### IN THE SUPREME COURT OF THE STATE OF DELAWARE

MATTHEW BOWEN and MELISSA	)
ELLIS, as parents and natural guardians of	) No. 580, 2005
EMILY BOWEN and MATTHEW	)
BOWEN and MELISSA ELLIS,	) Court Below: Superior Court
individually; and MARTIN GRIFFIN and	) of the State of Delaware in
TRUDI GRIFFIN, as parents and natural	) and for New Castle County
guardians of DARRIN GRIFFIN and	)
MARTIN and TRUDI GRIFFIN,	) C.A. No. 97C-06-194
individually,	)
	)
Plaintiffs Below,	)
Appellants,	)
	)
V.	)
	)
E. I. DUPONT DE NEMOURS & CO.,	)
INC.,	)
	)
Defendant Below,	)
Appellee.	)

Submitted: July 12, 2006 Decided: September 15, 2006

Before **STEELE**, Chief Justice, **HOLLAND**, **BERGER**, **JACOBS**, Justices, and **STRINE**, Vice Chancellor,\* constituting the *court en banc*.

Upon appeal from the Superior Court. **AFFIRMED**.

Thomas C. Crumplar, Jacobs & Crumplar, Wilmington, Delaware; Joel S. Perwin (argued) admitted *pro hac vice* for appellants.

James W. Semple, Morris, James, Hitchens & Williams, LLP, Wilmington, Delaware for appellees.

## **STEELE**, Chief Justice:

<sup>\*</sup>Sitting by designation pursuant to Del. Const. Art. IV § 12.

The plaintiffs-appellants, Bowen, *et al.*, appeal from the Superior Court's Order excluding two of the plaintiffs' experts' opinions and the resulting grant of summary judgment in favor of the defendant-appellee, E. I. Du Pont de Nemours and Company, Inc. The appellants claim that the trial judge abused his discretion by excluding their proffered experts' opinions because: (1) the experts were sufficiently qualified through their personal study and experience to offer opinions in certain areas in which they lacked formal training; and (2) the experts' methodologies underlying their opinions were verifiable and therefore reliable. We conclude that the trial judge did not abuse his discretion when he excluded the plaintiffs' proffered expert opinions. Accordingly, we affirm the Superior Court's Order excluding the proffered expert testimony and granting summary judgment to the defendants.

#### FACT AND PROCEDURAL BACKGROUND

This appeal concerns two of eight personal injury actions that parents from England, Scotland, Wales, and New Zealand filed in 1997 on behalf of their minor

Matthew Bowen and Melissa Ellis, as parents and natural guardians of Emily Bowen and Matthew Bowen and Melissa Ellis individually; and Martin Griffin and Trudi Griffin, as parents and natural guardians of Darren Griffin and Martin and Trudi Griffin, individually.

children.<sup>2</sup> The families allege that their exposure to Benlate, a chemical agricultural product that DuPont manufactured, caused the children to be born with birth defects.

On August 18, 1997, DuPont moved to dismiss the all of the complaints on grounds of *forum non conveniens*. The trial judge granted DuPont's motion on August 28, 1998. We reversed that judgment, on June 14, 1999, and remanded so the litigation could continue in Delaware.<sup>3</sup> On July 24, 2001, DuPont filed a motion to dismiss all the actions as time barred. The trial judge dismissed six of the eight actions on April 25, 2002. The families appealed and we again reversed the trial judge's dismissal.<sup>4</sup>

On May 20, 2003, the plaintiffs moved to consolidate the cases for further proceedings. The trial judge, on April 27, 2004, consolidated the cases for pretrial purposes, but refused to try all eight cases together.<sup>5</sup> He ordered the cases to be

The Bowen, Griffin, and Memon families are from England and Wales. The Brown, Copeland and Johnstone families are from Scotland. The Ison and Hanham families are from New Zealand.

<sup>&</sup>lt;sup>3</sup> See Ison, et al. v. E.I. DuPont De Nemours & Co., 729 A.2d 832 (Del. 1999) (holding that the existence of a more convenient forum alone was an insufficient ground for dismissal without a showing of overwhelming hardship to defendant).

See Brown, et al. v. E.I. DuPont de Nemours & Co., 820 A.2d 362 (Del. 2003) (holding 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).

Ison v. E.I. DuPont De Nemours & Co., 2004 Del. Super. LEXIS 129 (Del. Super. Ct. 2004)

grouped in four pairs, with each pair to be tried separately. The trial judge scheduled the claims made by and on behalf of Emily Bowen and Darren Griffin to be tried first. Those claims are the subject of this appeal.<sup>6</sup>

Between 1970 and 1995, DuPont produced and sold the fungicide, Benlate. The product's active ingredient, benomyl, was designed to prevent and cure fungal infections in plants and crops. Although Benlate was only available for commercial use in the United States, the fungicide was approved and sold for residential use in the appellants' home country, the United Kingdom.

During the early stages of their pregnancies, Melissa Ellis and Trudi Griffin were exposed to Benlate. In 1993, Ellis came in contact with Benlate through her and her husband's repeated use of the product in their indoor vegetable garden in Cardiff, Wales. Ellis' neck, arms, hands, legs, and feet were wetted both from the mist of a sprayer used to apply a Benlate dilution and from contact with the saturated vegetation. Griffin claims only one exposure to Benlate: she was covered by a Benlate mist when her father-in-law sprayed an apple tree and some vegetation in his garden in Norfolk, England.

Their trial was initially scheduled to begin on October 12, 2004 and conclude on or before December 3, 2004. The scheduling of the other three trials remains pending until the resolution of the Bowen/Griffin matters. *See generally Bowen v. E. I. du Pont de Nemours & Co.*, 2005 Del. Super. LEXIS 239, \*5-\*7 (Del. Super. Ct. 2005) (recounting the procedural history in more detail).

The appellants allege that their exposures to Benlate led to Emily's and Darren's birth defects. Emily was born August 9, 1994 with several physical deformities and neurological defects. Emily has microphthalmia<sup>7</sup> and coloboma<sup>8</sup> bilaterally, and is visually disabled. Emily also suffers from heart, ear, and psychomotor developmental defects. Darren was born on November 23, 1995 with microphthalmia, cataract, and blindness of the right eye. DuPont's pediatric ophthalmologist diagnosed Darren's condition as Persistent Primary Hyperplastic Vitreous (PPHV).

Although Emily's consulting geneticist, Dr. Michael A. Patton, initially disagreed, DuPont maintained from the start of this litigation that Emily's injuries and condition constituted CHARGE,<sup>9</sup> a syndrome that is generally believed to be genetic, as opposed to environmental, in origin.<sup>10</sup> Dr. Patton concluded in 2002, and maintained in 2003, that Emily did not meet the diagnostic criteria for

Microphthalmia or microphthamos is defined as "a birth defect with abnormal smallness of one or both eyes." *The Mosby Medical Encyclopedia*, at 505 (revised ed. 1992).

Coloboma is defined as "a birth defect in which a cleft extends along the edge of the eyeball. This affects the iris, ciliary body, or the blood vessel layer (choroid)." *Id.* at 192.

CHARGE is an acronym for a syndrome consisting of  $\underline{\mathbf{C}}$  oloboma of the eye,  $\underline{\mathbf{H}}$  eart defects,  $\underline{\mathbf{A}}$  tresia of the choanae,  $\underline{\mathbf{R}}$  etardation or neural abnormalities, and  $\underline{\mathbf{E}}$  ar abnormalities. *Bowen*, 2005 Del. Super. LEXIS 239 at \*13, n9.

<sup>&</sup>lt;sup>10</sup> *Bowen*, 2005 Del. Super. LEXIS 239 at \*12-\*13.

CHARGE, but acknowledged that his opinion could change depending on her physical development and any developments in the science related to CHARGE.<sup>11</sup>

In 2004, researchers published a study identifying a possible genetic cause of CHARGE.<sup>12</sup> Those researchers believed that various deletions within the genetic code for the CHD7<sup>13</sup> protein inhibit gene expression, which in turn leads to the birth defects constituting CHARGE. After testing ordered by the Superior Court,<sup>14</sup> two separate genetic laboratories confirmed that Emily has a CHD7 mutation.<sup>15</sup>

Given the results of the genetic testing and changes in the diagnostic criteria for CHARGE, Dr. Patton now believes that Emily has CHARGE. He also believes that Emily's CHD7 mutation was a substantial cause of her birth defects and her current condition. Dr. Patton acknowledges, however, that he is not qualified to

<sup>11</sup> *Id. at* \*14.

The study (hereinafter "the Vissers study") was first presented in the medical journal "Nature Genetics." 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.

<sup>13</sup> CHD7 refers to a chromodomain helicase DNA-binding protein, which is involved in unzipping a cell's DNA allowing for gene expression and DNA replication.

On July 12, 2004 DuPont moved for the Superior Court to order the genetic testing. The trial judge granted the motion on October 15, 2004, and allowed further discovery and supplementation of the expert reports. Trial was rescheduled for May 9, 2005. *See Bowen*, 2005 Del. Super. LEXIS 239 at \*18-\*19.

See Id. Darren Griffin's genetic test results were negative for CHD7.

rule out any environmental factors, such as Benlate, as a possible cause of Emily's condition.<sup>16</sup>

Dr. Charles V. Howard, in contrast, maintains that his expertise in teratology<sup>17</sup> and toxicology<sup>18</sup> qualifies him to opine that Benlate is a cause of Emily's condition. 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 teaches courses in anatomy, microscopy and morphology. Dr. Howard belongs to several professional organizations, including the British Society of Toxicological Pathologists and the Society for Developmental Pathology.<sup>19</sup>

When he formulated his original opinion that Benlate caused Emily's birth defects, Dr. Howard relied partially on Dr. Patton's preliminary conclusion that Emily did not have CHARGE. Dr. Howard also relied upon his education, training, research regarding Benlate, and the finding of Dr. MacIntosh with regard to the amount of Benlate that was dermally absorbed by Ellis. Despite earlier

<sup>16</sup> *See Id. at* \*20-21.

Teratology is defined as "the study of the causes and effects of inborn malformations and developmental abnormalities." *The Mosby Medical Encyclopedia*, at 754.

Toxicology is defined as "the scientific study of poisons, their detection, their effects, and methods of treatment for conditions they produce." *Id.* at 779.

<sup>&</sup>lt;sup>19</sup> *Bowen.* 2005 Del. Super. LEXIS 239 at \*15.

acknowledging that he might need to alter his opinion if Dr. Patton's genetic assessment of Emily changed, Dr. Howard currently adheres to his opinion that Benlate is "a" cause of Emily's condition. Dr. Howard similarly concluded that Benlate caused Darren's birth defects.<sup>20</sup>

The appellants chose Dr. David L. MacIntosh to provide an opinion that calculates the pregnant mothers' dermal exposure to Benlate as well as the amount of Benlate that would have been absorbed into the mothers' bloodstreams. Dr. MacIntosh professed to be a dermal exposure expert, but concedes that he has only a working knowledge about dermal absorption. Dr. MacIntosh received both his undergraduate degree in Decisional Science, in 1988, and his master's degree in Environmental Science, in 1991, from Indiana University. He received his doctorate in Environmental Health in 1995, from the Harvard School of Public Between 1996 and 2002, Dr. MacIntosh taught graduate and Health. undergraduate courses in environmental chemical air quality and hazardous waste management at the University of Georgia; and in 2002, he became a senior associate with Environmental Health and Engineering, Inc., in Newton, Massachusetts.<sup>21</sup>

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<sup>&</sup>lt;sup>20</sup> See Bowen, 2005 Del. Super. LEXIS 239 at \*16-17.

Bowen, 2005 Del. Super. LEXIS 239 at\*10-\*11.

Dr. MacIntosh 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.<sup>22</sup>

Relying solely upon a model formula provided by the EPA in its publication entitled "Dermal Exposure Assessment Principles and Applications," Dr. MacIntosh calculated the amount of Benlate that would have been absorbed through the skin of the pregnant mothers. He based his inputs for the EPA's formula upon the mothers' testimony regarding their exposures to Benlate and on several assumptions he derived therefrom. In choosing the EPA model and in formulating his opinion in general, Dr. MacIntosh did not consider any existing studies concerning the dermal absorption of Benlate, including a study commissioned by the appellants in 2000. The record is not clear why the appellants chose to provide Dr. MacIntosh with these studies well after he had

<sup>&</sup>lt;sup>22</sup> *Id. at* \*11.

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 http://www.epa.gov/ncea/pdfs/derexp.pdf (cited in Bowen, 2005 Del. Super LEXIS 239 at \*19, n8.)

<sup>&</sup>lt;sup>24</sup> See Bowen, 2005 Del. Super. LEXIS 239 at\*12.

already formulated his opinion, and even then, only the week before he was deposed.

On April 11, 2005, DuPont filed several supplemental motions based upon the recent genetic test results and the expert opinions filed in response by the plaintiffs' expert witnesses. Relying upon D.R.E. 702, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, <sup>25</sup> and its Delaware progeny, <sup>26</sup> Dupont moved to exclude parts of Dr. Patton's testimony. On similar grounds, DuPont also renewed a March 23, 2003 motion to exclude the testimony of Drs. Howard, Randall L. Tackett, <sup>27</sup> MacIntosh, Mitchell W. Sauerhoff, <sup>28</sup> and Robert F. Smith <sup>29</sup>. The trial judge granted DuPont's motions concerning Drs. Patton, MacIntosh, and Howard. <sup>30</sup>

The trial judge limited Dr. Patton's testimony on the grounds of relevance and competency because of Dr. Patton's admitted lack of expertise in teratology

<sup>&</sup>lt;sup>25</sup> 509 U.S. 579 (1993).

See e.g., Nelson v. State, 628 A.2d 69 (Del. 1993); M.G. Bancorporation v. LeBeau, 737
 A.2d 513 (Del. 1999).

Dr. Tackett, as an expert in pharmacology, was to provide testimony regarding the properties of Benlate as a human teratogen and its effects on fetal development at differing levels of exposure.

Dr. Sauerhoff, having been retained as an expert in over three hundred cases relating to the causal effect of substances, along with evaluating the methodology of opposing experts, was to testify that Drs. Howard, Tackett and MacIntosh followed standard methodologies accepted in their respective disciplines in rendering their opinions.

The trial judge explained that, for reasons about which he was unaware, the plaintiffs withdrew Dr. Smith as an expert witness. *Bowen*, 2005 Del. Super. LEXIS 239 at \*17, n17.

<sup>30</sup> Bowen, 2005 Del. Super. LEXIS 239 at \* 23.

and toxicology.<sup>31</sup> He excluded Dr. MacIntosh's opinion regarding dermal absorption (1) because Dr. MacIntosh was not a qualified dermal absorption expert and (2) because the methodology Dr. MacIntosh used to reach his conclusions was not reliable.<sup>32</sup> Because Dr. Howard relied upon Dr. MacIntosh's testimony to establish that Benlate was dermally absorbed and transferred to the fetuses, the trial judge excluded Dr. Howard's testimony concerning the teratogenic effects of Benlate on Emily Bowen and Darren Griffin.<sup>33</sup> The trial judge also excluded Dr. Howard's testimony regarding a possible interaction between Benlate and Emily Bowen's CHD7 mutation on the grounds that that opinion concerned genetics, and Dr.Howard was not a qualified geneticist.<sup>34</sup>

Because the plaintiffs necessarily relied on the testimony of Drs. Patton, MacIntosh, and Howard to establish that Benlate is a human teratogen and a specific cause of the plaintiffs' injuries, the trial judge granted DuPont's motion for summary judgment. The appellants now ask this Court to reverse the evidentiary rulings and the resulting grant of summary judgment. After briefing and oral

*Id.* at \*23-24.

*Id.* at \*24.

*Id.* at \*24-\*25.

*Id.* at \*24.

argument before a panel on May 24, 2006, we requested supplemental memoranda<sup>35</sup> and held *en Banc* oral arguments on July 12, 2006. We now affirm.

#### **DISCUSSION**

The appellants argue that the trial judge abused his discretion by excluding the testimony of Drs. Howard and MacIntosh, and consequentially entering summary judgment in DuPont's favor on the assumption that the appellants could not go forward without that testimony. Appellants contend that the trial judge focused too narrowly upon the experts' formal specialties and training, as opposed to their personal study and experience when he analyzed the experts' qualifications. The appellants also claim that their experts' methodologies were reliable and that any alleged flaws in their methods should have been left for the jury to weigh. We conclude that the trial judge did not abuse his discretion by excluding Dr. MacIntosh's testimony. Because Dr. Howard necessarily relied upon Dr. MacIntosh's testimony to establish that Benlate was dermally absorbed and reached the fetuses, we need not address the trial judge's decision to exclude Dr. Howard's specific theories regarding Benlate.

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The appellants' supplemental memorandum was required to identify the scientific studies, cited within the record, which they relied upon as the basis for the expert opinions that: (1) Benlate causes birth defects; (2) a CHD7 gene mutation is a cause of CHARGE, but it is not the sole cause of that birth defect; and (3) Benlate, acting in conjunction with the mutated gene, is a concurrent cause of CHARGE. The appellants were also asked to determine on which of the three listed opinions Dr. Howard is qualified to render an opinion. In response, the appellee's supplemental memorandum was required to concede or dispute the scientific reliability of each of the studies listed in the appellants' supplemental memorandum and identify the rationale or basis for any dispute.

Delaware Rule of Evidence 702 governs the admission of expert testimony.

That rule provides:

[i]f 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 or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

D.R.E. 702 is substantially similar to Federal Rule of Evidence 702, which the United States Supreme Court interpreted in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 36 *Daubert* specifically addressed the admissibility of scientific testimony under F.R.E. 702. In *Kumho Tire Co., Ltd. v. Carmichael*, 37 the Court extended the *Daubert* holdings to apply to all expert testimony concerning "scientific, technical or other specialized" matters. Though the United States Supreme Court's interpretations of F.R.E. 702 in *Daubert* and *Kumho* are only binding upon federal courts, this Court has expressly adopted their holdings as correct interpretations of D.R.E. 702. 38

<sup>&</sup>lt;sup>36</sup> 509 U.S. 579 (1993) ("Daubert").

<sup>&</sup>lt;sup>37</sup> 526 U.S. 137 (1999).

<sup>&</sup>lt;sup>38</sup> *M.G. Bancorporation v. Le Beau*, 737 A.2d 513, 521 (Del. 1999).

Accordingly, D.R.E. 702 "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony...is not only relevant, but reliable.'"<sup>39</sup> The trial judge acts as the "gatekeeper" in deciding whether an expert's testimony "has a reliable basis in the knowledge and experience of [the relevant] discipline."<sup>40</sup> The foci of a *Daubert* analysis are the "principles and methodology" used in formulating an expert's testimony, not on the expert's resultant conclusions.<sup>41</sup> To help determine whether an expert's "principles and methodology" are rooted in science and derived from the scientific method,<sup>42</sup> the *Daubert* Court identified several factors that may be useful to a trial judge acting as the "gatekeeper:"

- (1) whether a theory or technique has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique had a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.<sup>43</sup>

<sup>&</sup>lt;sup>39</sup> *Id.* (quoting *Daubert*, 509 U.S. at 589).

<sup>40</sup> *Id.* at 523.

<sup>&</sup>lt;sup>41</sup> *Daubert*, 509 U.S. at 595.

<sup>42</sup> *Id.* at 590.

<sup>43</sup> *Id.* at 590-94.

These factors identified in *Daubert* are not a "definitive checklist or test."<sup>44</sup> Rather, the "inquiry must be 'tied to the facts' of a particular 'case,'"<sup>45</sup> because "the factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."<sup>46</sup>

Consistent with *Daubert*, we apply a five-step test to determine the admissibility of scientific or technical expert testimony. The trial judge must determine whether:

- (1) the witness is qualified as an expert by knowledge, skill experience, training or education;
- (2) the evidence is relevant;
- (3) the expert's opinion is based upon information reasonably relied upon by experts in the particular field;
- (4) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and
- (5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.<sup>47</sup>

<sup>44</sup> See Kumho, 526 U.S. at 150 (quoting Daubert, 509 U.S. at 593).

See Id. (quoting Daubert, 509 U.S. at 591).

See Id. (quoting the Solicitor General from the Brief for United States as Amicus Curiae).

<sup>&</sup>lt;sup>47</sup> Tolson v. State, 900 A.2d 639, 645 (Del. 2006); Eskin v. Carden, 842 A.2d 1222, 1227 (Del. 2004).

The party seeking to introduce the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence.<sup>48</sup>

We review a trial judge's decision to exclude expert testimony for abuse of discretion.<sup>49</sup> "This deferential standard of review is simply a recognition that trial judges perform an important gatekeeping function and, thus, 'must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."<sup>50</sup>

Although a motion to exclude expert testimony is frequently case dispositive, a deferential abuse of discretion standard of review is congruent with the trial judge's prescribed role as "gatekeeper." <sup>51</sup>

We find that the trial judge did not abuse his discretion when he decided to exclude Dr. MacIntosh's testimony. A review of the record establishes that the trial judge, as gatekeeper, appropriately excluded Dr. MacIntosh's opinion

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)); See also Oddi v. Ford Motor Co., 234 F.3d 136, 145 (3d Cir. 2000); Cook v. Sheriff of Monroe County, 402 F.3d 1092, 1107 (11th Cir. 2005); Marmo v. Tyson Fresh Meats, 2006 U.S. App. LEXIS 19609, \*14 (8th Cir. 2006); Nelson v. Tennessee Gas Pipeline Co., 243 F.3d 244, 251 (6th Cir. 2001); Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592, n10 (U.S. 1993).

<sup>&</sup>lt;sup>49</sup> Le Beau, 737 A.2d at 522 (citing General Electric Co. v. Joiner, 522 U.S. 136, 141-42 (1997)).

<sup>&</sup>lt;sup>50</sup> Garden v. State, 815 A.2d 327, 338 (Del. 2003) (quoting Kumho, 526 U.S. at 152).

See, e.g., Lust by & Through Lust v. Merrell Dow Pharms., 89 F.3d 594, 597 (9th Cir. 1996); Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318 (7th Cir. 1996).

concerning dermal absorption. Dr. MacIntosh is not qualified to offer a dermal absorption opinion. Even assuming *arguendo* that Dr. MacIntosh is qualified, his testimony is not admissible because his underlying methodology is not reliable.

The appellants argue that the trial judge determined Dr. MacIntosh's qualifications in an overly restrictive manner. They suggest that Dr. MacIntosh is an exposure expert and does not profess to be an absorption expert. The appellants also dispute the trial judge's finding that Dr. MacIntosh "provided expert testimony in the field of absorption." Rather, the appellants claim that Dr. MacIntosh mechanically applied the Potts-Guy model, a methodology that they claim he is qualified to employ.

Dr. MacIntosh, however, did more than simply plug inputs into a model. Moreover, his alleged "working knowledge" of dermal absorption did not qualify him even to choose the Potts-Guy model. While we recognize that at times an expert may be qualified by criteria outside of his formal training or designated specialty, <sup>52</sup> we must scrutinize an expert's qualifications with "due regard for the

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See, e.g., Caro v. Woodford, 280 F.3d 1247 (9th Cir. 2002), cert. denied, 536 U.S. 951 (2002) (allowing a toxicologist with expertise in pesticide toxicology to testify regarding a criminal defendant's brain damage); McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995) (holding a clinician's extensive experience sufficient to permit him to opine that the plaintiff's medical condition was caused by exposure to a toxin); Hopkins v. Dow Corning Corp., 33 F.3d 1116 (9th Cir. 1994) (finding a toxicologist, although not a medical doctor, to be qualified to testify regarding causal connection between breast implant and plaintiff's disease).

specialization of modern science."<sup>53</sup> Dr. MacIntosh's use of the Potts-Guy model raised questions that only a dermal absorption expert would be qualified to answer. The trial judge noted, and Dr. MacIntosh admitted, that the Potts-Guy model is the least favored method of measuring dermal absorption. In fact, the EPA guidelines recommend this model be used only when no comparable human studies exist.<sup>54</sup>

Dr. MacIntosh does not have the requisite qualifications, formal or otherwise, to opine why it was appropriate to choose the least favored, as opposed to other, methods of measuring dermal absorption. Nor is Dr. MacIntosh qualified to opine about any of the alleged flaws with the Potts-Guy model. It is apparent from the record that Dr. MacIntosh's utilization of the Potts-Guy model is "not cut and dried," and that only a dermal absorption expert would be qualified to answer the questions surrounding the adequacy and choice of the Potts-Guy model. Dr. MacIntosh may not be permitted to "hide behind" the allegedly reliable Potts-Guy model and be relieved from having to defend its applicability. Therefore, we find

<sup>&</sup>lt;sup>53</sup> Dura Auto. Sys. of Ind., Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002).

<sup>&</sup>quot;[W]hen chemical specific data are unavailable...[t]his method should be used in the absence of actual field data." *Standard Operating Procedures for Residential Exposure Assessments*, EPA Scientific Advisory Panel (SAP) September 1997 Meeting. "The uncertainties associated with this assessment stem from the use of an assumed permeability coefficient." *Id*.

<sup>&</sup>lt;sup>55</sup> *Dura Auto...* 285 F.3d at 614.

Id. ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science. A theoretical economist, however able, would not be allowed to testify to the findings of an

that the trial judge reasonably concluded that Dr. MacIntosh is not qualified to offer an opinion concerning dermal absorption.

We also conclude the trial judge did not abuse his discretion by finding that Dr. MacIntosh's methodology was unreliable. Dr. MacIntosh's exclusive reliance on the Potts-Guy model and his ignorance of existing studies measuring human dermal absorption of Benlate is disconcerting.<sup>57</sup> Despite the EPA guidelines' recommendation that the Potts-Guy model only be used when there are no comparable human studies, Dr. MacIntosh failed to inquire about any existing studies<sup>58</sup> before reaching his conclusion.<sup>59</sup> Even more troubling is the failure of plaintiffs' counsel's to provide Dr. MacIntosh with actual existing studies known

econometric study conducted by another economist if he lacked expertise in econometrics and the study raised questions that only an econometrician could answer. If it were apparent that the study was not cut and dried, the author would have to testify; he could not hide behind the theoretician.").

See Hamilton County Emergency Communs. Dist. v. Orbacom Communs. Integrator Corp., 2005 U.S. Dist. LEXIS 21639, 17 (D. Tenn. 2005) (finding it significant that an expert "relied exclusively upon information and interpretations provided by [the party that hired him as an expert]" and conducted nothing more than "the most cursory of investigations into the reliability of many of the sources upon which he relied for benchmark data.").

See In re Rezulin Prods. Liab. Litig., 2004 U.S. Dist. LEXIS 3104 (D.N.Y. 2004) (holding "the dispositive fact" to be that the expert ignored "directly relevant scientific data in violation of [recognized] standards.").

See Claar v. Burlington N. R.R., 29 F.3d 499, 502-03 (9th Cir. 1994) ("In order to qualify as scientific knowledge, an inference must be derived by the scientific method. Coming to a firm conclusion first and then doing research to support it is the antithesis of this method.") (internal citations omitted).

to them, especially the "TNO Study"<sup>60</sup> which plaintiffs' counsel themselves commissioned for the Benlate related litigation of *Bourne v. Dupont*.<sup>61</sup> Given the limitations in the EPA guidelines for using the Potts-Guy model, Dr. MacIntosh's failure to consider the existing human dermal absorption studies was clearly a failure to employ "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."<sup>62</sup>

The appellants contend that, even if "better" studies exist for calculating the dermal absorption rate of Benlate, the Potts-Guy model is, nonetheless, a peer-reviewed, published, and widely accepted methodology. The issue, however, is not whether the Potts-Guy model is ever a reliable tool. Rather, the issue is the methodology that underlies how to determine to rely exclusively upon the Potts-Guy model and to ignore or discard "more favorable" methodologies. Conceivably a scenario will arise where a qualified dermal absorption expert, *after considering* 

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).

<sup>&</sup>lt;sup>61</sup> 189 F. Supp. 2d 482 (D. W. Va. 2002), *aff'd* 85 Fed. Appx. 964, 2004 WL 117634 (4th Cir. W. Va. 2004).

<sup>62</sup> Kumho, 526 U.S. at 152.

<sup>63</sup> Cf. United States v. DICO, Inc., 266 F.3d 864, 870 (8th Cir. 2001) (finding an expert's use of a model "passes scrutiny under Daubert" because the model "is sanctioned by the EPA and is considered a standard model that is acceptable and commonly used by [experts in the relevant field]." (emphasis added)). Utilizing the Potts-Guy model without first considering available human studies is neither standard nor common.

comparable human studies as recommended by the EPA guidelines, will employ the Potts-Guy model. In such a scenario, the appellants would be correct in arguing that any potential flaws of experts choice of the Potts-Guy model would affect the weight given to it by the jury and not its admissibility.

But that scenario did not occur in this case. Dr. MacIntosh's failure to follow the recognized EPA guidelines for using the Potts-Guy model, due to his own ignorance of the existing human studies and the complicity of the plaintiffs' counsel, directly undermines the reliability of his methodology.

D.R.E. 702 requires that a proffered expert opinion be "the product of reliable principles and methods" reliably applied to the facts of each case. Here, the record supports the trial judge's conclusion that Dr. MacIntosh was not qualified to give a dermal absorption opinion and that the opinion he did proffer was not the product of a reliable methodology. For those reasons, we conclude that the trial judge did not abuse his discretion when he excluded Dr. MacIntosh's opinion. Because Dr. MacIntosh's opinion is critical to establishing Dr. Howard's contentions that Benlate specifically caused the children's birth defects, we need not reach or address the issue of Dr. Howard's qualifications or methodology. <sup>64</sup>

We decline to address the appellant's argument that the trial judge abused his discretion by excluding evidence about governmental studies and warnings. The appellants specifically "request[ed] the Court, *if it reverses the Superior Court's orders and Judgment*, to address this issue, in order to avoid the necessity of a retrial." Opening Br. pg 32. Because we are not reversing the Superior Court's order, we decline to address this issue.

# **CONCLUSION**

For the foregoing reasons, the judgment of the Superior Court is affirmed.