**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

**IN AND FOR NEW CASTLE COUNTY**

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| MATTHEW BOWEN, et al., | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A. No. 97C-06-194 (CHT) |
| | ) | |
| E. I. DU PONT DE NEMOURS AND COMPANY, INC., | ) | |
| | ) | |
| | ) | |
| Defendant. | ) | |

**Opinion Regarding Defendant's Motions to Exclude Plaintiffs' Expert Witnesses and for Summary Judgment**

**Submitted: May 21, 2004**
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**TOLIVER, JUDGE**

## STATEMENT OF FACTS AND NATURE OF THE PROCEEDINGS

### Factual Background

As noted in prior proceedings, the plaintiffs are eight minor children and their parents who have alleged that the children suffered injuries manifested at birth as a result of the exposure of the children's mothers to an agricultural product sold under the trade name of Benlate. Benlate was manufactured by the defendant, the DuPont Company. More specifically, the plaintiffs contend that the mothers of the children were dermally exposed to Benlate during the early stages of their pregnancies. Once deposited, the Benlate was alleged to have passed thru the skin to the developing fetus via the placenta where it acted to retard fetal growth and cell development. The product, which the plaintiffs allege is a human teratogen,[1] was being used as directed at the time of the exposure.

The exposure and births in question are alleged to

[1] A teratogen is defined as "a drug or other agent that causes abnormal prenatal development." *PDR Medical Dictionary*, at 1796 (Lippencott, Williams and Wilkins, 2nd Ed. 2000).

have taken place between 1984 and 1995.[2] All but two of the mothers were so exposed in a non-commercial setting while spraying plants or trees during gardening or were in the presence of someone who was engaged in such spraying. The remaining two were exposed during the course of their employment.[3] The injuries the children suffered which the plaintiffs attribute to Benlate include anophthalmia and microphthalmia[4] as well as other forms of arrested development, physical, emotional and intellectual.

Of the eight children, three were from Scotland, (Brown, Copeland and Johnstone), three were from

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[2] The dates of birth are as follows: Emily Bowen, August 9, 1994; Darren Griffin, November 23, 1995; Phillip Brown, February 15, 1984; Khalid Memom, June 24, 1985; Gary Copland, June 6, 1992; Blake Ison, November 13, 1993 and Jesse Hanham, November 10, 1990.

[3] The location of the spraying, inside versus outside, and who was spraying the Benlate mixture as well as the number of times the exposure took place and the conditions existing at the time, varied from mother to mother. For example, Darren Griffin's mother was exposed to Benlate on one occasion while her father-in-law was spraying trees and/or shrubbery and she was standing approximately fifteen feet away with her husband. Emily Bowen's mother, however, sprayed the plants in the garden in their residence herself on several occasions. She was also present at times when Emily Bowen's father sprayed the same plants. Ison and Hanham were the mothers who were alleged to have been exposed to Benlate while engaged in occupations away from their homes.

[4] Children afflicted with anophthalmia are born with no eyes and those suffering from microphthalmia are born with very small eyes.

England and Wales (Bowen, Griffin and Memon) and two originated from New Zealand (Ison and Hanham). Two separate lawsuits were filed on June 24, 1997 (Civil Action Nos. 97C-06-193 and 97C-06-194) by the Bowens, Griffins, Isons and Hanhams. On July 15, 1997, a third suit was filed by the Browns, Copelands, Johnstones and Memons (Civil Action No. 97C-07-113).

The defendant denies that Benlate is a human teratogen or that it otherwise was responsible for the problems experienced by the plaintiffs. Those problems, the defendant contends, were caused by factors independent of the defendant and Benlate. In addition, the defendant affirmatively raised other defenses in response to the plaintiffs' claims of liability.

Benlate is described as a fungicide developed by the defendant primarily for commercial agricultural use and is designed to prevent and cure fungal infections in plants and crops. The defendant first placed the product on the market for sale in 1970. Although it was only sold commercially in the United States, the

product was available for purchase for home use outside the United States, and in particular, in the United Kingdom and New Zealand where the exposures complained about herein took place. The sale of Benlate was halted and it was withdrawn from all markets in 1995.

**Relevant Procedural History**

**A. Pre-Trial Motions**

The defendant moved to dismiss the litigation on grounds of *forum non conveniens* on August 18, 1997. This Court granted the defendant's motion on August 28, 1998. The plaintiffs appealed and the Delaware Supreme Court reversed on June 14, 1999. On remand, the Court directed that the prosecution of the matter continue in this jurisdiction.

On July 24, 2001, the defendant again moved to dismiss the cases filed by the plaintiffs, this time on statute of limitation grounds. The matter was briefed and argument held on March 28, 2002. On April 25, 2002, this Court ruled that six of the eight claims did run afoul of 10 *Del. C.* §8119, and granted the relief

sought as to those cases. Only the claims on behalf of Emily Bowen and Darren Griffin, in part, survived. The plaintiffs again appealed and the Delaware Supreme Court again agreed with the plaintiffs. The Court ruled that the statute of limitations did not begin to run until the technology and/or knowledge was available to allow the plaintiffs to discover that their injuries, obvious from birth, were caused by the negligence of another. Shortly thereafter, the prosecution of those claims, also known as the "remanded cases", resumed.

On May 20, 2003, the plaintiffs moved to consolidate the three cases for purposes of pretrial proceedings and for trial itself, based upon the existence of common questions of law and fact. The cases had essentially proceeded on a common course until that point in time. The defendant opposed the motion in so far as it requested that the cases be tried together as one cause of action. It argued that the defense would suffer undue prejudice given the nature of the cause of action and the injuries the

plaintiffs claimed resulted from the use of Benlate. On April 27, 2004, this Court granted the plaintiffs' motion as to the consolidation of the cases for pretrial purposes, but refused to order that all eight causes of action be tried together.

Instead, the Court ordered the cases grouped in pairs, resulting in four trials. The claims made by and on behalf of Emily Bowen and Darren Griffin were to be tried first given the fact that the prosecution of those two cases had suffered the least interruption by the appellate proceedings relating to the statute of limitations issues described above. Their trial was initially scheduled to begin on October 12, 2004 and conclude on or before December 3, 2004. It is this first trial that is the focus of this opinion.[5]

### B. Motion to Exclude Plaintiffs' Expert Witnesses Based Upon DRE 702

As was to be expected, both sides retained numerous experts to provide assistance in preparing the case for

[5] The scheduling of the other three trials is pending the resolution of the Bowen/Griffin matters, at least at this level.

trial generally as well as for purposes of testifying at trial concerning general and specific causation. Additional experts were retained to assist with issues relating to damages and other matters involved in presenting the case at trial. Indeed, neither side showed any reluctance in this regard.[6] The defense proposed experts in the fields of genetics, teratology, ophthalmology, pharmacokinetics, dermal absorption, toxicology and pharmacology as well as other areas related to birth defects and the causes thereof. The plaintiffs engaged in similar efforts to obtain support for their causes of action. However, it is the plaintiffs' choice of experts in the fields of genetics, teratology, toxicology, dermal exposure and dermal absorption, that is the primary focus of this segment of the litigation. They are Dr. Charles V. Howard, Dr. David L. MacIntosh, Dr. Michael A. Patton, Dr. Mitchell W. Sauerhoff and Dr. Randall L. Tackett.

[6] It is difficult to ascertain the exact number of expert witnesses retained by the parties. However, based upon the proposed pretrial stipulation filed with the Court, it appears that each side has hired no less than twenty-five witnesses who were to be called as "experts".

Dr. Tackett, the record reflects, received his undergraduate degree in biology in 1975 followed by a master's degree in pharmacology in 1977 and a doctorate in pharmacology as well in 1979. He also has twenty-five years experience in research, writing and teaching pharmacology. At the time Dr. Tackett became involved in this matter, he was primarily employed as a professor at the University of Georgia College of Pharmacology, but has also published extensively in that field, acted as a peer reviewer for society journals and participated in reviewing grants for the American Heart Association.[7] Although he was initially assigned a broader role in terms of general and specific causation, after a defense motion directed to that end, his role was ultimately limited to providing testimony as an expert regarding the properties of Benlate as a human teratogen and its effects on fetal development at differing levels of exposure.

Dr. Sauerhoff received undergraduate and graduate

[7] In addition, Dr. Tackett taught at two other colleges as an adjunct professor, presumably on the same subjects.

degrees in biology and toxicology. He is a member of the faculty at the University of Connecticut School of Medicine and College of Pharmacy. His formal education was followed by employment in those fields for several large corporations for over twenty-three years. During that period of time, Dr. Sauerhoff has claimed responsibility for over one thousand toxicity investigation and safety studies in addition to substantial experience in human risk assessment. He also has experience with the rules and regulations of the Environmental Protection Agency ("EPA") and the Food and Drug Administration.

Dr. Sauerhoff has been retained as a expert in over three hundred cases relating to the causal effect of substances, along with evaluating the methodology of opposing experts. He opined in that regard that Drs. Howard, Tackett and MacIntosh followed standard methodologies accepted in their respective disciplines in rendering conclusions regarding the causal relationship between Benlate and the injuries suffered by Emily Bowen and Darren Griffin.

Dr. McIntosh was retained by the plaintiffs to provide an opinion regarding dermal exposure and absorption of Benlate. He attended Indiana University where he received his undergraduate degree in Decisional Science in 1988 and his master's degree in Environmental Science in 1991. He was awarded his doctorate in Environmental Health from the Harvard School of Public Health in 1995. Dr. McIntosh began his professional career in 1996 as a professor at the University of Georgia in its Department of Environmental Health Science, College of Agriculture and Environmental Sciences. He taught graduate and undergraduate courses in environmental chemical air quality and hazardous waste management. In 2002, he became a senior associate with Environmental Health and Engineering, Inc., Newton, Massachusetts.

Dr. McIntosh has acted as a consultant with the EPA and the World Health Organization. He has presented papers and speeches on topics relating to human exposure to environmental contaminants, and has regularly published articles in peer reviewed

scientific journals discussing human exposure to pesticides in residential settings. His research has included human exposure to chemical hazards in community and occupational settings.

Using a model formula provided by the EPA in its publication entitled "Dermal Exposure Assessment Principles and Applications",[8] Dr. McIntosh calculated the amount of Benlate that would have been absorbed thru the skin of the mothers of Emily Bowen and Darren Griffin. That assessment was based upon the testimony provided by the Bowen and Griffin mothers concerning the uncovered areas of their bodies that came into contact with the Benlate spray. He did not attempt to estimate the amount or quantity of the spray, as opposed to the area covered, and relied completely on the EPA model and formula in reaching his conclusions.

The defendant has contended from the start of this litigation that Emily Bowen's injuries and condition

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[8] *Dermal Exposure Assessment: Principles and Applications*, Exposure Assessment Group, Office of Health and Envtl. Assessment, U.S. Envtl. Protection Agency, Interim Report, EPA/600/8-91/011B, January 1992, *referring to*, Potts RO, Guy RH. *Predicting Skin Permeability*, Pharm. Res., 9(5):663-669, 1992, *available at* www.epa.gov/nceawww1/pdfs/derexp.pdf (last visited June 16, 2005).

constitute CHARGE Syndrome, which is generally thought to be genetic, as opposed to environmental, in origin.[9] The plaintiffs disputed this contention and initially offered the testimony and opinions of Dr. Patton. Dr. Patton's qualifications as an expert in the field of genetics in this case are not questioned by the defense.

Based upon his initial examinations and review of her medical records and related information, Dr. Patton concluded in 2002 and in 2003 that Emily Bowen's features did not constitute CHARGE Syndrome. Dr. Patton agreed with two other physicians that had seen her during this period of time, that Emily Bowen did not meet enough of the criteria that would make such a

[9] "CHARGE" is an acronym which stands for Coloboma (absence of or defect in ocular tissue), heart defect, atresia of choanae (blockage between back of nose and mouth), retarded growth and development, genital hypoplasia (arrested development) and ear anomalies. Lalani SR, Safiullah AM, Molinari LM, Fernbach SD, Martin DM, Belmont JW. *SEMA3E Mutation in a Patient with CHARGE Syndrome*. J.Med.Genet. 41:99, 2004. According to Dr. Patton's declaration, CHARGE is defined as an association of features or pattern of malformations which occur together more commonly than by happenstance. Dr. Patton also stated that the principal debate seems to have been whether there is a common underlying cause or causes.

diagnosis appropriate.[10] As a result and given the state of the science at that time, he concluded that her problems did not have any recognizable root in genetics. However, he acknowledged that if his findings relative to her physical condition or the state of the science changed, his opinion could change.

As his curriculum vitae reveals, Dr. Howard is a medical doctor and lecturer at the University of Liverpool in Liverpool, England, where he received his medical training from 1965 to 1970. He began at that institution in 1971 and assumed his current position as a senior lecturer in 1991 in the Department of Human Anatomy and Cell Biology. In that position, he teaches courses in anatomy, microscopy and morphology.[11] Dr.

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[10] Dr. Patton seemed most concerned with whether Emily Bowen did or did not have genital abnormalities as determinative of whether she had CHARGE Syndrome. Because he was not able to complete a genital examination, he could not determine whether her genitalia were abnormally developed or developing, at least when he last saw her in 2003.

[11] Microscopy is defined as the "investigation of minute objects by means of a microscope." *PDR Medical Dictionary*, at 1116. Morphology is the "science concerned with the configuration or the structure of animals and plants." *Id.* at 1131. Anatomy is the "science of the morphology or structure of organisms." *Id.* at 71.

Howard belongs to several professional organizations, including the British Society of Toxicological Pathologists and the Society for Developmental Pathology. He considers himself a toxicologist[12] and a fetal pathologist,[13] and is not, by his own admission, an expert in genetics.

Dr. Howard, relying on the initial opinions of Dr. Patton, i.e., that Emily Bowen's birth defects did not constitute the "CHARGE Syndrome", ruled out genetics as a cause.[14] Given that conclusion and Dr. McIntosh's findings relative to the amount of Benlate that was dermally absorbed, Dr. Howard, based upon his education, training, research and experience regarding Benlate, concluded that Benlate was a human teratogen

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[12] A toxicologist is "a specialist or expert in toxicology," which is defined as "the science of poisons, including their course, chemical composition, action, tests, and antidotes." *Id*. at 1849.

[13] A pathologist is "a specialist in pathology; a physician who practices, evaluates, or supervises diagnostic tests, using materials removed from living or dead patients, and functions as a laboratory consultant to clinicians, or who conducts experiments or other investigations to determine the causes or nature of disease changes." *Id*. at 1332.

[14] In addition, Dr. Howard indicated that since he was not a geneticist, if Dr. Patton's opinion changed as to whether Emily Bowen's injuries constituted CHARGE Syndrome, his opinion would likely have to change as well.

to which Emily Bowen was exposed while being carried in her mother's uterus. It was that exposure, he opined, that proximately caused the birth defects experienced by Emily Bowen.

Dr. Howard also ruled out genetics as the cause of Darren Griffin's eye deformities. Relying on Dr. McIntosh as to the amount of Benlate that was dermally absorbed by Darren Griffin's mother, and his finding that Benlate was a human teratogen, Dr. Howard went on to conclude that Benlate was the cause of the condition about which the Griffins complained.

The defendant, based upon DRE 702 in light of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[15] and its Delaware progeny,[16] moved, on March 23, 2003, to exclude the testimony of Drs. Howard, Tackett, MacIntosh, Sauerhoff and Dr. Robert F. Smith.[17] The initial briefing on the motion was completed and the parties agreed to proceed to a hearing on the memorandum

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[15] 509 U.S. 519, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993).

[16] *Nelson v. State*, 628 A.2d 69 (Del. 1993).

[17] For reasons with which are unknown to the Court, the plaintiffs withdrew Dr. Smith as an expert witness.

submitted. That hearing was held on June 18 and 19, 2003, followed by post hearing submissions, including exhibits. Proposed findings of fact and conclusions of law relative to the issues raised at and by the Daubert hearing were filed with the Court on April 2 and May 21, 2004. The motions were taken under advisement.

### C. Further Genetic Testing

As a part of their preparation for the Bowen/Griffin trial, the parties engaged in an intense exchange of pleadings. A total of no less than twenty-four motions in limine concerning matters related to the then upcoming trial were filed by both sides. Those matters were addressed and resolved at or shortly after hearings held on September 9 and September 20, 2004.

In the midst of that flurry of activity, based upon newly developed genetic testing methodologies and the results of related testing in the six remanded cases, the defendant moved, on July 12, 2004, to subject Emily Bowen and Darren Griffin to testing for gene mutations

that had been cast as causes of conditions similar to those suffered by the instant plaintiffs. That motion was initially denied and the defendant, after supplementing the record, moved the Court to reconsider. Over the plaintiffs' objections, the Court, on October 15, 2004, ordered that the testing take place and continued the trial.[18] The Court allowed further discovery which included supplementation of expert witness reports that might be affected by the results of the testing. Based upon that sequence of events, the trial was rescheduled to begin on May 9, 2005.

In January 2005, the parties became aware of the results of the additional testing. The tests revealed that Emily Bowen's genetic profile contained a gene, CHD7, which had mutated. The geneticists who discovered that mutation as well as those who confirmed its existence, now believe it is the cause of CHARGE Syndrome. While not all individuals with CHARGE

[18] For unrelated reasons, the plaintiffs were allowed to add an expert witness, an economist, that had not been previously listed as testifying at trial.

Syndrome tested up to that point in time had the aforementioned mutation, it appears that each individual with the CHD7 mutation was diagnosed with CHARGE Syndrome.[19] The defense contends as a result that Emily Bowen not only has CHARGE Syndrome, but that it was caused by the CHD7 mutation which is genetic in origin only. Stated differently, there were no environmental or external causes.[20]

Two of the plaintiffs' experts, Dr. Howard and Dr. Patton, have responded to the additional test results with conclusions that are different than those originally offered.

Dr. Patton, notwithstanding his previous conclusion that Emily Bowen did not exhibit CHARGE Syndrome and that he could rule out genetics as a cause of her afflictions, now believes that the CHARGE Syndrome

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[19] The study first identifying the CHD7 mutation as a cause of CHARGE Syndrome, was presented in the medical journal "Nature Genetics" in its August 2004 edition (hereinafter the Vissers Study"). Vissers, L., Brunner, H., et. al., *Mutations in a New Member of the Chromodomain Gene Family Cause CHARGE Syndrome*, Nature Genetics 36(9): 955, 2004.

[20] The results of the testing were negative as to Darren Griffin.

diagnosis is correct. He further opines that the mutated CHD7 gene played a substantial role in bringing about that condition. However, he could not rule out a teratogenic cause in general or Benlate specifically, because as he conceded, he is not qualified to do so in that he is not a teratologist, a toxicologist or an expert in either field.

By contrast, Dr. Howard, continues to argue that Benlate is somehow the cause of Emily Bowen's problems and now believes that the CHD7 acted together with Benlate to bring about those injuries. In spite of that position, he does concede that it is very likely that Emily Bowen has CHARGE Syndrome. That concession is based upon Dr. Patton's supplemental findings upon which Dr. Howard relied since he has no expertise in the field of genetics. He further acknowledged that Benlate is not responsible for the mutation in question and that he knows nothing about the CHD7 gene other than what he read in one article on the subject, i.e., the Vissers Study.[21]

[21] Vissers, *supra* note 19.

Although he is able to maintain his view of Benlate as a human teratogen, Dr. Howard is not able to state how or in what percentage or proportion Benlate and the CHD7 mutation act together to produce CHARGE Syndrome in Emily Bowen. Nor is he aware of any testing or studies which confirm or support his theory regarding the interaction between Benlate and the CHD7 mutation.

**D. Supplemental and Renewed DRE 702 Motions**

On April 11, 2005, the defendant filed several supplemental motions based upon the recent genetic test results and the expert opinions filed in response by the plaintiffs' expert witnesses. As to Dr. Patton, the defendant sought to exclude any reference to the possibility that there could be causes of CHARGE Syndrome other than those rooted in the CHD7 mutation and/or the science of genetics. That motion was based upon Dr. Patton's admitted lack of expertise in any other relevant discipline. Dr. Howard was challenged in terms of his causation opinion and his reliance upon the differential diagnosis of Dr. Sauerhoff in light of

Dr. Patton's amended opinion. Lastly, the defendant renewed its original motions in limine based upon the Delaware Rules of Evidence and *Daubert*. As might be expected, the plaintiffs opposed those motions and filed their response in support thereof on April 24, 2005.

Argument was held on April 27 and 28, 2005. At the conclusion of that presentation, the Court granted the defendant's motions as to Dr. Patton, Dr. McIntosh and Dr. Howard. Given those findings, the defendant's motion for summary judgment was also granted as to both plaintiffs.[22] This Court reasoned that without the testimony of those witnesses the plaintiffs could not establish that Benlate was a human teratogen or that it was the specific cause of the injuries being complained of by either plaintiff.

The motion as to Dr. Patton was granted limiting his testimony as requested on grounds of relevance and

[22] The defendant filed this motion for summary judgment on March 17, 2003, listing six arguments in support thereof. The last argument referenced the *Daubert* issue and that the defendant's motion in that regard that was to be, and was in fact, filed on March 23, 2003. The dispositions of the remaining arguments are not relevant for present purposes.

competency based upon his admitted lack of expertise in teratology and toxicology. The defense motion as to Dr. McIntosh was granted based upon the Court's finding that he was not qualified as an expert in the field of dermal absorption as well as the finding that his opinions were not relevant and were based upon methodology that was not reliable.

Dr. Howard's exclusion was based upon two separate and distinct problems with his opinions.

First, Dr. Howard was excluded as an expert witness in Emily Bowen's case based upon Dr. Patton's amended opinion that Emily Bowen's injuries could be deemed genetic in origin and Dr. Howard's reliance on Dr. Patton as an expert in that area. Since he could not, given his lack of expertise and/or qualification as a geneticist, provide an opinion resting in genetics or otherwise supporting his post-CHD7 discovery theory that the CHD7 mutation and Benlate acted together, Dr. Howard could not testify as a expert witness as to Emily Bowen via DRE 702.

Second, his opinions as to both Emily Bowen and

Darren Griffin were barred based upon the Court's exclusion of Dr. McIntosh. That in turn meant that the plaintiffs were without expert testimony that could establish that Benlate was dermally absorbed and transferred to the fetus via the placenta. If no such testimony was introduced, Dr. Howard could not testify as to any causal link between Benlate and the purported birth defects.

## DISCUSSION

As indicated above, the defendant's motion is based upon DRE 702, which states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion . . . .

This rule is identical to its federal counterpart, Rule 702, which was first interpreted by the United States Supreme Court in *Daubert* as it applied to scientific

experts. It was extended in *Kumho Tire Co., Ltd. v. Carmichael*[23] to witnesses with technical and other specialized knowledge testifying under this rule. The Delaware Supreme Court has adopted those interpretations.[24] It is in light of those cases and their progeny that the Court's decisions relating to defendant's motions and the plaintiffs' expert witnesses must be examined.

Before the United States Supreme Court adopted the prevailing interpretation of DRE 702 in *Daubert*, the holding in *Frye v. United States,*[25] was utilized to determine the admissibility of scientific testimony provided by an expert witness. The *Frye* case concerned the admissibility of the results from a systolic blood pressure test, more commonly referred to as a "lie detector test". The court, without citing to any reported legal authority, stated:

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[23] 526 U.S. 137, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999).

[24] *Nelson,* 628 A.2d *at 74; State v. Jones*, 2003 WL 21519842, at *2 (Del. Super.), *citing M.G. Bancorporation, Inc. v. LeBeau*, 737 A.2d 513, 522 (Del. 1999).

[25] 54 App. D.C. 46, 293 F. 1013 (D.C. 1923).

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stage is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs*.[26] (Emphasis added.)

To put it simply, in order for evidence to be admissible under *Frye*, the principles on which the evidence is based, had to be "generally accepted" within the relevant scientific community.

The *Frye* test was eventually superceded by the adoption of the Federal Rules of Evidence and *Daubert.* In considering a new standard for admissibility of scientific evidence, the United States Supreme Court in *Daubert* reviewed the Federal Rules of Evidence generally and in particular, the preeminent roles of Rules 401, 402 and 702. The Court noted that Rule 402 dictates that all relevant evidence is admissible

[26] *Frye*, 54 App. D.C. at 47.

unless otherwise provided by law. Rule 401 defines relevant evidence as that having "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Finally, the Supreme Court noted that the introduction of expert testimony was governed by Rule 702.[27]

With these rules as guidelines, the Court announced its decision rejecting the *Frye* test. Instead, the trial judge is required not only to insure that evidence is relevant, but must also confirm that the evidence is reliable. Relevance and reliability are, therefore, the guiding principles to be used in determining the admissibility of expert testimony. And, it is the trial judge who must perform that exercise before the evidence is put before the jury.[28] However, before all else, there must be a determination that the evidence must constitute scientific knowledge.

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[27] Unless otherwise noted, the federal rules referenced in this opinion are identical to their Delaware counterparts.

[28] *Daubert*, 526 U.S. at 592-593.

Under the first prong of the test, the trial court must make the preliminary "assessment of whether the reasoning or methodology underlying the testimony is scientifically valid."[29] The judge must determine whether the testimony is rooted in the methods and procedures of science and derived from the scientific method.[30] To assist in making that assessment, the United States Supreme Court set out a list of factors. This list includes, but is not limited to:

1) Whether a theory or technique has been tested;[31]

2) Whether it has been subjected to peer review and publication;[32]

3) Whether a technique had a high known or potential rate of error and whether there are standards

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[29] *Id.* at 590.

[30] *Id.*

[31] *Id.* at 590-594.

[32] *Id.*

controlling its operation;[33] and

4) Whether the theory or technique enjoys general acceptance within a relevant scientific community.[34]

The second prong of the *Daubert* analysis tests the relevance of the expert evidence to the facts of the case in which it is being offered. It is often stated as whether the theory "fits" the facts and/or circumstances in the case, and requires "a valid scientific connection to the pertinent inquiry as a precondition to admissibility."[35] The judge must determine if the information will be helpful to the trier of fact in deciding a fact in issue.

Rule 104 of both the Delaware and Federal Rules of Evidence defines the role of the trial judge as the gate-keeper. All of the factors referenced in *Daubert* are not required and need not be applied in each

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[33] *Id.* This factor is not a "*sine qua non* of admissibility", but subjecting theories to review is a component of "good science". Just because a theory has been published will be relevant but not dispositive in determining the scientific validity. *Id.* at 593.

[34] *Id.* at 590-594.

[35] *Id.* at 591.

controversy. The gate-keeping function must be tied to the facts of each case.[36] Where the question of the admissibility is a close one, exclusion of the expert evidence is not appropriate where cross examination, the presentation of contrary evidence and careful instruction regarding the burden of proof will insure that the jury is not mislead or confused.[37]

Lastly, it is not necessary that the judge decide the admissibility of scientific evidence with the degree of certainty required in scientific circles.[38] Rather, Rule 104 only requires the judge to find that the expert's reasoning and methodology is scientifically valid by a preponderance of the evidence.[39] The focus of the inquiry must be on the actual principles and methodology, not on the applicable conclusions generated as a result.[40]

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[36] *Id.* at 592-593 & 597.

[37] *Id.* at 596.

[38] Wright & Gold, 29 Fed. Prac. & Proc. Evid. § 6266 (1997).

[39] *Id.*, *citing Bourjaly v. U.S.*, 483 U.S. 171, 175 (1987).

[40] *Daubert*, 526 U.S. at 594.

As stated above, the Delaware Supreme Court has clearly embraced *Daubert*. Prior to the adoption of the Delaware Rules of Evidence, our Supreme Court consistently held that *Frye* was not the sole criteria to be used in considering the admissibility of expert testimony.[41] It has, consistent with *Daubert*, formulated the test of admissibility via Rule 702 as follows:

> 1) the witness is 'qualified as an expert by knowledge, skill, experience, training or education . . .';[42]
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> 2) the evidence is relevant and reliable;[43]
>
> 3) the expert's opinion is based upon information 'reasonably relied upon by

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[41] *Nelson*, 628 A.2d at 73, *citing Santiago v. State*, 510 A.2d 488, 489 (Del. 1986). *See also*, *Whalen v. State*, 434 A.2d 1346, 1354-55 (Del. 1981); *Fensterer v. State*, 509 A.2d 1106, 1109, n.1 (Del. 1986).

[42] *Cunningham v. McDonald*, 689 A.2d 1190, 1193 (Del. 1997), *citing Nelson*, 628 A.2d *at* 74.

[43] *Id.*

> experts in the particular field . . .';[44]
>
> 4) the expert testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue . . .';[45] and
>
> 5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.[46]

It is apparent that the above quoted language includes the factors contained in the first and second prongs of the test set out in the holdings of *Daubert* and cases interpreting Rule 702 which followed *Daubert*. Indeed, the first three *Daubert* factors are in fact included within the requirement that the evidence be relevant and reliable as stated above in the second

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[44] *Id.*

[45] *Hart v. Resort Investigations & Patrol*, et. al, 2004 WL 2050511 (Del. Super.), *citing Mason v. Rizzi*, 843 A.2d 695 (TABLE) (Del.), *citing United States v. Downing*, 753 F.2d 1224, 1242 (3d. Cir. 1985).

[46] *Cunningham*, 689 A.2d at 1193, *citing Nelson*, 628 A.2d. at 74.

requirement for admissibility. The fourth *Daubert* factor is included within the requirement set forth above in the third.[47] To the extent it was not otherwise clear that the requirement that the expert testimony "fit" the facts of the case so as to assist the jury in carrying out its function is included in the fourth criteria, this Court, in *Hart v. Resort Investigations & Patrol,*[48] resolved any such ambiguity in the affirmative. Lastly, in Delaware as well, it is the party seeking to introduce the expert evidence, who bears the burden of proving its admissibility.[49]

As noted above, the plaintiffs have labeled Benlate as a teratogen generally capable of causing birth defects in humans, which did in fact cause the injuries to Emily Bowen and Darren Griffin. The defendant has said that Benlate did not contribute to those injuries,

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[47] *Podrasky v. T & G, Inc.*, 2004 WL 2827710 (Del. Super.), *citing Daubert*, 526 U.S. at 593-594.

[48] 2004 WL 2050511 (Del. Super.).

[49] *Minner v. Am. Mortgage & Guar. Co.*, 791 A.2d 826, 843 (Del. Super. Ct. 2000), *citing Nat'l Bank of Commerce v. Dow Chem. Co.*, 965 F.Supp. 1490, 1497 (D. Ark. 1996), *aff'd* 133 F.3d 1132 (8th Cir. 1998); *Schmaltz v. Norfolk & W. Ry. Co.*, 878 F.Supp. 1119, 1120 (D. Ill. 1995).

and challenged the expert witnesses employed by the plaintiffs in those regards. The defendant has argued that the proposed testimony is either not relevant, or to the extent that it is relevant, it must be excluded via DRE 403. It also argued, pursuant to DRE 702, that the witnesses in question do not qualify as experts nor are their opinions admissible in light of the *Daubert* line of cases.

The Court viewing the record as it stood at the close of the supplemental discovery, agreed with the defendant in substantial part. As a predicate, it assumed arguendo, that Dr. Howard and Dr. Tackett were experts in their respective fields of teratology and toxicology, and that they relied upon Dr. Patton and Dr. McIntosh in reaching their opinions as to Benlate. It was based upon those assumptions and reliance along with the authority referenced above that resulted in the orders entered on May 9, 2005. That which follows is the Court's reasoning underlying those rulings.

**Dr. Howard's Testimony Regarding Emily Bowen**

In order to establish the cause of a condition, an expert must not only be able to state the cause of a condition, the witness, or the party offering the testimony, must also be able to exclude other possible/putative causes. In scientific circles, this is known as performing a differential diagnosis. It is a commonly accepted method of addressing the issue of the origin or cause of a medical condition.[50] As the Fourth Circuit Court of Appeals stated in *Westberry*, such a diagnosis:

> . . . is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated. A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptom and then eliminating each of these potential causes until reaching

[50] *Westberry v. Gislavid Gummi AB*, 178 F.3d 257 (4th Cir. 1999). *See also, Long v. Weider Nutrition Group, Inc.*, 2004 WL 1543226, at *6 (Del. Super.), citing *Zuchowicz v. U.S*, 140 F.3d 381 (2nd. Cir. 1998); *Heller v. Shaw Indus.*, 167 F.3d 146 (3rd Cir. 1999)(other citations omitted).

> one that cannot be ruled out or determining which of those that cannot be excluded is the most likely . . . . (Citations omitted.)[51]

In the instant case, both sides have referenced this method of addressing the question of causation. The defense argues that the plaintiffs must not only be able to attribute responsibility for Emily Bowen's injuries to Benlate, they must also be able to exclude the most likely cause of Emily Bowen's problems, genetics and CHARGE Syndrome. The plaintiffs state that they did perform a differential diagnosis via the testimony of Dr. Patton and Dr. Howard and were able to establish Benlate as the cause of her problems. That conclusion was based upon the negative results of prior chromosomal based genetic testing. Two years later, as indicated above, dramatic advances had been made thus allowing the more precise testing of Emily Bowen and Darren Griffin ordered here.

When Dr. Patton changed his diagnosis following the CHD7 test results, Dr. Howard could no longer exclude

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[51] *Westberry,* 178 F.3d at 262-263.

genetics as, in the words of Dr. Patton, a "substantial cause" of the injuries in question. Dr. Howard then amended his opinion that Benlate was the sole cause of Emily Bowen's injuries to conclude that Benlate interacted with the CHD7 mutation to proximately bring about the problems visited upon her. Dr. Howard did so without any expertise in genetics, having very little knowledge about CHD7 or how, when, and to what degree it combined with Benlate to cause the injuries complained about. Moreover, he admitted that his theory has never been tested, peer reviewed or otherwise subjected to professional scrutiny.

The Court's decision to exclude Dr. Howard as a witness in Emily Bowen's case was based in the first instance on DRE 702's requirement that the witness be "qualified". The Court's order limited Dr. Patton's testimony that the CHD7 mutation was a substantial cause of her difficulties and excluded any testimony relative to other possible causes about which Dr. Patton was not qualified to address. The order as to Dr. Patton severed any link to the field of genetics

other than to the aforementioned testimony relating to the CHD7 mutation. Given the fact that Dr. Howard admits that he is not a geneticist and has no training, education or experience generally, or specifically, as to CHD7, he is not qualified via DRE 702 to opine relative to any interaction between CHD7 mutation and Benlate. Nor can he perform a valid differential diagnosis excluding CHD7 or genetics as a cause of the injuries visited upon Emily Bowen under the circumstances.[52]

Dr. Howard's amended opinion and proposed testimony was further excluded because it was not reliable and therefore runs afoul of DRE 402 and 702. His theory regarding the interaction between the CHD7 mutation and Benlate as the cause of Emily Bowen's injuries has not been validated by any scientific discipline, study or entity. It has not been the subject of any peer review nor has it been accepted by any relevant scientific

[52] In espousing his amended or supplemental theory, Dr. Howard has apparently forgotten his deposition testimony where he stated that if Dr. Patton's opinion relative to CHARGE and genetics as the source of Emily Bowen's problems changed, his view concerning causation would be similarly affected.

community.[53] There was no testing or publication of this theory prior to the discovery of the CHD7 mutation and its link to CHARGE Syndrome. It is readily apparent as a result, that the theory did not arise out of research or testing but was a product of the instant litigation, a factor which supports its rejection.[54]

Lastly, there is no evidence of any cause other than the CHD7 mutation. Dr. Howard is unable to explain how, why, or where the CHD7/Benlate combination works. Nor have the plaintiffs been able to otherwise produce any testimony, at least from those qualified to provide it, that there exists a disease or disability producing gene, in this case CHD7, which requires the presence of an environmental agent to manifest itself. The position advocated by the defense is clear - the mutated CHD7 gene was the sole and proximate cause of Emily Bowen's CHARGE Syndrome. That theory has substantial support in the record in that it has been

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[53] In this case, at the very least, the relevant community had to include teratologists and/or geneticists given the nature of the theory being advanced.

[54] *In Re Rezulin Prods. Liab. Litig.*, 2005 WL 583751, at *17 (S.D.N.Y.).

tested, peer reviewed and published, apparently without consequential dissent.

The Court must further conclude that Dr. Howard's revised opinion is not sufficiently tied to the facts of the case so as to assist the jury in resolving any of the issues involved in this case. It is not the product of reliable scientific principles and methods. In short, while it does relate to causation, the proposed testimony is nothing more than an unsupported theory, or "ipse dixit".[55]

No other conclusion is viable under the Delaware Rules of Evidence or *Daubert*. The trial court does not have to apply all of the *Daubert* factors, but it must apply them to the facts of each case as is appropriate in its role as the gate-keeper. Cross examination, presentation of contrary evidence or legal instruction would not cure the deficiencies found in Dr. Howard's opinions. Moreover, to allow the testimony as proposed

[55] "Ipse dixit" is a Latin phrase translated as "He himself said it". Its use is appropriate in this case because the only support Dr. Howard seems to have for his theory is his own opinion and/or view of the case. That is certainly not enough under *Daubert,* and it is even less likely that it would survive if this jurisdiction were to follow *Frye.*

would allow the jury to engage in speculation or result in confusion as well as undue prejudice to the defense given the facts of this case thereby running afoul of DRE 403 as well.[56] In such circumstances, again, given the nature of the injuries and those suffering them, there is a pressing need for the Court to exclude the evidence in question.[57]

**Limitations on the Testimony of Drs. McIntosh, Howard and Tackett Regarding Emily Bowen and Darren Griffin**

The Court previously held that Dr. McIntosh was not qualified to provide expert testimony in the field of dermal absorption via DRE 702. At best, Dr. McIntosh has expertise in exposure assessment as opposed to dermal absorption. His curriculum vitae reveals that

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[56] DRE 403 reads:

> Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues or misleading the jury, or by consideration of undue delay, waste of time or needless presentation of cumulative evidence.

[57] *Lynch v. Merrell-National Labs.*, 830 F.2d 1190, 1196-1197 (1st Cir. 1987)(Citations omitted).

his education and experience is concentrated in analysis and/or assessment of hazards and materials in the environment as well as the exposure of humans thereto. Nothing in his career since it began in 1996 reveals any activity even remotely related to the opinion offered in this litigation. His professional affiliations and organizational memberships also confirm this view.

To be even more specific, prior to this litigation, Dr. McIntosh had never been involved in any work with respect o Benlate or its active ingredient, benomyl. These cases were his first such involvement. He had never engaged in any work or had any professional experience related to dermal absorption, generally or specifically relative to Benlate. Nor was he aware of studies relative to human dermal absorption prior to his retention as an expert in this case, including the "TNO Study" commissioned by plaintiffs' counsel in *Bourne v. Dupont*.[58] Dr. McIntosh had not authored any

[58] 189 F. Supp. 2d 482 (D. W. Va. 2002), *aff'd* 2004 WL 117634 (4th Cir. W. Va. 2004). Not only had Dr. McIntosh not heard of any of the studies prior to his retention, a total of ten, but he had not been

articles or belonged to any professional society or group related to dermal absorption and had not participated in any peer journal review or had any knowledge of sources of information he considered authoritative.

Most telling is his own admission regarding his alleged expertise. According to Dr. McIntosh, while he might be an expert in dermal exposure, dermal absorption is a specialized area in which he was not an expert but had only a working knowledge of the subject. Unfortunately for the plaintiffs, there is no authority in support of the proposition that a "working knowledge" is the equivalent of "expertise" for purposes of DRE 702, at least not in these circumstances.

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informed of their existence by counsel for plaintiffs who certainly knew of them and had copies before Dr. McIntosh wrote his initial reports. He did, during the week of his deposition, learn of the existence of one such study, involving Benlate and rats, which was referenced as the "Covance Study". Frederick W. Thalacker, *C-Benomyl: Pharmacokinetics in Female Rats Following Oral, Intravenous, Dermal, and Dietary Routs of Administration*, E.I. DuPont de Nemours & Co. (May 24, 1999). Dr. McIntosh still was not told of the TNO Study. The TNO Study involved testing the absorption of Benlate thru human skin. W.J.A. Meuling, R. Engel, A.A. Vink, L. Roza, *Dermal Absorption of Benlate WP50 in Human Volunteers*, TNO Voeding, Netherlands Organization for Applied Science (May 25, 2000).

Based upon all of the above, the Court must conclude that Dr. McIntosh is not qualified as an expert in the field of dermal absorption. Moreover, even if Dr. McIntosh did prove to be qualified to provide an opinion concerning dermal absorption, his opinion on the subject runs afoul of both prongs of *Daubert* and the Court's action excluding him as a witness was appropriate in any event.

In the first instance, the testimony is not reliable, i.e., it was not based upon a relevant methodology. It had not been tested, subjected to peer reviewed publication or been accepted within any recognized scientific community relating to dermal absorption prior to its use here.[59] This is also the first time this model and formula had been used to calculate the rate of dermal absorption of Benlate. And, its use had not been replicated or otherwise validated since the model was so employed by Dr. McIntosh.

[59] As was the case with Dr. Howard, it is unlikely that the proposed testimony and/or opinions by Dr. McIntosh, given this finding, would have been admissible under *Frye* either.

Most significantly, the EPA guidelines recommended this model be used only when no comparable human studies exist, a point that Dr. McIntosh confirmed. It is the least favored method of measuring dermal absorption, with human studies being the most preferred followed by animal in vitro studies. The model, as Dr. McIntosh further concedes, fails to provide and/or allow for the calculation of the amount of Benlate that covered the skin of the mothers of Emily Bowen and Darren Griffin.

Dr. McIntosh's proposed testimony further fails the relevancy prong of the *Daubert* analysis. Both sides agree, and Dr. McIntosh concedes, that to calculate what was absorbed, you must know how much, or the amount of Benlate, that got on the skin. As noted by Dr. McIntosh, use of the Potts/Guy model does not allow for this estimation to be made. To make matters even more questionable, Dr. McIntosh admittedly made no attempt to estimate the amount deposited on the skin of the mothers, did not personally visit the scenes of the

spraying,[60] or test the sprayer used by the Bowens notwithstanding its availability.[61] If the amount on the skin can not be determined, it is readily apparent that one can not calculate the amount absorbed into the body and ultimately passed on to the fetus at critical stages of its development.

Under these circumstances, the testimony will not assist the trier of fact to understand and resolve issues in the litigation. Neither side seems to dispute the proposition that any substance can be toxic at some level. The question which results is at what level, assuming again, arguendo, it is a human teratogen, would Benlate have interfered with the fetal development of Emily Bowen and Darren Griffin. Dr. McIntosh's testimony does not assist in resolving that question. Furthermore, given the fact that Dr. Howard

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[60] Apparently Dr. McIntosh did review a total of up to ten pictures of the scenes of both of the areas sprayed provided by plaintiffs' counsel as well as the weather reports for those locations at or about the times the exposures in question allegedly took place.

[61] It is unclear from Dr. McIntosh's deposition testimony whether the sprayer used by Ms. Griffin's in-laws was ever available and/or was tested. In light of Dr. McIntosh's decision not to test the Bowen sprayer, and without more, the Court will assume the Griffin sprayer was not subjected to testing either.

and Dr. Tackett rely on Dr. McIntosh to calculate how much Benlate was passed on to those fetuses, a jury would more likely be mislead or confused if Dr. McIntosh's opinions, in light of the methodology employed and the results thereof, were allowed into evidence to establish causation.

For those reasons, the defendant's motion to exclude the opinions and/or testimony of Dr. McIntosh was granted. As a result, neither Dr. Tackett or Dr. Howard can rely on the information contained therein as to Emily Bowen or Darren Griffin. The testimony, having been deemed unreliable and not relevant, can not be used to form the basis for their opinions relative to any causal link between Benlate and the injuries for which the plaintiffs seek compensation. However, the decision is limited to the facts of this case. Given the disposition of the motions barring the testimony of Drs. Howard, Tackett and McIntosh, and the resultant grant of summary judgment in favor of the defendant, it is not necessary to reach any motions which have not been resolved to date in this case.

Whether these decisions apply to the six remanded cases remains to be decided. Also yet to be answered is whether Drs. Howard, Tackett and Sauerhoff qualify and/or may testify as experts in those cases. The Court will schedule a status conference to begin to grapple with those issues in the near future at the convenience of the parties.

**CONCLUSION**

For the foregoing reasons, the Court entered the orders relative to Drs. Patton, Howard and McIntosh on May 9, 2005. It was based upon the May 9 orders that the defendant's motion for summary judgment was granted on that same date. There was no need as a result to proceed to a trial on the merits.

**Charles H. Toliver, IV**
**Judge, Superior Court**