underlying facts of a case and alternative risk factors subjects the expert to the intense scrutiny of cross-examination at trial. This Court will not exceed its role as a trier of fact and will not portend itself a self-authenticating scientific/medical sage on complex issues related to expert opinions.

After employing his differential diagnosis and ruling out Patient Walsh's identified risk factors; Dr. Brautbar then evaluated Patient Walsh's cytogenetic markers ("fingerprints") with epidemiological findings and cytogenetic aberrations as related to organic solvents, such as benzene, to AML from dermal absorption and respiratory inhalation. (Brautbar Report, pp. 63-64). Dr. Brautbar noted that "two of Mr. Walsh's chromosome abnormalities in chromosome 5 and chromosome 7, have been strongly linked to benzene exposure in multiple studies as described above." (Id. at p. 64). As a result, Dr. Brautbar could not rule out occupational exposure to benzene-containing solvents as a cause of Patient Walsh's leukemia. (Id.). It is significant to note that Sir Bradford Hill's ninth factor is to consider analogy for purposes of association and causation:

(9) Analogy: In some circumstances it would be fair to judge by analogy. With the effects of thalidomide and rubella before us we would surely be ready to accept slighter but similar evidence with another drug or another viral disease in pregnancy.

Hill AB. The Environment and Disease: Association or Causation? *Proc. Royal Soc. Med.* 1965; 58:295-300 at 299.

This Court is tasked with assessing the cytogenetic fingerprint methodology employed by Dr. Brautbar to determine whether novel science was involved under the rubric of the Frye test standard. This Court recognizes that the Defendants' Motions to Exclude Plaintiffs' Causation Experts challenge the conclusions reached by Drs. Rossetti, Zambelli-Weiner, and Brautbar as

related to the Patient Walsh's secondary AML.

A challenge to scientific methodology for purposes of determining novel science cannot be based upon disagreement with an opposing expert's conclusions. It is not uncommon for trials to be "battles of the experts" based upon differing conclusions reached by differing experts in their respective and relevant fields of expertise employing proper methodology.

a. Specific Causation - Dose Response³⁰

Defendants assert that Plaintiff has failed to provide evidence that Patient Walsh was exposed to a dose of any of the products that could have been a substantial contributing cause of Patient Walsh's AML and claim Plaintiff cannot sustain his burden of proof on product-specific causation. (See, e.g., ECF 357, p. 4, ¶12-13).

Our Pennsylvania Supreme Court in *Rost v. Ford Motor*, 151 A.3d 1032 (Pa. 2016) citing to *Gregg*³¹ and *Betz*³², established the "frequency, regularity, and proximity" test in asbestos product liability litigation to address the dose-response issue.

Together, *Gregg* and *Betz* establish two basic precepts important to resolution of the issues presented here. First, expert testimony based upon the notion that "each and every breath" of asbestos is substantially causative of mesothelioma will not suffice to create a jury question on the issue of substantial factor causation. Second, to create a jury question, a plaintiff must adduce evidence that exposure to defendant's asbestos-containing product was sufficiently "frequent, regular, and proximate" to support a jury's finding that defendant's product was substantially causative of the disease.

Rost v. Ford Motor, 151 A.3d 1032, 1044 (Pa. 2016). This Court applies the same "frequent, regular, and proximate" principle to the facts underlying causation in the matter sub judice:

Rather than offering "each and every breath" theoretical constructs, causation experts must provide concrete testimony of causal attribution by assessing the frequency, regularity, and proximity of the plaintiff's exposure to the defendant's product. *Gregg*, 943 A.2d at 226-27. This assessment, in turn, requires a focus on the precise nature of the plaintiff's exposure to the defendant's product, not on other asbestos-containing products. As we advised in *Gregg*, the *Tragarz* "frequency, regularity, and proximity" factors should be applied "in an evaluative fashion as an aid in distinguishing cases in which the plaintiff can adduce evidence that there is a sufficiently significant likelihood that the defendant's product caused his harm." *Id.* at 225; see also *Lindstrom v. A-C Prod. Liab. Trust*, 424 F.3d 488, 493 (6th Cir. 2005) ("The requirement ... is that the plaintiff make a showing with respect to each defendant that the defendant's product was a substantial factor in plaintiff's injury."). . . .

Rost v. Ford Motor, 151 A.3d at 1048.

The Plaintiff has proffered deposition testimony of Patient Walsh's co-worker Blaise Santoriello (Pltf. Brf. Opp., ECF 278 at Exhibit 8) and Patient Walsh's own handwritten notes summarizing products used (Pltf. Brf. Opp., ECF 278 at Exhibit 9) to support his contention of Patient Walsh's frequent, regular, and proximate exposures to Defendants' products containing either benzene-related chemicals or carcinogen-related chemicals. (See *Brautbar Report*, Exhibits B and C).³³ As such, Plaintiff has adduced evidence that Patient Walsh was exposed to said products during his 38 years as a golf course groundskeeper and superintendent. Drs. Zambelli-Weiner and Brautbar, in part through application of epidemiological methodology, the cytogenetic biomarker ("fingerprint") methodology combined with incorporating Patient Walsh's exposure history to specific products, opined that the exposures while engaged in golf course maintenance were sufficient to support their conclusions regarding specific causation.

Pursuant to the guidance provided by *Rost*, *Gregg*, and *Betz* as applied herein; this Court finds that Patient Walsh's exposures identify sufficient contact with each of the remaining Defendant's identified product(s) to satisfy the "frequency, regularity, and proximity" test as set forth in *Brautbar Exhibits B and C*, when coupled with Plaintiff's medical and expert testimony. The Plaintiff's proffered record evidence establishes a basis to overcome Defendants' Motion for Summary Judgment as there remains genuine issues of material fact relating to the conclusions reached by experts. At this juncture, it is for the jury to decide the validity, credibility, and weight of the respective expert conclusions and to resolve the issue of substantial causation.

VI. Conclusion

The methodology employed by Plaintiff's Experts does not rely upon novel science nor novel methodology in their respective relevant scientific communities – epidemiology and forensic pathology. Doctors Zambelli-Weiner and Brautbar's use of extrapolation from scientific data contained within the cited reports and studies contained within their Expert Reports and accompanying references, including use of logical inferences, are methodologies generally accepted and used by scientists within their relevant scientific community.

This Court concludes that Plaintiff's Medical Experts, Nachman Brautbar, M.D. (forensic pathology) and April Zambelli-Weiner, Ph.D., M.P.H. (epidemiology) followed reliable and generally accepted methodology in their relevant fields in Plaintiff establishing a scientifically-based theory of specific causation in this case. This Court concludes that the Plaintiff's Experts proffered evidence resulting from scientific research which has been conducted in a fashion that is generally recognized as being sound, and is not the fanciful creation of a renegade researcher. See *Walsh*, 234 A.3d at 466 (Wecht, J., concurring)(citing to *Blum ex. Rel. Blum v. Merrell Dow Pharm., Inc.*, 764 A.2d 1, 9-10 (Pa. 2000)).

The weight, credibility, and totality of evidence contained within Plaintiff's and Defendants' Expert Opinions including conclusions, albeit in dispute, both include variations of the hierarchy of generally accepted epidemiologic evidence (e.g., meta-analyses, experimental designs, randomized controlled trials, large sample trials, randomized cluster trials, observational designs, cohort studies, case-control studies, descriptive studies, prevalence studies, cross-sectional studies, ecological studies, case series, and case reports) and methodologies to support their respective positions. Moreover, the absence of ruling in or ruling out alternative risk factors in an expert's application of an accepted methodology will subject the proponent's expert extrapolations, inferences, and conclusions to the rigors of cross-examination. It is well-recognized that vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking purported shaky but admissible evidence.

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

Walsh, 234 A.3d at 457 quoting Trach, 817 A.2d at 1117 (emphasis added).

It is not the province of this trial court to evaluate the conclusions reached by the experts in this case. How effectively and convincingly an expert employs a given methodology is a matter for the jury to assess. See Walsh, 234 A.3d at 466 (Wecht, J., concurring).

Questions concerning the quality and persuasiveness of the applications and conclusions must be resolved by the collective judgment of the jury. Aided by the crucible of the parties' adversarial presentations, the jury is just as capable as the average judge of weighing the parties' competing accounts, identifying and rejecting particular applications of generally accepted principles and methods that either depart from standard practice in the field or lack a sufficient evidentiary foundation.

Walsh, 234 A.3d at 467 (Wecht, J., concurring).

What constitutes novel scientific evidence has historically been decided on a case-by-case basis. See *Com. v. Puksar*, 951 A.2d 267, 275 (Pa. 2008); and *Com. v. Dengler*, 890 A.2d 372, 382 (Pa. 2005). Based upon the record submitted for review: the expert reports of Dr. Brautbar (forensic pathology) and Dr. Zambelli-Weiner (epidemiology); the epidemiological publications, reports, and studies cited by both doctors; the respective methodologies used by Drs. Zambelli-Weiner and Brautbar (epidemiological analysis and cytogenetic "fingerprint" extrapolation as applied to findings of diagnosing secondary AML); and the expert opinion on causation between occupational chemical exposure to carcinogenic-related pesticide products and resultant secondary Acute Myeloid Leukemia – it is this Court's conclusion that the methodologies employed do not involve novel scientific evidence, nor does it implicate principles that have not gained general acceptance in the fields of pathology or epidemiology. This Court, at this juncture, intentionally does not address the conclusions reached by any respective expert in their relevant scientific community based upon the methodologies employed. Any objections by Defendants to the means by which Drs. Zambelli-Weiner or Brautbar formulated their opinions and conclusions affects the weight and credibility, rather than the admissibility of their opinions at this juncture. Therefore, the Defendants' Motions to Exclude the Plaintiffs' Causation Experts' testimony under Rule 207.1 will be denied.³⁵

In furtherance of this Trial Court's Opinion, all parties are well-advised to heed the prospective admonition of Sir Austin Bradford Hill:

All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.

Hill AB. The Environment and Disease: Association or Causation? *Proc. Royal Soc. Med.* 1965; 58:295–300 at 300. Sir Bradford Hill's admonition is a touchstone for this Court as this matter proceeds.

The parties' experts shall be subject to cross-examination at trial regarding the conclusions reached by their methodology and their use of extrapolation and logical inferences based upon their referenced scientific evidence. No party is prohibited nor precluded from cross-examination of expert opinion; the application of reports, studies, or data to methodology; implication of other risk factors and causes related to Acute Myeloid Leukemia; or conclusions at the time of trial, pending further Order of Court.

WHEREAS, the following ORDER of this same date is entered and incorporated herein.

BY THE COURT:

/s/Ignelzi, J.

¹ Each Defendant having filed its own Joinder or Motion to Exclude in the following chronological order. "ECF" means "electronic court filing" identified by number on the Department of Court Records docket:

- See (Bayer Motion to Exclude Testimony of April Zambelli-Weiner and Nachman Brautbar and for Summary Judgment, ECF 357 filed October 26, 2020);
- See (Monsanto Motion to Exclude Testimony of April Zambelli-Weiner and Nachman Brautbar and for Summary Judgment, ECF 359 filed October 26, 2020);
- See (BASF Motion to Exclude Testimony of April Zambelli-Weiner and Nachman Brautbar and for Summary Judgment, ECF 360 filed October 27, 2020);
- See (Deere Joinder in Bayer's Renewed Motions to Exclude Testimony of April Zambelli-Weiner and Nachman Brautbar and for Summary Judgment, ECF 363 filed October 27, 2020); and
- See (Sygenta Renewed Motion to Exclude Testimony of Drs. April Zambelli-Weiner and Nachman Brautbar and for Summary Judgment, ECF 367 filed October 28, 2020).

² Plaintiff and Defendants incorporate their pre-remand Frye Motions and Responses, e.g.:

- See (Plaintiff's Brief in Opposition to Motion to Exclude Expert Witness Testimony, ECF 278, filed March 9, 2016);
- See (Defendants' Joint Motion to Exclude Expert Testimony of April Zambelli-Weiner and Nachman Brautbar, ECF 282, filed March 9, 2016); and also
- See (ECFs 274-318 for related pre-remand Motions, Appendices, and Briefs).

³ *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

⁴ In the Fifth Judicial Circuit of Pennsylvania - Court of Common Pleas of Allegheny County – Civil Division; this Court is assigned to the Commerce and Complex Litigation Center pursuant to Allegh. L. R. 249, which also includes complex tort and class action lawsuits.

See https://www.alleghenycourts.us/civil/commerce_complex_litigation.

In addition to commercial and/or complex litigation, this undersigned jurist is also assigned to preside over general docket cases and jury trials. Under normal circumstances, Allegheny County Civil Division Courts generally operate on a calendar conducting trials during the months of January, March, May, September, and November. See https://www.alleghenycourts.us/civil/civil_division_court_calendar. Throughout the year, this Court is also assigned and conducts conciliations, mediates scheduled settlement negotiations, and addresses the innumerable procedural and substantive discovery and pretrial issues raised by litigants in the complex and general docket cases assigned.

In addition to the above-assigned responsibilities, this Court is also the assigned Special Motions Judge for pretrial discovery matters. See Allegh. L. R. 208.3(a)(5). As Special Motions Judge, during every month of the year, this Court reviews and addresses 25-40 new motions per week with oral argument in addition to its other responsibilities which requires coordination of scheduling among multiple litigants, daily review of innumerable motions, pleadings, exhibits, interrogatories, documents, case law, analysis of factual and legal issues, and the drafting and issuance of Opinions and Orders. The undersigned Court staff includes positions for one law clerk, one tipstaff, and one secretary. This Court is unique and appreciative in having three lawyers amenable to filling the above three positions on a full-time basis notwithstanding inherent budget constraints incommensurate with their education, professional training, experience, and skills for the complex legal matters to which they are assigned. This Court Staff's tireless commitment to addressing all of their manifold responsibilities in a timely and professional manner is beyond reproach.

In context during the time that the within Frye Motion was pending on remand, this Court operated remotely as motions, hearings, and oral arguments were presented by video conferencing via Microsoft Teams format per Emergency Orders per COVID-19 circumstances. Documents for review were submitted in electronic format, and voluminous submissions also required production of hard copy for delivery to the Court and additional logistic considerations.

⁵ The respective reports are dated as follows:

- Garabrant Report dated March 30, 2015
- Lichtman Report dated March 31, 2015
- Phillips Report dated May 6, 2015
- Greenberg Report dated May 10, 2015
- Ross Report dated May 11, 2015

⁶ See also: (Monsanto's Motion and Brief in Support of its Renewed Motion to Exclude and Motion for Summary Judgment, ECFs 358 and 359; BASF's Motion and Brief in Support of Renewed Motion and for Summary Judgment, ECFs 360 and 361; Deere's Joinder Motion and Supplemental Brief in Support of Renewed Motions to Exclude Testimony and for Summary Judgment, ECFs 362 and 363; Sygneta's Motion and Brief in Support of Renewed Motion to Exclude Testimony and for Summary Judgment, ECFs 366 and 367.

⁷ As per the guidance of our Supreme Court in *Walsh*, *infra*, -- and in this ever-changing fast-paced scientific, medical, and technological era -- it behooves experts with the guidance of learned counsel to incorporate a clear, concise, and complete explanation of the methodologies employed that be contained in a separate introductory section in expert reports. Indeed, the world has changed and has become more complex since the adoption of the Frye test in 1923 and counsel in conjunction with experts should be mindful of the strictures identified in *Walsh* related to the examination of methodology for purposes of a trial court's evaluation of Defendants' Motions to Exclude Expert Testimony pursuant to Pa.R.Civ.P. 207.1.

⁸ Sir Albert Bradford Hill, *The Environment and Disease: Association or Causation*, 58 Proc. Royal Soc. Med. 295 (1965). Albeit, the Supreme Court characterizes the Bradford Hill Methodology as the Bradford Hill "Criteria", this Court acknowledges that the Bradford Hill Methodology contains "nine different viewpoints" per the author himself. Use of and adoption of the term "criteria" herein does not imply nor connote that any criterion is to be evaluated by this trial court as having any more or less weight than any other criterion. The terms "criteria", "viewpoints", or "factors" shall be used interchangeably herein as related to the Methodology. It is not the function of this Court to evaluate the application or conclusions reached by experts in their use of the Bradford Hill Methodology, but rather to evaluate whether the Bradford Hill Methodology is an accepted methodology in the relevant scientific community per Frye and used as a basis for the respective expert's application of facts to the methodology and conclusions reached.

⁹ In Defendants' previous Joint Brief in Support of Motion to Exclude it appears defendants conflated the Frye standard with the more restrictive Daubert standard. (See Deft. Joint Brf. Mtn. Excl., ECF 282). As noted by our Supreme Court in *Walsh*, there remains clear distinctions between the Frye and Daubert standards.

Daubert jurisdictions generally grant trial courts substantially broader discretion to stop expert testimony at the courtroom door. Federal Rule of Evidence 702 provides: 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 will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

F.R.E. 702. Subparagraphs (b) and (d) have no counterpart in Pennsylvania's corresponding rule, and it is there that the "gatekeeping" mandate in its strongest sense lives.

Walsh, 234 A.3d at 467.

¹⁰ Defendant's criticize Dr. Zambelli-Weiner for only relying on 18 studies and contend that Dr. Zambelli-Weiner was to "conduct an epidemiological literature search ... and review all articles published reporting on studies relating to the relevant topic and considering all of those studies..." (ECF 365 at 12, 28).

¹¹ PubMed is a free resource supporting the search and retrieval of biomedical and life sciences literature with the aim of improving health—both globally and personally. The PubMed database contains more than 32 million citations and abstracts of biomedical literature. <https://pubmed.ncbi.nlm.nih.gov/about/>

¹² Cytogenetics is the branch of genetics that studies the structure of DNA within the cell nucleus. This DNA is condensed during cell division and form chromosomes. The cytogenetic studies the number and morphology of chromosomes. Using chromosome banding techniques (classical cytogenetics) or hybridization fluorescently labeled probes (molecular cytogenetics). The number and morphology of chromosomes in a cell of a particular species are always constant, in most cells of the body (with the exception of reproductive cells and others such as the liver). This is a characteristic of each specie, in humans such as the number of chromosomes is 46.

See <https://www.genome.gov/genetics-glossary/Cytogenetics>.

¹³ “Bonassi, S.; et al. Chromosomal aberrations and risk of cancer in humans: an epidemiologic perspective. *Cytogenet Genome Res.* 2004;104(1-4):376-82; Bonassi, S.; et al. Chromosomal aberrations in lymphocytes predict human cancer independently of exposure to carcinogens. *Cancer Res.* 2000 Mar 15;60(6):1619-25; Benassi, S.; et al. Are chromosome aberrations in circulating lymphocytes predictive of future cancer onset in humans? Preliminary results of an Italian cohort study. *Cancer Genet Cytogenet.* 1995 Feb;79(2):133-5; Bonassi, S.; et al. Chromosomal aberration frequency in lymphocytes predicts the risk of cancer: results from a pooled cohort study of 22 358 subjects in 11 countries. *Carcinogenesis.* 2008 Jun;29(6):1178-83; Eastmond, D.A.; et al. Mutagenicity testing for chemical risk assessment: update of the WHO/IPCS Harmonized Scheme. *Mutagenesis.* 2009 Jul;24(4):341-9; Hagmar, L.; et al. Chromosomal aberrations in lymphocytes predict human cancer: a report from the European Study Group on cytogenetic biomarkers and health (ESCH). *Cancer Res.* 1998 Sep 15;58(18):4117-21; Liou, S.H.; et al. Increased chromosome-type chromosome aberration frequencies as biomarkers of cancer risk in a blackfoot endemic area. *Cancer Res.* 1999 Apr 1;59(7):1481-4; Rossner, et al. Chromosomal aberrations in lymphocytes of healthy subjects and risk of cancer. *Environ Health Perspect.* 2005 May;113(5):517-20; Vodicka, P.; et al. Chromosomal damage in peripheral blood lymphocytes of newly diagnosed cancer patients and healthy controls. *Carcinogenesis.* 2010 Jul;31(7): 1238-41.” See Brautbar Report, 2/17/2014, p. 20-21.

¹⁴ This Court acknowledges that this citation is in the context of a workers’ compensation claim applying a different legal standard, however the fundamental definition of epidemiology and its relevance and use to establish general causation remains applicable to the case sub judice.

¹⁵ The four Western Pennsylvania Hospital Cytogenetic Results reports are dated: 10/23/2008 (specimen collected 10/9); 10/29/2008 (specimen collected 10/23); 11/17/2008 (specimen collected 11/7); and 1/15/2009 (specimen collected 1/7).

¹⁶ Dr. Zambelli-Weiner addresses the Bradford Hill Methodology in her report by answering five self-posed scientific inquiries which incorporate elements of the nine factors (See Zambelli-Weiner Report at pp. 14-15). Whether Dr. Zambelli-Weiner’s analysis included or excluded any or all of the criteria, or the reasons therefore, are based upon her causal assessment using the Bradford Hill criteria as a guide and not for strict application. Any challenges to her application of the methodology goes to the credibility and/or weight of her conclusions. See *infra*, Discussion, Section A; and Hill AB, *The Environment and Disease*, 1965; 58:295–300 at 299. Dr. Brautbar’s October 22, 2015 Supplemental Report directly addresses each of the nine Bradford Hill factors: consistency of the association; strength of the association; specificity of the observed association; temporal relationship of the observed association; biological gradient; biological plausibility; coherence; experimental evidence (from human populations); and analogy.

17 The third study of the eight referenced by Dr. Zambelli-Weiner relates to golf course superintendents:

A proportionate mortality study (23) showed that golf course superintendents experienced excess mortality in general (PMR=136, 95% CI=121-152) and that death from leukemia occurred at an increased level (PMR=162, 95% CI=83-316) as did Non-Hodgkin’s Lymphoma (PMR=237, 95% CI=137-410).

(See Zambelli-Weiner 7/18/2012 Report, p. 7) (referencing citation 23 to: Kross BC, Burmeister LF, Ogilvie LK, Fuortes LJ, Fu CM. Proportionate Mortality Study of Golf Course Superintendents. *Am J Ind Med* 1996; 29(5):501-6).

¹⁸ As set forth on the Chart at ECF 365 at p. 6, *infra*:

- BASF (1 product): Touche®;
- Bayer (4 products): Bayleton®, Chipco® 26019/26GT Flo, Dylox®, and Sevin®;
- Deere (1 product): Manicure®;
- Monsanto (1 product): Roundup®;
- Sygenta (6 products): Banner/Banner Maxx®, Daconil®, Heritage®, Medallion®, Sentinel®, and Subdue®.

¹⁹ The respective expert reports herein are dense, complex, and contain voluminous exhibits and specific scientific references. In ascertaining the logical inferences of scientific methodologies for purposes of the Frye Test, the burden was placed on this Court to understand the Plaintiff’s analytical path without scientific expertise to identify the universe of benzene chemicals and thus uses the term “benzene-related” to describe those chemicals listed in Brautbar’s Report which purport to contain some variation of benzene. (See Brautbar Report, 2/17/2014 at p. 64) (“Moreover, tw[o] of Mr. [Patient] Walsh’s chromosome abnormalities in chromosome 5 and chromosome 7, have been strongly linked to benzene exposure in multiple epidemiologic studies as described above”). This Court also undertook the task to ascertain which specific Defendant products did not contain benzene-related chemicals which Plaintiff ascribes as genotoxic thereby alleging causation to disease. The burden on this Court to ascertain the analytical path without a clear explanatory map from counsel required the Court to analytically connect scientific evidence with logical inference to comprehend Plaintiff’s theory of causation as to the varying pesticide products pursuant to Plaintiff’s Experts’ methodologies. Simply put, this Court had to put the Plaintiff’s proverbial puzzle pieces together to see their methodological picture. As set forth herein at footnote 6; a clear, concise, and complete explanation of Plaintiff’s theory was not readily evident, thereby requiring the Court to determine the nature of the thirteen pesticides to distinguish those specific products from the nebulously-defined universe of “pesticides-as-a-class.” Cf. “Herbicides,” “fungicides,” and/or “insecticides” as-a-class.

This Court is mindful of the apocryphal quip attributed to Abraham Lincoln, “calling a tail a leg doesn’t make it a leg.” See George W. Julian, *Lincoln and the Proclamation of Emancipation*, in *Reminiscences of Abraham Lincoln by Distinguished Men of His Time* 227, 242 (Allen Thorndike Rice ed., Harper & Bros. new & rev. ed. 1909) (1886) (“[H]e used to liken the case to that of the boy who, when asked how many legs his calf would have if he called its tail a leg, replied, ‘Five,’ to which the prompt response was made that calling the tail a leg would not make it a leg.”). Analogously, calling a product a pesticide does not make it, ipso facto, a human carcinogen for purposes of the current applicable legal standards relating to expert methodology and causation. As ascertained by the Court’s thorough analysis of the record herein, the Plaintiffs’ Experts provided the necessary information to support general and specific causation, but not without considerable effort to connect the dots.

Again, parties submitting expert reports, Frye motions, and replies thereto (if requested by the court) are well-advised to directly address the methodology at issue without convoluting the legal issues by seeking the Court to wander into highly nuanced and complex scientific rabbit holes. It is the responsibility of the parties to assure that their respective experts’ reports contain concise summaries of the methodologies employed that are prima facie understandable to the layperson. To be clear, this guidance is not intended to chill the zealous advocacy of any party or to inhibit resolution of legitimate expert methodological disputes. It is intended to establish a norm for submission of expert reports and Frye motion practice in conformity with the guidance provided by our Pennsylvania Supreme Court in *Walsh*, *infra*.

²⁰ As identified by cross-referencing (see footnote 18, *infra*, identifying benzene-related chemicals) the active ingredients identified on the Chart, *infra*, with Brautbar Exhibit B; the following purported associations of active ingredient to benzene-related chemical are proffered as related to seven products:

- Propiconazole: Benzene
- Triadimefon: Dodecylbenzenesulfonic acid
- Iprodione: Benzoate
- Chlorothalonil: Benziaothiazolin (2 products)
- Fludioxonil: Benzodioxol
- Carbaryl: Benziaothiazolin

²¹ As identified by cross-referencing (see footnote 18, *infra*, identifying carcinogenic chemicals) the active ingredients identified on the Chart, *infra*, with Brautbar Exhibit C; the following purported associations of active ingredient to carcinogen-related chemical are proffered as related to six products:

- Trichlorfon: chromosomal aberrations (Brautbar, Ex. C at p. 18-19)
- Azoxystrobin: chromosomal aberrations (Id. at Ex. C at p.12)
- Glyphosate: genotoxicity (Id. at Ex. C at pp. 2-5)
- Cyproconazole: DNA damage (Id. at p. 14)
- Mefanoxam / Metalaxyl: chromosomal aberrations (Id. at p. 14-16)
- Vinclozolin: genotoxicity (Id. at p. 17)

²² A karyotype is an individual's collection of chromosomes. The term also refers to a laboratory technique that produces an image of an individual's chromosomes. The karyotype is used to look for abnormal numbers or structures of chromosomes. See <https://www.genome.gov/genetics-glossary/Karyotype>.

²³ Myelodysplastic syndrome (MDS) is a disease that is associated with decreased production of blood cells. Blood cells are produced in the bone marrow, and the blood cells of people with MDS do not mature normally. There are three major types of blood cells—red blood cells, white blood cells and platelets. Patients with MDS can have decreased production of one, two, or all three types of blood cells.

See <https://medical-dictionary.thefreedictionary.com/myelodysplastic+syndrome>

²⁴ Any medical or scientific conclusion(s) to be reached from this or any other distinction in the cytogenetic results are intentionally not addressed by this Court on remand as per the guidance of our Supreme Court in *Walsh v. BASF*, 234 A.3d 446 (Pa. 2020). At this juncture, this trial court does not sit as a super-scientific arbiter of expert conclusions related to the complexities of the human genome and cytogenetics. However, this current constraint does not preclude any challenge by the parties at the time of trial relating to the medical / scientific conclusions reached, the basis upon which any conclusion relies, the manner a methodology is applied to reach expert conclusions, or challenges to the respective weight and/or credibility of the methodology’s application.

²⁵ Footnote added. “Myelodysplastic”: referring to dysplasia of myelocytes and other elements of the bone marrow, a chronic disease that in time may evolve into acute myelogenous leukemia.

See <https://medical-dictionary.thefreedictionary.com/myelodysplasia>. See also n.9 *infra*.

²⁶ Footnote added. “Dyspoietic”: relating to abnormal formation of blood cells.

See <https://medical-dictionary.thefreedictionary.com/dyspoietic>.

²⁷ Footnote added. “Iatrogenic”: denoting response to medical or surgical treatment, usually denotes unfavorable responses. See <https://medical-dictionary.thefreedictionary.com/iatrogenic>.

²⁸ “Differential Diagnosis” is the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings. See <https://medical-dictionary.thefreedictionary.com/differential+diagnosis>.

As identified by the Pennsylvania Superior Court in this matter:

Dr. Brautbar used the differential diagnosis theory, which is generally accepted in the scientific community, to arrive at his opinion that long-term pesticide exposure was the cause of Decedent’s AML. See *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 756 (3d Cir. 1994) (affirming for purposes of the Frye prong of the Daubert inquiry, that differential diagnosis is widely accepted technique, subjected to peer review, used by the medical community to rule in or out alternative causes).

Defendants focus herein on the expert physician Dr. Brautbar's inability to quantify Mr. Walsh's exposure to each specific product and to opine that each of those exposure levels significantly or substantially increased the risk of AML. That is not the proper subject for a Frye inquiry. An expert's ability to opine with a reasonable degree of scientific or medical certainty that exposure to a particular defective product substantially caused or contributed to the injury goes to the legal sufficiency of the expert testimony, not to whether the science is generally accepted. Summary judgment, not Frye, is the appropriate vehicle for addressing that question. See *Howard v. A.W. Chesterton Co.*, 621 Pa. 343, 78 A.3d 605, 607–08 (2013) (per curiam).

Walsh, 191 A.3d 838, 848 (Pa. Super. 2018) (internal footnotes omitted) (Order of Superior Court affirmed and remanded with instructions by Pennsylvania Supreme Court per Walsh, *infra*, 234 A.3d 446 (Pa. 2020)).

²⁹ As stated in *Cummins v. Rosa*, 846 A.2d 148, 150-151 (Pa. Super. 2004) which cited to *M.C.M. v. Milton S. Hershey Med. Ctr. of the PA State Univ.*, 834 A.2d 1155, 1158-59 (Pa. Super. 2003):

[T]he Frye test sets forth an exclusionary rule of evidence that applies only when a party wishes to introduce novel scientific evidence obtained from the conclusions of an expert scientific witness. *Trach v. Fellin*, 817 A.2d 1102, 1108–09 (Pa. Super. 2002) (emphasis added). Under Frye, a party wishing to introduce such evidence must demonstrate to the trial court that the relevant scientific community has reached general acceptance of the principles and methodology employed by the expert witness before the trial court will allow the expert witness to testify regarding his conclusions. *Trach*, 817 A.2d at 1108–09, 1112 (emphasis added). However, the conclusions reached by the expert witness from generally accepted principles and methodologies need not also be generally accepted. *Id.*, 817 A.2d at 1112. Thus, a court's inquiry into whether a particular scientific process is “generally accepted” is an effort to ensure that the result of the scientific process, i.e., the proffered evidence, stems from “scientific research which has been conducted in a fashion that is generally recognized as being sound, and is not the fanciful creations [sic] of a renegade researcher.” See *id.*, 817 A.2d at 1111 (quoting *Blum v. Merrell Dow Pharms., Inc.*, 564 Pa. 3, 9–10, 764 A.2d 1, 5 (2000) (Cappy, C.J., dissenting)).

³⁰ Dose Response is the relationship between the intensity of an exposure, e.g., to an infectious pathogen, physical stressor, or a toxin, and its effect on living organisms. See <https://medical-dictionary.thefreedictionary.com/dose+response>

³¹ See *Gregg v. V-J Auto Parts, Co.*, 943 A.2d 216 (Pa. 2007) (Pennsylvania Supreme Court held that trial court properly considered frequency, regularity, and proximity of decedent's asserted exposure in determining existence of a fact question on the issue of causation.

³² See *Betz v. Pneumo Abex, LLC*, 44 A.3d 27 (Pa. 2012) (Pennsylvania Supreme Court affirms trial court rejection of expert causation testimony based upon faulty “each and every breath – single asbestos fiber” construct.

³³ As set forth in *Pltf. Brf. Opp.*, ECF 278 at pp.15-23 and Brautbar Exhibits B and C; Patient Walsh's exposure periods to the following products has been proffered:

- BASF (1 product): Touche®: 11/22/1993 to 10/7/2004
- Bayer (4 products): Bayleton®: 7/12/1988 to 8/3/2005
Chipco® 26019/26GT Flo: 5/11/1988 to 7/20/2004
Dylox®: 4/30/1999 to 9/14/2005
Sevin®: 7/14/1990 to 8/22/1991
- Deere (1 product): Manicure®: 9/9/1999 to 7/22/2004
- Monsanto (1 product): Roundup®: No specific dates – used everywhere – 3x/summer months
- Sygenta (6 products): Banner/Banner Maxx®: 6/17/1988 to 7/22/2004
Daconil®: 4/22/1988 to 6/17/2005
Heritage®: 6/11/1997 to 9/7/2003
Medallion®: 11/22/2002 and 4x/year 2002 to 2005
Sentinel®: 6/4/1997 to 7/4/2002
Subdue®: 6/28/1988 to 8/11/2005

³⁴ “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.” *Walsh*, 234 A.3d at 462-463 (internal citations omitted).

³⁵ This Court has been tasked to review and analyze cartons of notebooks and electronic-formatted copies containing the parties' pleadings, briefs, expert reports, supporting exhibits, and deposition transcripts related to complex scientific issues that have been in legal contention since 2010.

For example, the Defendants' pre-remand Frye Motions involved conducting Plaintiffs' Experts' depositions. Dr. Zambelli-Weiner's deposition involved three days of testimony with a 701 page transcript, an additional 39 exhibits each containing multiple pages of complex scientific data and research, and the Zambelli-Weiner documents are four inches thick. Dr. Brautbar's deposition involved four days of testimony with a 940 page transcript, an additional 59 exhibits each containing multiple pages, and the Brautbar documents are one foot thick. The notebook containing the expert reports, curricula vitae, and references of Zambelli-Weiner, Brautbar, Garabrant, Greenberg, Lichtman, Phillips, and Ross contains documents totaling three inches thick. The aforementioned is but a representative slice of the entire body of work presented to this Trial Court on remand notwithstanding 375 electronic docket entries in the Court of Common Pleas and the Superior and Supreme Court Opinions.

Albeit this Court whole-heartedly accepts its judicial responsibility with a zeal for discerning jurisprudential challenges and rendering decisions; the time and effort required of this or any other trial court to ascertain the respective positions of the parties, the factual underpinnings, scientific methodologies, trial and appellate history, and application of law to render a decision related to the Defendants' Frye Motion was not made any easier by the density of the parties' related pleadings and expert reports. Trial courts do not sit nor can function as scientific review boards with litigants presuming any given court's expertise in unraveling the varying complex and nuanced scientific, medical, or technological conclusions in dispute and presented in erudite, if not recondite nomenclature. This is not a critique of expert testimony – it is a confession of the trial court's inherent limitation within the parameters of addressing methodology in the Frye motion context.

To be clear, this Trial Court as a pragmatic arbiter of complex legal issues expects henceforth, that parties submitting expert reports and Frye motion challenges in the Court of Common Pleas of Allegheny County shall abide by and be constrained by our Supreme Court's guidance in Walsh, *infra* and the parameters set forth herein. Counsel shall be mindful of Rules of Prof. Conduct, Rule 3.2, 42 Pa.C.S.A., Expediting Litigation, wherein, "A lawyer shall make reasonable efforts to expedite litigation consistent with the interests of the client." Egregious conduct exceeding the bounds of advocating a good faith basis for a methodology, failing to clarify a methodology or a challenge thereto, shall subject the offending party to sanction; including but not limited to an award of counsel fees.

Simply stated, expert reports should clearly define the methodology(ies) employed and Frye Motion challenges should clearly define the objection(s) to the proffered methodology(ies). The expert's explanation of method should be clear on its face and ascertainable by the layperson in a separate introductory section. It is the responsibility of experts and learned legal counsel to be concise in defining the proffered methodology. This Court does not have the academic luxury, judicial province, nor scientific credentials to render a Thomist analysis on the complex scientific nuances offered by competing experts dancing opinions on the head of a pin. To expect otherwise, would place a jurist in the position of advocate and flip jurisprudence on its head.

As a prospective admonition, learned counsel is best served to employ their professional legal training to address methodology and not conclusions for purposes of Frye motion challenges. It is the burden of counsel and experts to make clear the methodology employed – the court cannot, as a practical or jurisprudential matter, sift through hundreds, if not, thousands of pages of complex scientific documents – to search, find, and comprehend the analytical basis of an expert's method in the relevant scientific community. This admonition is particularly pertinent in toxic tort cases whereby issues of general and specific causation are essential elements as defined by our Supreme Court. The responsibility to be clear, concise, and readily comprehensible is upon the parties. Frye motions are not the judicial mechanism for challenging an expert's opinion beyond the scope of the proffered methodology(ies) as applied in the relevant scientific community nor to conduct a mini-trial on ultimate factual issues or expert conclusions if granted a hearing on the Frye motion. The parameters for the Frye motion are self-limiting to methodology, not conclusions reached.

The above-stated trial court standard in no manner prejudices whether any expert report or a Frye motion challenge to an expert's methodology will be favorable or unfavorable to any party and is not an indictment of the parties in the case sub judice. In effect, with the guidance provided by our Superior and Supreme Courts in Walsh, *infra*, this standard applies to the scope of the Frye motion. Moreover, the trial court's limited scope of reviewing the relevant expert report(s) and Frye motion, does not preclude any party from filing motions for summary judgment, *limine*, or objections at the time of trial related to admissibility or other legal issues pertaining to expert testimony. A word to the wise is sufficient: an expert's methodology or objections thereto should be clear, concise, and comprehensible as applied by the relevant scientific community for purposes of the Frye Test standards.

ORDER OF COURT

AND NOW to-wit, this 15th day of November, 2021, based upon the foregoing Memorandum Opinion Re: Defendants' Motions to Exclude Plaintiff's Causation Experts and Motions for Summary Judgment, incorporated herein; it is hereby ORDERED:

1. Defendants BASF Corporation's; Bayer Cropscience LP's, Bayer Corporation's, Bayer Cropscience Holding Inc.'s; Deere & Company's; Monsanto Company's; and Sygenta Crop Protection, Inc.'s respective Motions to Exclude Testimony of Plaintiff's Experts, April Zambelli-Weiner, Ph.D. and Nachman Brautbar, M.D., pursuant to Pa.R.Civ.P. 207.1 and 1035.2 are DENIED; and
2. Defendants' accompanying Motions for Summary Judgment are DENIED.

BY THE COURT:
/s/Ignelzi, J.

In the Interest of: K.T., a minor child, Appeal of: Allegheny County Children Youth and Family Services and Child's Legal Counsel

Involuntary Termination of Parental Rights—Standard of Appellate Review

- *When reviewing denial of petition to terminate parental rights, appellate courts must apply abuse of discretion standard.*
- *Involuntary Termination of Parental Rights – Statutory ground under 23 Pa. C.S. §2511(a) must be proven by clear and convincing evidence.*
- *Involuntary Termination of Parental Rights – Bifurcated analysis is required, with first focus on conduct of parent.*
- *Involuntary Termination of Parental Rights – Once statutory grounds for termination are proven under 23 Pa. C.S. §2511(a), second focus under 23 Pa. C.S. §2511(b) is on needs and welfare of child, on case-by-case basis.*

- *Involuntary Termination of Parental Rights – Where Mother has continuing issues with substance abuse, has diagnoses of several mood and personality disorders and experiences issues with focus and stress, has a history of criminal violations and is unable to understand the role of drugs in her life, statutory grounds for termination of parental rights have been established under 23 Pa. C.S. rights have been established under 23 Pa. C.S. §2511(a)(2), (5) and (8).*
- *Involuntary Termination of Parental Rights – Where evidence proved that Child had emotional bond with Mother, was eager to spend time with mother and reluctant to leave, and there had been no significant period of time when Mother and Child were not in contact, held that permanently severing that bond would have detrimental impact on Child and evidence failed to demonstrate that termination of parental rights would meet needs and welfare of child; rather, it would adversely affect Child.*

Docket No.: DP-091-2017, TPR No.: AP-197-2019, 1245 WDA 2021, 1279 WDA 2021.

In the Court of Common Pleas of Allegheny County, Pennsylvania, Orphans' Court Division. Children's Fast Track.
Regan, J.—November 22, 2021.

OPINION

On October 13, 2021, following a two-day hearing on the above-captioned matter in which natural Mother was present and was represented by counsel, this Court issued an order denying the petition of the Allegheny County Office of Children, Youth and Families ("CYF") for the involuntary termination of the parental rights of K.T. ("Mother"). With respect to Mother, this Court found that CYF had satisfied their burden with respect to grounds alleged pursuant to 23 Pa.C.S.A. § 2511(a)(2), (5) and (8) but that CYF failed to meet its burden pursuant to 23 Pa. C.S.A. § 2511(b) and therefore, the petition to involuntarily terminate Mother's rights was denied. CYF and the child's counsel subsequently filed an appeal. For the reasons set forth below, the Order of this Court denying CYF's petition to involuntarily terminate Mother's rights should be affirmed.

A. RELEVANT FACTUAL HISTORY

The child in this case was born on June 17, 2016. At the time of the proceeding, the child was 5 years old. The child was born of Mother, and her father is Edward Mitchell. Paternity was established via genetic testing.

Mother first came to the attention of CYF dating back to 2009, but the present case regarding child began upon child's birth in 2016 when child was born drug exposed, resulting in concerns about Mother's substance use. (Tr. 1 at 12). The agency investigated and the family was accepted for services. *Id.* At that time, the agency was concerned with housing instability as well as substance use, due to admitted use of THC and alcohol, as well as the child testing positive for cocaine. (Tr. 1 at 13). Mother was referred to Pennsylvania Organization for Women in Early Recovery (POWER) for a drug and alcohol assessment and to Our Family for assistance in finding housing, as well as in-home assistance through Family Resource. (Tr. 1 at 13 and 14). Mother also began regular urine screens with CYF in December of 2016. (Tr. 1 at 79). At this time, mother lived with her mother, the child's maternal grandmother. (Tr. 1 at 16).

Due to continued substance use and housing instability, as well as a report of an incident involving Mother's older child, CYF removed the child from the home on March 7, 2017. (Tr. 1 at 15 and 16). By this time, CYF had also become concerned with Mother's mental health. (Tr. 1 at 26). At a shelter hearing on March 10, 2017, child was placed with maternal grandmother. (Tr. 1 at 16). The CYF goals for reunification at the time were for Mother to complete her POWER assessment, attend urine screens, and follow any other recommendations, as well as participate in supervised visits with the child. (Tr. 1 at 26).

In June of 2017, the child was re-placed with her godmother, Nykishia Partee, an adoptive resource, where she has remained since that time. (Tr. 1 at 28). Since child's placement with Ms. Partee, Mother has made allegations regarding the lack of care provided to her by Ms. Partee. (Tr. 2 at 11). During this time, Mother completed a POWER assessment and had been recommended for inpatient treatment. (Tr. 1 at 63). She checked herself into Gateway on September 27, 2017, but on October 25, 2017, started at Sojourner House. *Id.* Mother left Sojourner House without completing the program. (Tr. 1 at 65).

In December of 2017, Mother completed an intake at Family Links after a referral from CYF for mental health concerns. (Tr. 1 at 85).

In January of 2018, Mother was referred to the SHORES program and attended an initial assessment. *Id.* She was discharged in May of 2018 after missing too many appointments. (Tr. 1 at 66). Also, in May of 2018, the child, Mother, and the foster mother underwent the first of three evaluations by Dr. Rosenblum. (Tr. 2 at 72 and 73).

Mother completed another assessment, reported by SHORES on June 21, 2018, was recommended intensive outpatient services, but agreed to twice a week, in-home counseling. (Tr. 1 at 68). Mother successfully completed the SHORES program and was discharged, having accomplished her goal. (Tr. 1 at 72). In October of 2018, Mother was permitted to have overnight visits Friday to Saturday for three weeks, which moved to Friday to Sunday for as long as they went well. (Tr. 1 at 126).

Due to concerns about Mother's sobriety, visits were moved back to supervised visits. *Id.* Mother was referred to POWER again in March 2019. (Tr. 1 at 73). The assessment was completed, and no recommendations were made at that time. (Tr. 1 at 74). In an April 15, 2019 Permanency Review Order, visits were moved back to unsupervised day and overnight visits and permission from the court was granted for the Child to return to Mother's care when Mother's new housing was assessed. See CYF Exhibit #1 Court Orders. On May 8, 2019, the Court granted CYF's Motion for supervised visits. *Id.* Mother was again referred to POWER in May of 2019 but did not comply with this referral. (Tr. 1 at 74). In a June 17, 2019, Permanency Review Order, the Court ordered supervised visits for Mother at the Agency and granted CYF's request to schedule a Goal Change Hearing. See CYF Exhibits #1. Mother began drug and alcohol treatment again at Mon Yough around July of 2019 but stopped attending in April 2020 due to the COVID-19 pandemic. (Tr. 1 at 75). The second of three evaluations by Dr. Rosenblum occurred at this time. (Tr. 2 at 72 and 73).

From the initiation of her urine screens, Mother was being tested at the McKeesport location, but after a dispute with staff in August of 2019, she began testing at the Family Law Center location in downtown Pittsburgh. (Tr. 1 at 80). When COVID-19 resulted in the closing of this location around March of 2020, there was a lapse in testing. (Tr. 1 at 81). Also, during this period, there was a lapse in Mother's supervised visits due to the closure of CYF offices. (Tr. 1 at 127). Mother was permitted virtual contact with the child, but these were irregular. *Id.* In July of 2020, supervised visits were allowed to begin in Mother's home, which remains to be the case today. (Tr. 1 at 127 and 128).

Mother began testing at the McKeesport location again in August of 2020. (Tr. 1 at 81). Mother began treatment at Jade Wellness on August 19, 2020, and completed an intensive outpatient program on November 27, 2020, and, while having stepped down a level of care, is still engaged with them. (Tr. 2 at 138). Mother has been fairly compliant with outpatient care at Jade Wellness, which consists of weekly outpatient group sessions and monthly individual sessions. (Tr. 2 at 139). The final of three

evaluations by Dr. Rosenblum also occurred around this time. (Tr. 2 at 72 and 73). Dr. Rosenblum testified that Mother has always been honest with him regarding her history with substance abuse and with her relationships with men. (Tr. 2 at 74). He further stated that, while Mother has a history of reacting emotionally and with anger to stressors, she has admitted these as problems and he has noted progress in both her ability to focus and her ability to articulate her concerns. (Tr. 2 at 75). Dr. Rosenblum notes that her substance abuse had been particularly hard for her to address, but that she has made efforts. *Id.* He cites her inability to come to terms with the role that drugs, and alcohol have played in her life as the reason for continuing substance abuse issues but noted that it was possible that in her last intensive outpatient program, she had begun to develop a better understanding of that role. (Tr. 2 at 80). He stated that he had diagnosed her with personality disorders and that she showed signs of a mood disorder, but that there were avenues for change. (Tr. 2 at 83). Regarding Mother's interactions with the child, Dr. Rosenblum stated that Mother is very concerned with the child's appearance and whether the foster mother is providing adequate care and can be obsessive over these things, detracting from her time with the child. (Tr. 2 at 86). However, he noted that, otherwise, Mother is very nurturing and loving in her interactions with the child. (Tr. 2 at 86). He also stated that the child is always very glad to see her mother. *Id.* Dr. Rosenblum stated that, while the child seems to regress in maturity around the mother, some of this is due to the inherently limited interactions they have in addition to Mother's concerns about the child's care and appearance. (Tr. 2 at 88). He went on to testify, however, that the love that Mother has for the child could be shaped into a supportive role wherein Mother is able to support the foster mother, a connection to the child's biological mother would be beneficial to her. (Tr. 2 at 128). Dr. Rosenblum concluded by saying that he would like to see the relationship between Mother and child continue, but that this benefit does not outweigh the need for the opportunity for the child to move on with her life. (Tr. 2 at 129 and 130).

Mother's record of summary citations and a criminal conviction was a concern of CYF in petitioning for the Termination of Parental Rights. (Tr. 1 at 30). On September 2, 2014, Mother was sentenced to one year of probation after a conviction for simple assault. (Tr. 1 at 101). On both February 9 and February 12 of 2016, she pled guilty to a summary citation of disorderly conduct, during which time she was pregnant with the child. (Tr. 1 at 108, 109, and 110). On February 27, 2018, Mother pled guilty to a summary citation of retail theft. (Tr. 1 at 112). On February 13, 2018, Mother pled guilty to a summary citation of harassment subject to other physical conduct. (Tr. 1 at 114). On April 19, 2018, Mother pled guilty to summary citations of defiant trespassing and disorderly conduct. (Tr. 1 at 110). On August 29, 2019, Mother pled guilty to a summary citation of disorderly conduct. (Tr. 1 at 118).

CYF filed the Petition for Termination of Parental Rights in October of 2019. (Tr. 1 at 76). Before this time, Mother had been scheduled for a total of 57 drug screens and had attended 34 of them. (Tr. 1 at 84). At the time of the filing, there was an outstanding summary citation for disorderly conduct, engaging in fighting. (Tr. 1 at 115). The guilty plea was entered on November 14, 2019. *Id.* In February of 2020, Mother pled guilty to a summary citation for harassment. (Tr. 1 at 116). On October 8, 2020, she pled guilty to a summary citation for criminal mischief and harassment. *Id.*

As of 2019, Mother's housing has been stabilized and has been deemed appropriate by CYF. (Tr. 1 at 54 and 55).

CYF has stated that the only reasons for concern with Mother's unsupervised visits was Mother's sobriety and not returning the child in a timely fashion, not the interactions between Mother and the child. (Tr. 1 at 130). CYF also testified that Mother was communicative and that the majority of the frustration she had with the programs referred to her was the conflicts they posed with her work schedule. (Tr. 1 at 132). They further testified that Mother has been willing to work with her employer to get to as many appointments as possible. *Id.* Mother was able to successfully complete a POWER mentoring program, POWER Connections, in January of 2021. (Tr. 1 at 133). Mother has successfully completed parenting classes through the Raising Safe Kids program. (Tr. 1 at 163). Mother was also able to successfully complete another parenting program, Adults and Children Together (ACT), on October 8, 2020, which is a program she participated in of her own free will. (Tr. 2 at 149). Mother is also currently compliant with the Family Links program for her mental health goals. (Tr. 1 at 135). Further, since the filing of the petition, Mother has attended 11 of 15 scheduled urine screens. (Tr. 1 at 140). Further, CYF testified that, while there are concerns about continued sobriety and the fact the child has been in care for several years, Mother has made much progress during that time. (Tr. 1 at 147). Due to her successful participation in the Jade Wellness program, she has not been referred to POWER for a drug and alcohol assessment. (Tr. 1 at 177).

On March 22, 2021, and May 13, 2021, a two-day hearing was held on CYF's Petition for Involuntary Termination of Parental Rights. By July 12, 2021, all the parties filed their Findings of Fact and Conclusions of Law. On October 13, 2021, entered its order finding that CYF had satisfied their burden with respect to grounds alleged pursuant to 23 Pa.C.S.A. § 2511(a)(2), (5) and (8) but that CYF failed to meet its burden pursuant to 23 Pa.C.S.A. § 2511(b) and therefore, the petition to involuntarily terminate Mother's rights was denied. On October 20 and 25, 2021, CYF and the child's counsel respectively filed their Notice of Appeal to the Superior Court and Concise Statement of Matters Complained on Appeal.

ISSUES ON APPEAL

In their Statements of Matters Complained of on Appeal, CYF and the child's counsel assert that this Court committed an error of law and/or an abuse of discretion in failing to find that CYF had proved by clear and convincing evidence that termination of Mother's rights would best serve the developmental, physical, and emotional needs and welfare of the minor child.

B. STANDARD OF REVIEW

When reviewing an appeal of the denial of a petition to terminate parental rights, our Courts apply an abuse of discretion standard.

[A]ppellate courts must apply an abuse of discretion standard when considering a trial court's determination of a petition for termination of parental rights. As in dependency cases, our standard of review requires an appellate court to accept the findings of fact and credibility determinations of the trial court if they are supported by the record. In *re: R.J.T.*, 9 A.3d 1179, 1190 (Pa. 2010). If the factual findings are supported, appellate courts review to determine if the trial court made an error of law or abused its discretion. *Id.*; see also *In re R.I.S.*, 36 A.3d 567, 572 (Pa. 2011) (plurality). As have often been stated, an abuse of discretion standard does not result merely because the reviewing court might have reached a different conclusion. *Id.*; see also *Samuel-Bassett v. Kia Motors America, Inc.*, 34 A.3d 1, 51 (Pa. 2011); *Christianson v. Ely*, 838 A.2d 630, 634 (Pa. 2003). Instead, a decision may be reversed for an abuse of discretion only upon demonstration of manifest unreasonableness, partiality, prejudice, bias, or ill-will. *Id.*

As we discussed in *R.J.T.*, there are clear reasons for applying an abuse of discretion standard of review in these cases. We observed that, unlike trial courts, appellate courts are not equipped to make the fact-specific determination on a cold record, where the trial judges are observing the parties during the relevant hearing and often presiding over numerous other hearings regarding the child and parents. *R.J.T.*, 9 A.3d at 1190. Therefore, even where the facts could support an opposite result, as is often the case in dependency and termination cases, an appellate court must resist the urge to second guess the trial court and impose its own credibility determination and judgment; instead we must defer to the trial judges so long as the factual findings are supported by the record and the court's legal conclusions are not the results of an error of law or an abuse of discretion. *In re Adoption of Atencio*, 650 A.2d 1064, 1066 (Pa. 1994).

In re I.E.P., 87 A.3d 340, 343-44 (Pa. Super. 2014) (quoting *In re Adoption of S.P.*, 47 A.3d 817, 826-27 (Pa. 2012)).

Pennsylvania law allows for the termination of a parent's rights on any of the following grounds enumerated under 23 Pa.C.S.A. § 2511(a). With respect to this case, CYF alleged termination was warranted under the following grounds:

(2) The repeated and continued incapacity, abuse, neglect or refusal of the parent has caused the child to be without essential parental care, control or subsistence necessary for his physical or mental well-being and the conditions and causes of the incapacity, abuse, neglect or refusal cannot or will not be remedied by a parent.

(5) The child has been removed from the care of the parent by the court or under a voluntary agreement with an agency for a period of at least six months, the conditions which led to the removal or placement of the child continue to exist, the parent cannot or will not remedy those conditions within a reasonable period of time, the services or assistance reasonable available to the parent are not likely to remedy the conditions which led to the removal or placement of the child within a reasonable period of time and termination of the parental rights would best serve the needs and welfare of the child.

(8) The child has been removed from the care of the parent by the court or under a voluntary agreement with an agency, 12 months or more have elapsed from the date of removal or placement, the conditions that led to the removal or placement of the child continued to exist and termination of parental rights would best serve the needs and welfare of the child.

23 Pa.C.S. § 2511(a)(2), (a)(5), (a)(8).

Moreover, once the statutory grounds for involuntary termination of parental rights have been shown by clear and convincing evidence, the Court must consider whether the termination would meet the needs and welfare of the child under subsection § 2511(b):

(b) Other considerations. – The Court in terminating the rights of a parent shall give primary consideration to the developmental, physical and emotional needs and welfare of the child. The rights of a parent shall not be terminated solely on the basis of environmental factors such as inadequate housing, furnishings, income, clothing and medical care if found to be beyond the control of the parent. With respect to any petition filed pursuant to subsection (a)(1), (6), or (8), the Court shall not consider any efforts by the parent to remedy the conditions described therein which are first initiated subsequent to the giving of notice of the filing of the petitions.

23 Pa. C.S.A. § 2511(b).

Our Pennsylvania Supreme Court has stated that:

[I]f the grounds for termination under subsection (a) are met, a court “shall give primary consideration to the developmental, physical and emotional needs and welfare of the child. 23 Pa.C.S. § 2511(b). The emotional needs and welfare of the child have been properly interpreted to include “[i]ntangibles such as love, comfort, security, and stability.” *In re K.M.*, 53 A.3d 781, 791 (Pa. Super. 2012). *In re E.M.*, [620 A.2d 481, 485 (Pa. 1993)], this Court held that the determination of the child’s “needs and welfare” requires consideration of the emotional bonds between the parent and child. The “utmost attention” should be paid to the discerning effect on the child of permanently severing the parental bond. *In re K.M.*, 53 A.3d at 791. However, as discussed below, evaluation of a child’s bonds is not always an easy task.

In re T.S.M., 71 A.3d 215, 267 (Pa. 2013).

A parent’s own feelings of love and affection for a child, alone, will not preclude the termination of parental rights. *In re L.M.*, 923 A.2d 505, 512 (Pa. Super. 2007). Also, the extent of the bond-effect analysis when determining the best interests of the child in a termination proceeding necessarily depends on the circumstances of the particular case. *In re N.A.M.*, 33 A.3d 95 (Pa. Super. 2011).

Section 2511 requires a bifurcated analysis where at first the focus is on the conduct of the parent. If the party seeking termination proves through clear and convincing evidence that the parent’s conduct meets the statutory grounds for termination, the court then determines the needs and welfare of the children. *In re C.M.K.*, 203 A.3d 258, 261-262 (Pa. Super. 2019). Analysis under §2511(b) must necessarily be done on a case-by-case basis. *In re N.A.M.*, 33 A.3d 95 (Pa. Super. 2011).

C. DISCUSSION AND CONCLUSION

First, this Court recognizes that CYF has met its burden of proof through clear and convincing evidence in establishing the statutory grounds for involuntary termination of parental rights through the conduct of the parent pursuant to § 2511(a)(2), (5), and (8).

As noted above, Mother has had continuing issues with substance abuse, having attempted several times to abstain, with the help of CYF, which started at a young age. See Exhibit #3 Dr. Rosenblum Evaluation Reports pg. 3, 4, and 5. In her youth, Mother attended Woodland Hills school district, but dropped out after 9th grade. *Id.* at 3. While she has not earned her GED, she took classes while incarcerated after the birth of her first child. *Id.* She started hanging out at bars and started using marijuana at the age of 14 or 15. *Id.* This became a daily habit and she eventually started using cocaine, which was sometimes offered to her by patrons at the adult entertainment club where she worked. *Id.* Her early life has resulted in the diagnosis of several mood and personality disorders. *Id.* As a result, she has experienced issues focusing, as well as regulating her responses to stress. (Tr. 2 at 75). This had led to a history of summary citations and criminal charge(s). See CYF Exhibit #5 Criminal Docket. Mother has made

progress in dealing with her mental health concerns, as well as substance use concerns, but has had trouble improving her judgment and achieving and maintaining a stable pattern of adjustment. See Exhibit #3 Dr. Rosenblum Evaluation Reports at 26. Mother continues to be unable to understand the role of drugs in her life and how they affect behavior otherwise and, in combination with the other concerns regarding her mental health, this results in a guarded prognosis for improvement. (Tr. 2 at 80 and 83). Due to this evidence, CYF has established the statutory grounds for the termination of parental rights through the conduct of the parent pursuant to § 2511(a)(2), (5), and (8).

However, as stated above, in a termination of parental rights proceeding the inquiry is not only about the conduct of the parent. Section 2511 of the Adoption Act, 23 Pa.C.S.A. §§ 2101-2938, requires a bifurcated analysis:

Initially, the focus is on the conduct of the parent. The party seeking termination must prove by clear and convincing evidence that the parent's conduct satisfies the statutory grounds for termination delineated in Section 2511(a). Only if the court determines that the parent's conduct warrant termination of his or her parental rights does the court engage in the second part of the analysis pursuant to Section 2511(b): determination of the needs and welfare of the child under the standard of the best interests of the child. One major aspect of the needs and welfare analysis concerns the nature and status of the emotional bond between the parent and child, with close attention paid to the effect on the child of permanently severing any such bond.

In re L.M., 923 A.2d 505, 511 (Pa. Super. 2007) (citations omitted).

In the instant case, this court considered the evidence and testimony presented and found that CYF failed to demonstrate, clearly and convincingly, that termination would meet the needs and welfare of the Child. The evidence presented and submitted to this Court instead proved that the Child had an emotional bond with her Mother, and that permanently severing that bond would have a detrimental impact on the Child.

CYF called seven witnesses to testify at trial, while Mother's counsel called three witnesses.¹ Five witnesses called by CYF: William Pipkins, a Family Transportation Supervisor for A Second Chance; Myelodie Turner, a Point of Contact Caseworker for A Second Chance; Brett Basic, a police officer with the West Mifflin Borough Police Department; Ronald Bobick, a police officer with the West Mifflin Borough Police Department; and Ryan Miller, a police officer with the City of McKeesport, and the witnesses called by Mother's Counsel; Daniel Garrighan, the facility director at Jade Wellness Center; Jawanna Warren, site director at Clairton Family Center; and Lisa Penn, program manager for POWER, did not testify to the emotional bond between Mother and the child.

The first witness called by CYF, Amanda McCloy, caseworker for CYF, testified that, while the child does not often communicate to her regarding Mother directly, when being transported to visits, the child does look forward to seeing her mother. (Tr. 1 at 129). This is evidence that the child does have some emotional bond with her Mother. On cross-examination, Ms. McCloy testified that there were no CYF concerns with the interactions between the Child and Mother. Id. at 130.

Another witness called by CYF, Dr. Neil Rosenblum, the clinical psychologist who performed the individual and interactional evaluations of Mother and the Child, also testified to the emotional bond between Mother and the Child, as well as the effect of severing that bond. (Tr. 2 at 71). All parties stipulated to his qualifications as an expert. Id. He conducted an individual evaluation on the Child followed by an interactional evaluation between Mother and the Child on May 18, 2018, an interactional evaluation between Mother and the Child followed by an individual evaluation of the Mother on January 7, 2020, and an individual evaluation of Mother followed by an interactional evaluation between Mother and Child on December 14, 2020. See CYF Exhibit #3 Dr. Rosenblum Reports.

Regarding the emotional bond between Mother and Child, Dr. Rosenblum stated several times in the forensic evaluation that the child is eager to spend time with her mother. See CYF Exhibit #3 Dr. Rosenblum Reports. He testified that the child "certainly knows her mother. She is always glad to see her." (Tr. 2 at 84). He went on to say that the Child does have an attachment to Mother and that the Child "loves her, she enjoys seeing her and spending time with her." Id. at 89. While the child has sometimes referred to her foster mother as "mother" or "mom," at other, later times, she has referred to Mother as "mom" and her foster mother as "god mom." CYF Exhibit #3 at 20.

Regarding whether severing the bond between the mother and the child would adversely affect the child, he noted in his report after an evaluation that the child displayed reluctance at having to leave Mother at the end of the evaluation and began to cry. CYF Exhibit #3 at 3. The Child had to be carried out to the foster mother. Id. In addition to this, Dr. Rosenblum testified that there has been no significant period of time where Mother and the Child were not in some sort of contact. (Tr. 2 at 100). He stated further that Mother sees her Child more than many of the parents that he's evaluated who are in a similar situation. Id. Dr. Rosenblum testified at trial that it is beneficial to the child to maintain contact with biological relatives. (Tr. 2 at 109). He stated specifically that the child should be allowed to maintain some degree of contact with mother. Id. at 127. These statements regarding the benefit to the child of maintaining a bond with her Mother are evidence that permanently severing that bond would have an adverse effect on the child.

In conclusion, CYF proved by clear and convincing evidence that Mother's conduct satisfied the statutory grounds for termination delineated in Section 2511(a). However, the termination of a parent's rights to their child is not only about the conduct of the parent. See In re L.M., 923 at 511. The statutes put into law and the cases decided by the Legislature and Courts of this Commonwealth respectively require a bifurcated analysis. Id. If the court determines the parent's conduct warrants termination of her rights, then the court must determine the effect on the child of permanently severing the bond with their parent. Id. In the case at hand, the evidence clearly established that if the emotional bond between the child and her Mother was permanently severed, then the child would be adversely affected. Therefore, this court was within its discretion when it denied CYF's petition to terminate Mother's parental rights.

Therefore, for the reasons set forth in this Opinion, the decision of this court, in denying the involuntarily petition to terminate Mother's rights should be affirmed.

BY THE COURT:
/s/Regan, J.

¹ Neither Counsel for Father nor Counsel for the minor child called any witnesses.