



Thus, Medifast has simultaneously filed a motion for summary judgment.

We conclude that the endocrinologist, although qualified, cannot support his opinion with reliable medical or scientific evidence and that the nutritionist is not qualified to render a medical diagnosis and a medical causation opinion. We do not reach a third expert's opinion regarding the necessity of the adequacy of warnings because there is no reliable evidence of causation. Therefore, we shall grant both Medifast's motion to exclude the testimony of Ms. Loverdi's proffered witnesses and its motion for summary judgment.

### **Factual Background**

Angela Loverdi is a 58 year-old female with a family history of thyroid disease.<sup>2</sup> In an effort to lose weight, she began a Medifast diet plan in March of 2016.<sup>3</sup> The dietary program included Medifast calorie-restricted, meal substitution products.<sup>4</sup> According to the delivery frequency, Ms. Loverdi consumed no more than two to three Medifast products daily.<sup>5</sup> She continued to consume the diet products through late August 2016.<sup>6</sup>

In June of 2016, Ms. Loverdi began to experience "significant . . . thyroid and abdominal issues and injuries," such as stomach cramps, diarrhea, constipation, heart burn, malnutrition, lethargy, irritability, insomnia, decreased concentration, anemia,

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<sup>2</sup> Defs.' Statement of Undisputed Facts in Support of Defs.' Mot. for Summ. J. ¶ 3 (ECF No. 19-3) ("DSUF").

<sup>3</sup> Am. Compl. ¶ 13; DSUF ¶ 4.

<sup>4</sup> Am. Compl. ¶ 13; DSUF ¶ 4.

<sup>5</sup> Am. Compl. ¶ 14; DSUF ¶ 6; Williams Dep. 97:17-98:1 (ECF No. 18-5).

<sup>6</sup> Am. Compl. ¶ 14.

lightheadedness, and thyroid issues.<sup>7</sup> In August of 2016, she sought medical treatment from a general practitioner and an endocrinologist.<sup>8</sup> Six months later, in January of 2017, Ms. Loverdi had her first thyroid test, revealing marked hypothyroidism and high thyroid antibody titers, “consistent with a diagnosis of Hashimoto’s or autoimmune thyroid disease.”<sup>9</sup> Ms. Loverdi’s endocrinologist subsequently diagnosed her with Hashimoto’s disease, the most common cause of hypothyroidism.<sup>10</sup> After taking thyroid medication, her thyroid function gradually returned to normal.<sup>11</sup>

Believing that her thyroid condition was linked to her ingestion of the Medifast product, Ms. Loverdi and her husband, Charles, filed this action. Angela Loverdi asserts claims for negligence, products liability under §402(A) of the Restatement (Second) of Torts, breach of express and implied warranty, and misrepresentation. Charles Loverdi brings a loss of consortium claim. Ms. Loverdi contends that the soy protein ingredient in Medifast’s meal plan caused her to develop hypothyroidism and her injuries were the result of Medifast’s unsafe dietary products that defendants knowingly placed into the stream of commerce.<sup>12</sup> She also alleges that Medifast failed to give proper warnings and/or disclose the risk of injury, and made misleading and false representations that its products are nutritious, healthy, and good for weight loss.<sup>13</sup>

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<sup>7</sup> *Id.* ¶¶ 12-16, 19-24.

<sup>8</sup> A. Loverdi Dep. 29:10-17 (ECF No. 18-3).

<sup>9</sup> *Id.* 188:9-11; DSUF ¶ 11; Williams Dep. 35:10-36:5; Williams Report at 4 (ECF No. 18-4).

<sup>10</sup> A. Loverdi Dep. 188:9-11; DSUF ¶ 11; Williams Dep. 35:10-36:5; Williams Report at 4.

<sup>11</sup> Williams Report at 3.

<sup>12</sup> Am. Compl. ¶¶ 7-11.

<sup>13</sup> *Id.* ¶¶ 11-12, 27-28.

To prove her case, Ms. Loverdi retained Dr. Jonathan Williams and Dr. Kaayla Daniel as expert witnesses to opine that her ingesting the Medifast products caused or contributed to her thyroid disease. She relies on them and Dr. Richard George to establish that Medifast failed to warn its consumers of the soy-based dangers of its products. Medifast challenges each of these witnesses.

### **Analysis**

As “gatekeeper,” the trial judge must ensure that expert testimony is relevant and reliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). *Daubert* and its progeny have established a three-prong test for the admissibility of scientific expert testimony. The proponent of the testimony must demonstrate: (1) the expert’s qualifications; (2) the reliability of the proffered testimony; and (3) the fitness of the testimony, that is, the connection between the opinions and the issues in the case. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-743 (3d Cir. 1994); *see also In re Zolofit (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017).

*Jonathan Williams, M.D., M.MSc.*

Dr. Jonathan Williams opined that Ms. Loverdi’s development of autoimmune-related hypothyroidism, coupled with her pre-existing risk factors, “fit[]” with the onset of her consumption of the soy protein-based Medifast products.<sup>14</sup> He stated that Ms. Loverdi’s consumption of the Medifast products increased her risk of developing overt

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<sup>14</sup> Williams Report at 4.

hypothyroidism.<sup>15</sup> He also opined that Medifast’s products and websites were not accompanied by the proper soy-related warnings, cautions, and instructions.<sup>16</sup>

In his expert report, Dr. Williams explained that “[a]utoimmune thyroid disease is a condition wherein the body generates blocking or overstimulating antibodies affecting thyroid gland function.”<sup>17</sup> Grave’s disease is typically a condition of over-stimulation of thyroid hormone production resulting in “hyperthyroidism.”<sup>18</sup> Hashimoto’s disease typically blocks antibodies and prevents the formation of thyroid hormone resulting in the thyroid condition known as “hypothyroidism.”<sup>19</sup> Ms. Loverdi has Hashimoto’s disease, the most common cause of hypothyroidism.<sup>20</sup>

Dr. Williams attributed three factors to Ms. Loverdi’s increased risk of developing hypothyroidism.<sup>21</sup> First, her family history of thyroid disease increased her risk of developing Hashimoto’s.<sup>22</sup> Second, her sex did so because women are more likely than men to develop autoimmune thyroid disease.<sup>23</sup> Third, her age was a factor.<sup>24</sup> Thyroid dysfunction is more likely to occur after 50 years of age.<sup>25</sup>

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<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 4-5.

<sup>17</sup> *Id.* at 3.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> DSUF ¶ 11; Williams Dep. 35:10-36:5; Williams Report at 4.

<sup>21</sup> Williams Report at 3-4.

<sup>22</sup> *Id.* at 3.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

Dr. Williams opined that before starting the Medifast program, Ms. Loverdi “probably had a 25 percent chance, 35 percent chance of developing hypothyroidism because of her genetic predisposition, which is probably three, four, five times the background rate of a female, 50 year-old-Caucasian.”<sup>26</sup> Dr. Williams described the Medifast diet as the “tipping point” combined with the other factors that led to Ms. Loverdi’s hypothyroidism.<sup>27</sup>

Dr. Williams acknowledged that consumption of soy protein is generally safe.<sup>28</sup> But, he explained that the data supporting the safety of soy applies only “in the context of healthy individuals.”<sup>29</sup> He postulated that “[i]t is less certain, whether subsets of individuals who are not healthy, for example those predisposed to develop thyroid conditions such as autoimmune dysfunction, may be at relative increased risk for developing overt hypothyroidism from soy exposure.”<sup>30</sup> Thus, Dr. Williams opined that further study is needed because “[q]uestions remain regarding the susceptibility of non-healthy individuals, such as those with autoimmune tendency as Ms. Loverdi, to develop overt hypothyroidism when exposed to a soy product.”<sup>31</sup>

Dr. Williams is qualified to render an opinion in the field of endocrinology. He is a full-time board-certified endocrinologist at Brigham and Women’s Hospital and the Boston

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<sup>26</sup> *Id.*; Williams Dep. 55:12-16.

<sup>27</sup> Williams Dep. 54:3-6.

<sup>28</sup> Williams Report at 4.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

VA Healthcare System.<sup>32</sup> He is an assistant professor with Harvard Medical School and an adjunct assistant professor at Boston Medical Center.<sup>33</sup> He obtained a Bachelor of Science degree in microbiology with minors in chemistry and Spanish at Brigham Young University, a Doctor of Medicine from Hahnemann University, and a Master of Science from Harvard Medical School.<sup>34</sup> He received postdoctoral training at Brigham and Women's Hospital / Harvard Medical School.<sup>35</sup> Dr. Williams is the Lead Medical Research Officer for the Center for Clinical Investigations at Brigham and Women's Hospital.<sup>36</sup>

Medifast does not, nor could it, challenge Dr. Williams' qualifications as an expert endocrinologist. Medifast attacks his opinions as unreliable.<sup>37</sup> It argues that his opinion that soy causes hypothyroidism has not been properly tested or validated and has not been submitted to peer review.<sup>38</sup> According to Medifast, his opinion runs against the overwhelming weight of the scientific evidence that demonstrates that there is no causal link between soy protein and hypothyroidism.<sup>39</sup> It emphasizes that there is currently no

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<sup>32</sup> Williams Report at 2; Williams Dep. 10:3-12.

<sup>33</sup> Williams Report at 2; Williams Dep. 10:3-12.

<sup>34</sup> Williams Report at 2.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> Defs.' Mot. to Exclude Expert Witnesses at 6 (ECF No. 18-2) ("Mot.").

<sup>38</sup> Mot. at 7; Williams Dep. 48:1-20, 81:11-14.

<sup>39</sup> Mot. at 7 (citing 2015 European Food Safety Authority publication reviewing eleven published studies examining soy's potential effect on the thyroid involving 925 patients taking soy protein supplements and 576 serving as controls and concluding that the administration of the soy "is not associated with clinically relevant changes in thyroid function" (ECF No. 18-8)).

authoritative body which recognizes soy as a risk factor or a cause of hypothyroidism.<sup>40</sup> Indeed, the FDA identifies soy protein as one that is “generally recognized as safe.”<sup>41</sup>

Dr. Williams couched his opinion in qualified terms. He candidly admitted that there are no tests or studies that show that soy contributes to hypothyroidism in those predisposed to the condition, which he characterized as “unhealthy individuals.” He conceded that “[q]uestions remain regarding the susceptibility of non-healthy individuals, such as those with autoimmune tendency as Ms. Loverdi, to develop overt hypothyroidism when exposed to a soy product.”<sup>42</sup> The basis for his opinion is that it is “not [ ] unproven” that consumption of soy by one predisposed with hypothyroidism is at risk of developing the condition.<sup>43</sup> Remarkably, he did not opine or suggest that it has been proven.

Although Dr. Williams conceded that there has been no specific study involving “at risk” individuals such as Ms. Loverdi, he reiterated that research on soy and hypothyroidism with this population still “needs further study.”<sup>44</sup> In essence, by his own admission, Dr. Williams has no scientific or medical evidence to support his opinion. Because it has not been “unproven” does not mean it has been proven. On the contrary, there are no studies that establish a link between soy and hypothyroidism.

Dr. Williams’ testimony does nothing more than impermissively shift the burden of proof from the plaintiff to the defendant. He suggests that Medifast must prove the

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<sup>40</sup> Mot. at 7 (citing [www.thyroid.org](http://www.thyroid.org) and [www.mayoclinic.org](http://www.mayoclinic.org)).

<sup>41</sup> *Id.* (citing 21 C.F.R. §§ 182, 101.82).

<sup>42</sup> Williams Rep. at 4.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*; Williams Dep. 48:1-20, 76:1-11.



negative—that soy does not increase the risk of hypothyroidism for one predisposed to the condition when he himself cannot prove that it does.

In his deposition, Dr. Williams could point to only one study he claimed supports a possible link between soy and hypothyroidism.<sup>45</sup> The study did not include patients with a genetic predisposition for hypothyroidism and instead examined individuals who had “subclinical hypothyroidism,” those who displayed elevated thyroid levels which had not risen to overt hypothyroidism.<sup>46</sup> Dr. Williams did not know whether Ms. Loverdi had subclinical hypothyroidism before beginning the Medifast products.<sup>47</sup> Consequently, he could not say if Ms. Loverdi was a cohort in the study.

Dr. Williams acknowledged that Ms. Loverdi would have had to consume the minimum amount of soy protein that the subjects in the study consumed to develop overt hypothyroidism. Yet, he did not know how much she had actually consumed and conceded it likely did not reach triggering levels. Significantly, Dr. Williams also conceded that the authors of the study were unable to replicate the results in a repeat study of patients with subclinical hypothyroidism, ultimately concluding that soy consumption “was

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<sup>45</sup> Williams Dep. 94:5-15 (citing Thozhukat Sathyapalan et al., *The Effects of Soy Phytoestrogen Supplementation on Thyroid Status and Cardiovascular Risk Markers in Patients with Subclinical Hypothyroidism: A Randomized, Double-Blind, Crossover Study*, Volume 96, *The Journal of Clinical Endocrinology & Metabolism*, 1442-49 (2011) (ECF No. 18-12) (“Sathyapalan 2011 Study”).

<sup>46</sup> See Sathyapalan 2011 Study at 1443.

<sup>47</sup> Ms. Loverdi’s thyroid levels were first tested in January of 2017. See A. Loverdi Dep. 188:9-11; Williams Report at 4.

not associated with either deterioration of thyroid function or an increased rate of thyroid failure . . . .”<sup>48</sup>

The reliability requirement ensures that the expert’s opinion is supported by appropriate validation which establishes the standard of evidentiary reliability. *Daubert*, 509 U.S. at 590. The process or technique used by the expert must be “based on the methods and procedures of science.” *In re Paoli R.R. Yard*, 35 F.3d at 741-743. The proffered evidence must be based on “good grounds,” and the testimony must be more than “subjective belief or unsupported speculation.” *Id.* at 747.

Dr. Williams’ testimony linking Ms. Loverdi’s hypothyroidism to her ingestion of Medifast products is not based on reliable medical and scientific evidence. It is unsupported speculation. He cannot point to any reliable data that supports a causal link between soy-based foods and hypothyroidism. In fact, he acknowledges that such a connection has not been proven and further study is needed. Thus, Dr. Williams’ unsupported opinion that Medifast products caused or increased the risk of Ms. Loverdi’s hypothyroidism is unreliable.

*Kaayla Daniel, Ph.D.*

Dr. Kaayla Daniel opined that due to Ms. Loverdi’s health issues, she was at a “tipping point” where soy “pushed her over the edge” to develop thyroid disease.<sup>49</sup> She also opined that given the soy ingredients in its products and the alleged potential dangers, Medifast failed to properly warn users about the effects of soy in its products on

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<sup>48</sup> See Williams Dep. 109:11-113:7; Thozhukat Sathyapalan et al., *The Effect of Phytoestrogen on Thyroid in Subclinical Hypothyroidism: Randomized, Double Blind, Crossover Study*, Volume 8, *Frontiers in Endocrinology*, 1-6 (2018) (ECF No. 18-13).

<sup>49</sup> Pls.’ Opp’n to Mot. at 25 (ECF No. 21) (“Opp’n”); Daniel Dep. 33:21-34:1, 36:21-23 (ECF No. 18-10).

the thyroid and the need to consult physicians prior to starting Medifast's programs.<sup>50</sup> She opined that Medifast's failure to properly warn or caution users contributed to Ms. Loverdi's thyroid injuries.<sup>51</sup>

#### Qualifications

Dr. Kaayla Daniel is a nutritionist. She has a Bachelor of Arts degree in foreign literature and a Master of Science degree in the humanities from the University of Rochester.<sup>52</sup> She received a Doctor of Philosophy degree from the Union Institute and University in interdisciplinary arts and sciences with a concentration in nutritional sciences and anti-aging therapies in 2004.<sup>53</sup> She provides nutrition counseling to approximately 20 to 30 patients per year.<sup>54</sup> Dr. Daniel has also taught at Hawthorn University, Optimal Performance Institute, and Santa Fe Community College.<sup>55</sup> In 2005, Dr. Daniel authored the book *The Whole Soy Story: The Dark Side of America's Favorite Health Food*.<sup>56</sup>

As a threshold matter, Medifast contends that Dr. Daniel is not qualified to opine on medical causation or give testimony regarding appropriate labeling of food products.<sup>57</sup> Ms. Loverdi responds that Dr. Daniel is qualified because she is a nutritionist who works

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<sup>50</sup> Daniel Report at 8 (ECF No. 18-14).

<sup>51</sup> *Id.* at 8.

<sup>52</sup> *Id.* at 9-10.

<sup>53</sup> *Id.*

<sup>54</sup> Daniel Dep. 15:15-21, 21:18-23, 25:19-20.

<sup>55</sup> Daniel Report at 13.

<sup>56</sup> *Id.* at 10.

<sup>57</sup> Mot. at 24-25.

with individuals who have suffered adverse effects as a result of consuming soy.<sup>58</sup> Ms. Loverdi also contends that Dr. Daniel is qualified because she authored a book about soy and human consumption.<sup>59</sup>

Although Dr. Daniel stated that her book itself cites “numerous studies which indicate that soy may not be healthy for certain individuals in the population,” Ms. Loverdi concedes that Dr. Daniel did not cite these in her expert report.<sup>60</sup> Ms. Loverdi argues that because they are referenced in the book itself, Dr. Daniel has satisfactorily cited reliable bases for her opinions.<sup>61</sup>

Dr. Daniel is not qualified to offer a medical opinion. She is not a medical doctor and is not qualified to make medical diagnoses.<sup>62</sup> She has no expertise in epidemiology.<sup>63</sup> Dr. Daniel acknowledged that she defers to an endocrinologist regarding diagnosis and treatment of hypothyroidism.<sup>64</sup> She admitted she does not have experience reviewing product labels or websites to assess accuracy or compliance with regulations.<sup>65</sup> She has no expertise in determining an appropriate food product warning label.<sup>66</sup> In this case, she

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<sup>58</sup> Opp’n at 24.

<sup>59</sup> *Id.* at 26.

<sup>60</sup> *Id.* at 26-27.

<sup>61</sup> *Id.*

<sup>62</sup> Daniel Dep. 25:21-26:6, 28:1-6.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* 26:7-22.

<sup>65</sup> *Id.* 96:16-30.

<sup>66</sup> *Id.* 96:21-97:1.

is not qualified to opine on the cause or contributing factors of Ms. Loverdi's hypothyroid condition. Nor is she qualified to render an opinion regarding the efficacy of warnings.

#### Reliability

Not only is Dr. Daniel unqualified, her methodology in reaching her opinions is unreliable. She admitted that substantial evidence shows that soy protein is generally regarded as safe for healthy individuals.<sup>67</sup> Dr. Daniel echoed Dr. Williams that it has not been proven that soy is not safe for unhealthy individuals.<sup>68</sup> Although Dr. Daniel conceded that research shows no causal link between soy and hypothyroidism, Ms. Loverdi argues these studies have been conducted only on healthy individuals.<sup>69</sup> So, she contends that they do not apply to her because she was not healthy due to her family history, age, and post-menopausal state.<sup>70</sup>

Dr. Daniel testified that she can cite to "massive research for many years," including "70 years of studies having to do with the dangers of soy to the thyroid."<sup>71</sup> Upon further questioning, she was unable to name a single study other than the one cited in her expert report.<sup>72</sup> She conceded this was the only citation in her report, but argued that

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<sup>67</sup> Daniel Dep. 38:3-5.

<sup>68</sup> Daniel Dep. 26:7-22.

<sup>69</sup> Daniel Dep. 38:2-5, 59:9-15, 66:16-19.

<sup>70</sup> Opp'n at 27.

<sup>71</sup> Daniel Dep. 47:22-24, 49:1-9, 70:16-17.

<sup>72</sup> *Id.* (citing Yoshimochi Ishizuki et al., *The Effects on the Thyroid Gland of Soybeans Administered Experimentally in Healthy Subjects*, Volume 65, Nippon Naibunpi Gakkai Kashi (1991) (ECF No. 18-15)). The authors of this study did not find a causal link between soy protein and hypothyroidism in populations similar to Ms. Loverdi's. Instead, "the findings suggested that excessive soybean ingestion for a certain duration might suppress thyroid function and cause goiters in healthy people, especially elderly subjects." Ishizuki Study at 1.

she had “a whole book, 450 pages where [she] cited a thousand studies” upon which she relied in 2005 when she wrote her book.<sup>73</sup>

We conclude that Dr. Daniel is not qualified to offer opinions as to causation and appropriate warnings. Additionally, she has not proffered a reliable methodology to support her causation opinions. Instead, she parrots Dr. Williams’ opinions. Hence, her testimony is precluded as unreliable for the same reasons Dr. Williams’ is. See *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000); *Elcock v. Kmart Corp.*, 232 F.3d 734 (3d Cir. 2000).

*Richard George, Ph.D.*

Medifast also challenges Dr. Richard George, who has opined that Medifast’s website and packaging failed to contain adequate soy-related warnings and that Medifast’s website was deceptive and misleading to consumers such as Ms. Loverdi.<sup>74</sup>

In his deposition, Dr. George testified that he did not have “any expertise one way or the other as to whether or not soy protein in Medifast products causes hypothyroidism.”<sup>75</sup> Instead, he testified that his “basis for the proposed warning telling people that soy may cause serious health issues, including injury to [one’s] thyroid” was based on “the testimony of the deposition of Mrs. Loverdi and the expert work of Dr. Williams.”<sup>76</sup> Dr. George did no research on this medical causation issue.<sup>77</sup>

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<sup>73</sup> Daniel Dep. 53:3-54:1, 73:24-74:5.

<sup>74</sup> George Report at 11-13 (ECF No. 18-18).

<sup>75</sup> George Dep. 65:15-18 (ECF No. 18-17).

<sup>76</sup> *Id.* 66:4-19.

<sup>77</sup> *Id.*

Dr. George's testimony regarding warnings is relevant only if Medifast's soy-based product was defective and dangerous. Without expert opinion that soy is linked to hypothyroidism, there is no predicate for the need for warnings. Hence, we need not address the admissibility of Dr. George's testimony.

### **Conclusion**

Dr. Jonathan Williams and Dr. Kaayla Daniel's opinions are unreliable. Also, Dr. Daniel is unqualified to render an expert causation opinion. Dr. Richard George's opinions on the necessity and the adequacy of warnings relies on the unreliable opinions of Dr. Williams. Therefore, we shall grant Medifast's motion to exclude plaintiffs' experts.

Medifast has moved for summary judgment, contending that Ms. Loverdi cannot prove her claims without expert testimony. Ms. Loverdi agrees. Now that we have precluded expert opinion that the Medifast soy-based products caused or increased the risk of harm to her, Ms. Loverdi cannot prove her case. Therefore, we shall grant judgment in favor of Medifast. *See Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 165 (3d Cir. 1999) (holding that lack of causation evidence absent expert testimony is a proper ground for summary judgment).