

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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**ELIZABETH OHUCHE,**

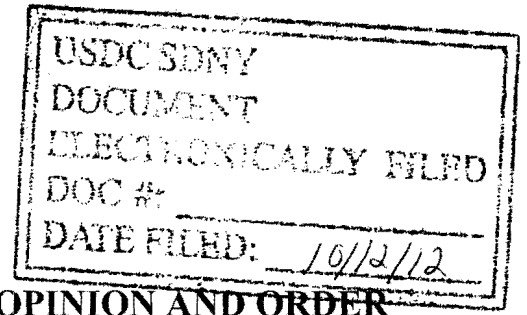
**Plaintiff,**

**- against -**

**MERCK & COMPANY, INC.,**

**Defendant.**  
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**SHIRA A. SCHEINDLIN, U.S.D.J.:**



**OPINION AND ORDER**

**11 Civ. 2385 (SAS)**

Pro se plaintiff Elizabeth Ohuche (“Ohuche” or “plaintiff”) brings this action against Merck Sharp & Dohme Corp. (formerly known as Merck & Co., Inc.) (“Merck” or “defendant”), alleging injuries sustained after being injected with ZOSTAVAX®. ZOSTAVAX® is a live attenuated virus vaccine manufactured by Merck and approved by the Food and Drug Administration (“FDA”) to help prevent shingles (herpes zoster).<sup>1</sup> Merck now moves for summary judgment seeking to dismiss plaintiff’s Complaint in its entirety. For the following reasons,

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<sup>1</sup> Shingles is a viral infection which often causes a painful rash that turns into clusters of blisters. Shingles occurs when a previously dormant chickenpox virus is reactivated in a person’s body. Shingles is most common in older adults and people who have weakened immune systems. There is no cure for shingles. See WebMD, <http://www.webmd.com/skin-problems-and-treatments/shingles/shingles-topic-overview>.

defendant's motion is granted.

## **I. BACKGROUND**

### **A. Plaintiff's Allegations**

Plaintiff alleges that her former primary care physician, Dr. Ina Itzkovitz, injected her against her will with ZOSTAVAX® on March 12, 2009.<sup>2</sup> A few days later, plaintiff “developed severe headache, fever and high temperature.”<sup>3</sup> Plaintiff’s “condition escalated daily with excruciating pains followed by mumps, boils and eruptions all over her face.”<sup>4</sup> Plaintiff’s condition was “accompanied with wicked clustered and painful rashes which are very difficult to treat.”<sup>5</sup> The eruptions on plaintiff’s skin came and went “with more pains, headaches, fever, tingling and discomfort.”<sup>6</sup> Plaintiff’s eyesight was also affected as she “lost partial sight at her right eye when the eruption occurred at her eyelid.”<sup>7</sup> Plaintiff claims that ZOSTAVAX® caused all of these adverse reactions.<sup>8</sup> Plaintiff further claims

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<sup>2</sup> See Complaint ¶¶ 2-4.

<sup>3</sup> *Id.* ¶ 5.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> See *id.* ¶¶ 6-7.

that her condition has gotten worse over the past two years and that she is “very ill and confined in bed.”<sup>9</sup> Plaintiff demands that Merck provide “a cure for her condition” and “compensate her for pains and suffering.”<sup>10</sup>

**B. ZOSTAVAX® Literature<sup>11</sup>**

In January 2009, Dr. Itzkovitz, who is board-certified in internal medicine, ordered the ZOSTAVAX® vaccine for plaintiff.<sup>12</sup> Ohuche received the ZOSTAVAX® vaccine approximately two months later, on March 12, 2009, pursuant to Dr. Itzkovitz’s recommendation.<sup>13</sup> The FDA-approved labeling accompanying ZOSTAVAX® provides information to healthcare providers about the vaccine’s efficacy and safety.<sup>14</sup> Information about the possible side effects of the ZOSTAVAX® vaccine appeared in the March 2009 FDA-approved labeling

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<sup>9</sup> *Id.* ¶ 13.

<sup>10</sup> *Id.* ¶ 16.

<sup>11</sup> The facts in this section are taken from defendant’s Statement of Material Facts Pursuant to Local Civil Rule 56.1 and in Support of Merck Sharp & Dohme Corp.’s Motion for Summary Judgment (“Def. 56.1”). Because plaintiff did not controvert any of the separately numbered paragraphs in Def. 56.1, they are deemed admitted for purposes of this motion. *See* Local Civil Rule 56.1(c).

<sup>12</sup> *See* Def. 56.1 ¶¶ 12-13.

<sup>13</sup> *See id.* ¶ 14.

<sup>14</sup> *See id.* ¶ 10.

and in the 2009 edition of the Physician's Desk Reference ("PDR").<sup>15</sup>

The FDA-approved labeling consists of a Product Circular<sup>16</sup> and a Patient Product Information Pamphlet.<sup>17</sup> The Product Circular for ZOSTAVAX® states that "[t]ransmission of vaccine virus may occur rarely between vaccinees and susceptible contacts."<sup>18</sup> The Product Circular lists the following adverse events associated with the ZOSTAVAX® vaccine: erythema, pain/tenderness, swelling, hematoma, pruritus, warmth and headache.<sup>19</sup> The Product Circular also states that "[w]ithin the 42-day post vaccination reporting period in the SPS, non-

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<sup>15</sup> See *id.* ¶ 27.

<sup>16</sup> See Exs. G & H to the 7/6/12 Declaration of David S. Gray, defendant's attorney ("Gray Decl."). Exhibit G is the Product Circular distributed on March 1, 2009, while Exhibit H is the Product Circular immediately preceding the March 1, 2009 Version. The two exhibits appear to be virtually identical. For the sake of convenience, future references will be to Exhibit G which, unless otherwise noted, contains the same language as Exhibit H.

<sup>17</sup> See *id.* Exs. I & J. Exhibit I is the Patient Product Information Pamphlet distributed on March 1, 2009, while Exhibit J is the Patient Product Information Pamphlet immediately preceding the March 1, 2009 Version. The two exhibits appear to be virtually identical. Thus, for the sake of convenience, further references will be to Exhibit I which, unless otherwise noted, contains the same language as Exhibit J.

<sup>18</sup> Ex. G § 5.1

<sup>19</sup> See *id.* § 6.1.1, Table 2, Injection-Site and Systemic Adverse Experiences Reported by Vaccine Report Card in  $\geq 1\%$  of Adults Who Received ZOSTAVAX or Placebo (0-42 Days Postvaccination) in the AE [Adverse Events] Substudy of the Shingles Prevention Study ("SPS").

injection-site zoster-like rashes were reported by 53 subjects (17 for ZOSTAVAX and 36 for placebo).”<sup>20</sup> The Product Circular lists the following additional adverse reactions identified during post-marketing use of ZOSTAVAX: pyrexia (fever), hypersensitivity reactions and rash.<sup>21</sup> The Patient Product Information Pamphlet lists the following side effects of ZOSTAVAX: redness, pain, itching, swelling, allergic reactions, fever and rash.<sup>22</sup> Substantially similar information is available from the 2009 PDR.<sup>23</sup>

Dr. Itzkovitz had not reviewed the Product Circular or the Patient Product Information Pamphlet for ZOSTAVAX® prior to vaccinating Ohuche.<sup>24</sup> Nor had Dr. Itzkovitz reviewed the section on ZOSTAVAX® contained in the 2009 edition of the PDR.<sup>25</sup> However, at the time Ohuche received the vaccine, Dr. Itzkovitz was aware of the nature of the vaccine and its possible side effects despite

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<sup>20</sup> *Id.* § 6.1.2. “In clinical trials in support of the initial licensure of the frozen formulation of ZOSTAVAX, . . . [t]he Oka/Merck strain was identified by PCR [Polymerase Chain Reaction] analysis from the lesion specimens of two subjects who reported varicella-like rashes (onset on Day 8 and 17).” *Id.*

<sup>21</sup> *See id.* § 6.2.

<sup>22</sup> *See* Ex. I at 2 (“What are the possible side effects of ZOSTAVAX?”).

<sup>23</sup> *See, e.g., id.* Ex. K, Excerpt From the 2009 PDR §§ 5.1, 6.1.1 and 17.2.

<sup>24</sup> *See* Def. 56.1 ¶ 23.

<sup>25</sup> *See id.* ¶ 24.

not having reviewed the FDA-approved labeling, the 2009 PDR excerpt on ZOSTAVAX®, or any publications about ZOSTAVAX® from the FDA, Centers for Disease Control, or the New England Journal of Medicine.<sup>26</sup>

At her deposition, Dr. Itzkovitz testified that she knew about the efficacy of ZOSTAVAX® because it had been discussed in board review courses that she previously attended.<sup>27</sup> Dr. Itzkovitz could not recall what she told Ohuche about the efficacy of ZOSTAVAX® before Ohuche was given the vaccine.<sup>28</sup> Dr. Itzkovitz did mention a two-page Handout that was given to patients who requested more information about the vaccine.<sup>29</sup> The Handout, entitled “Shingles Vaccine What You Need To Know,” contains the following language:

#### **4 What are the risks from shingles vaccine?**

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

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<sup>26</sup> *See id.* ¶ 25.

<sup>27</sup> *See* 5/30/12 Deposition of Dr. Ina Itzkovitz, Ex. E to the Gray Decl. (“Itzkovitz Dep.”), at 43.

<sup>28</sup> *See id.*

<sup>29</sup> *See id.* The Handout was obtained after the instant motion was fully briefed at the request of the Court.

No serious problems have been identified with shingles vaccine.

### **Mild Problems**

- Redness, soreness, swelling or itching at the site of the injection (about 1 person in 3).
- Headache (about 1 person in 70).

Like all vaccines, shingles vaccine is being closely monitored for unusual or severe problems.

Dr. Itzkovitz could not recall if Ohuche was given a copy of the Handout before she received the vaccine.<sup>30</sup> Dr. Itzkovitz did recall that she generally told patients that ZOSTAVAX® was “very safe.”<sup>31</sup>

### **C. Plaintiff’s Medical Records**

Several medical records for Ohuche include notations inconsistent with her allegation that she developed shingles-like symptoms shortly after receiving the ZOSTAVAX® vaccine. For example, notes from a consultation with Dr. Robert Simon, dated March 24, 2009, state that Ohuche is “Negative for rash.”<sup>32</sup> The medical records for another consultation on June 19, 2009, by Dr.

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<sup>30</sup> *See id.* at 45.

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

<sup>32</sup> Def. 56.1 ¶ 33 and Ex. L to the Gray Decl. at ITZKOV 000084.

Joseph Voll, indicate that Ohuche was “Negative for pruritus and rash.”<sup>33</sup> When Ohuche visited St. Luke’s Hospital on August 11, 2009, Dr. Kamal Medlej noted that she was “Negative for rash and pruritis.”<sup>34</sup>

It is not until November 12, 2010, that Ohuche’s medical records begin to document a rash.<sup>35</sup> During an office visit that day, Dr. Itzkovitz reported that the reason for Ohuche’s visit was “Rash around mouth. Itchy and dry. Going on for months. Just using face cream.”<sup>36</sup> In another office visit on March 11, 2011, Dr. Itzkovitz indicated that Ohuche “[h]ad bad facial rash and though[t] it was due to zostavax but unlikely since zostavax was given on 3/09.”<sup>37</sup> Dr. Itzkovitz further remarked that Ohuche had perioral dermatitis; “says had extensive blistering on face including lids but didn’t come in. Better now. Has appt with dermatologist. Feels it is related to zostavax but that was given 3/09. Has had it 5x over past 1-2 yrs.”<sup>38</sup> Finally, in Progress Notes dated November 30, 2011, Dr. Harrison F. Mitchell noted the following:

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<sup>33</sup> *Id.* and Ex. L at ITZKOV 00080.

<sup>34</sup> *Id.* ¶ 34 and Ex. M to the Gray Decl. at 1.

<sup>35</sup> *See* Def. 56.1 ¶ 32.

<sup>36</sup> Ex. L to the Gray Decl. at ITZKOV 000071.

<sup>37</sup> *Id.* at ITZKOV 000069.

<sup>38</sup> *Id.* at ITZKOV 000073.



Allergies:

SHE IS C/O RASH ON AND OFF SINCE 2009; FEELS IT STARTED AFTER SHE HAD A VACCINE FOR VARICELLA; THIS WAS FOLLOWED 3 DAYS LATER BY RASH, FEVER AND HEADACHES. WAS SEEN BY DERMMATOLOGIST [SIC] AND SEVERAL MD'S WHO FELT RASH NOT DUE TO VACCINE. HAS HAD OUTBREAKS SINCE WHICH APPEARS AS INDIVIDUAL PUSTULES ON FACE AND EXTREMITIES.<sup>39</sup>

Dr. Mitchell also noted that Ohuche had a “FEW MACULES ON CHEEKS” but that the “ETIOLOGY OF THE LESIONS ARE UNCLEAR.”<sup>40</sup>

In Plaintiff’s Opposition to Defendant’s Second Motion to Dismiss Plaintiff’s Case (“Pl. Opp.”), Ohuche has included several photographs of herself which distinctly show some sort of rash on her face.<sup>41</sup> The first such photograph is self-dated as having been taken on March 26, 2009.<sup>42</sup> Additional photographs are dated August 23, 2010, March 23, 2011, May 30, 2011, March 7, 2012, March 31, 2012, and April 16, 2012.<sup>43</sup>

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<sup>39</sup> Ex. N to the Gray Decl. at 1.

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

<sup>41</sup> *See* Pl. Opp. Exs. 1-7.

<sup>42</sup> *See id.* Ex. 1.

<sup>43</sup> Merck claims that it was not provided with an adequate opportunity, during fact discovery, to investigate the circumstances surrounding these photographs. *See* Response to Plaintiff’s Proposed Facts in Her Opposition to Merck Sharp & Dohme Corp.’s “Second Motion to Dismiss Plaintiff’s Case” at 3.

## II. LEGAL STANDARDS

### A. Summary Judgment

Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”<sup>44</sup> ““An issue of fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. A fact is material if it might affect the outcome of the suit under the governing law.”<sup>45</sup> “The moving party bears the burden of establishing the absence of any genuine issue of

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According to Merck,

Ms. Ohuche did not provide copies of those photographs to counsel for Merck until the June 14, 2012 pre-trial conference – after the close of fact discovery. Aside from viewing one image that may have been taken on April 2, 2012 during Ms. Ohuche’s April 20, 2102 deposition, counsel for Merck did not receive information concerning . . . the dates on which those photographs were purportedly taken until the requested information was enclosed as part of Ms. Ohuche’s Opposition.

*Id.* at 4.

<sup>44</sup> Fed. R. Civ. P. 56(a).

<sup>45</sup> *Fincher v. Depository Trust & Clearing Corp.*, 604 F.3d 712, 720 (2d Cir. 2010) (quoting *Roe v. City of Waterbury*, 542 F.3d 31, 35 (2d Cir. 2008)).

material fact.”<sup>46</sup> “When the burden of proof at trial would fall on the nonmoving party, it ordinarily is sufficient for the movant to point to a lack of evidence . . . on an essential element of the nonmovant’s claim.”<sup>47</sup> In turn, to defeat a motion for summary judgment, the non-moving party must raise a genuine issue of material fact. To do so, the non-moving party ““must do more than simply show that there is some metaphysical doubt as to the material facts,””<sup>48</sup> and ““may not rely on conclusory allegations or unsubstantiated speculation.””<sup>49</sup>

In deciding a motion for summary judgment, a court must ““construe the facts in the light most favorable to the non-moving party and must resolve all ambiguities and draw all reasonable inferences against the movant.””<sup>50</sup> However, “[c]redibility determinations, the weighing of the evidence, and the drawing of

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<sup>46</sup> *Zalaski v. City of Bridgeport Police Dep’t*, 613 F.3d 336, 340 (2d Cir. 2010).

<sup>47</sup> *Cordiano v. Metacon Gun Club, Inc.*, 575 F.3d 199, 204 (2d Cir. 2009).

<sup>48</sup> *Brown v. Eli Lilly & Co.*, – F.3d –, 10 Civ. 512, 2011 WL 3625105, at \*10 (2d Cir. Aug. 18, 2011) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)).

<sup>49</sup> *Id.* (quoting *Federal Deposit Ins. Corp. v. Great Am. Ins. Co.*, 607 F.3d 288, 292 (2d Cir. 2010)).

<sup>50</sup> *Brod v. Omya, Inc.*, – F.3d –, No. 09 Civ. 4551, 2011 WL 2750916, at \*7 (2d Cir. July 18, 2011) (quoting *Williams v. R.H. Donnelley, Corp.*, 368 F.3d 123, 126 (2d Cir. 2004)).

legitimate inferences from the facts are jury functions, not those of a judge.”<sup>51</sup>

“The role of the court is not to resolve disputed issues of fact but to assess whether there are any factual issues to be tried.”<sup>52</sup>

## **B. New York’s Product Liability Law**

New York law provides for product liability claims “under theories of negligence, strict liability, or breach of express or implied warranty.”<sup>53</sup> Under New York law, “a plaintiff may allege that a product is defective for any one of the following three reasons: (1) design defect, (2) a failure to warn, or (3) defect as a result of a manufacturing flaw.”<sup>54</sup>

In bringing suit against a drug manufacturer based upon a failure to warn, “a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries.” The plaintiff has the burden of proving that a defect exists and that this defect is the proximate cause of the plaintiff’s injury. A treating physician’s decision not to inform a patient of a side effect acts as an

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<sup>51</sup> *Kaytor v. Electric Boat Corp.*, 609 F.3d 537, 545 (2d Cir. 2010) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)) (emphasis removed).

<sup>52</sup> *Brod*, 2011 WL 2750916, at \*7 (quoting *Wilson v. Northwestern Mut. Ins. Co.*, 625 F.3d 54, 60 (2d Cir. 2010)).

<sup>53</sup> *Lewis v. Abbott Labs.*, No. 08 Civ. 7480, 2009 WL 2231701, at \*4 (S.D.N.Y. July 24, 2009).

<sup>54</sup> *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 82-83 (S.D.N.Y. 2001).

intervening cause which shields the drug manufacturer from any possible liability under a failure to warn theory.<sup>55</sup>

Thus, “a drug manufacturer, like any other manufacturer, can be held liable for a defective product under the theory of strict products liability. Unlike most other products, however, . . . prescription drugs [and vaccines] may cause untoward side effects despite the fact that they have been carefully and properly manufactured. For purposes of strict products liability, these drugs, aptly described as ‘(u)navoidably unsafe products,’ are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects.”<sup>56</sup>

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<sup>55</sup> *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992) (quoting *Glucksman v. Halsey Drug Co., Inc.*, 553 N.Y.S.2d 724, 726 (1st Dep’t 1990) (other citations omitted)). *Accord Plummer v. Lederle Labs. Div. of Am. Cyanamid Co.*, 819 F.2d 349, 356 (2d Cir. 1987) (“Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a ‘learned intermediary’ between manufacturer and consumer.”) (quotation marks and citation omitted).

<sup>56</sup> *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) (quoting *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (1979) (alteration in original)).

### III. DISCUSSION

Because plaintiff's Complaint does not state any particular causes of action, it must be construed to raise the strongest arguments possible.<sup>57</sup> Ohuche's Complaint is thus construed to allege a product liability claim for failure to warn under New York law.<sup>58</sup> A failure to warn claim is consistent with the statements made in plaintiff's opposition papers.<sup>59</sup>

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<sup>57</sup> See *Pabon v. Wright*, 459 F.3d 241, 248 (2d Cir. 2006) (citing *Burgos v. Hopkins*, 14 F.3d 787, 790 (2d Cir. 1994)).

<sup>58</sup> Plaintiff's Complaint is bereft of any allegations that would support a design or manufacturing defect claim. Furthermore, in opposing the instant motion, plaintiff has not offered any evidence to rebut the fact that she is unaware of any design or manufacturing defect in the ZOSTAVAX® vaccine. Compare Def. 56.1 ¶¶ 49-52 with Pl. Opp. at 6 ("Defendants [sic] are saying that Plaintiff has not identified any manufacturing defect in the vaccine that she received or any defect in the design of ZOSTAVAX or a reasonable alternative design for the vaccine. This is ridiculous. If the doctor who ordered the vaccine and the Health Center that carried the vaccine do not know the information, how does one expect the Plaintiff, a lay person in the field of science and medicine[,] to know the answer?").

<sup>59</sup> See Pl. Opp. at 7 ("Had the information been available to Dr. Itkovitz [sic] before she prescribed or ordered the ZOSTAVAX for Plaintiff, Dr. Itkovitz would have advised Plaintiff."). See also *id.* at 15 ("They supplied their product, ZOSTAVAX, . . . to Dr. Ina Itkovitz without any explanation, literature or training regarding ZOSTAVAX. . . . Defendants [sic] failed to give adequate instruction to Dr. Itkovitz so that she could pass such information to her patient (Plaintiff).").

## A. Causation in Fact

Under New York law, direct causation, or causation in fact, is a requisite element in a products liability action regardless of whether a claim is for negligence, breach of warranty, or strict liability.<sup>60</sup> Thus, Ohuche must first establish that Merck's ZOSTAVAX® vaccine was the actual cause of her injuries.<sup>61</sup> Furthermore, "where there are complex medical issues, in order for plaintiff to prove that her alleged injuries were caused by [Merck's vaccine], she must introduce expert medical testimony establishing causation."<sup>62</sup> Expert testimony, however, is not always required to establish direct causation.<sup>63</sup>

Merck argues that Ohuche has failed to present a disputed issue of material fact with regard to direct causation. Defendant cites *Saari v. Merck & Co.*

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<sup>60</sup> See *Saari v. Merck & Co., Inc.*, 961 F. Supp. 387, 392 (N.D.N.Y. 1997).

<sup>61</sup> See *Lindsay*, 637 F.2d at 90–91 ("A plaintiff who seeks recovery for an injurious side effect from a properly manufactured prescription drug must prove that the drug caused her injury . . .").

<sup>62</sup> *Saari*, 961 F. Supp. at 392. Accord *Krasnopolsky*, 799 F. Supp. at 1348 ("Notably, the [plaintiffs] have failed to submit any type of expert proof, in an affidavit or otherwise, which would establish any causation between [plaintiff's] injury and the alleged negligence of [defendant].").

<sup>63</sup> See *Fane v. Zimmer, Inc.*, 927 F.2d 124, 131 (2d Cir. 1991) (stating that the jury could have found direct causation from the characteristics of the product and "plaintiff's description of how the accident happened") (quotation marks and citation omitted).

*Inc.* for the proposition “that courts considering other vaccine cases have repeatedly held that a [mere] temporal association between an alleged injury and a vaccination is insufficient evidence to support a finding of causation in fact.”<sup>64</sup> In this case, however, there is more than mere temporal proximity between the date of Ohuche’s vaccine and the onset of her symptoms. Here, the medical literature regarding ZOSTAVAX®, including the FDA-approved labeling issued by Merck, explicitly states that the vaccine could cause adverse reactions including shingles-like sores, headache, fever and rash. *Saari* is therefore distinguishable given the direct link between the medical literature and Ohuche’s symptoms, coupled with the allegedly close temporal proximity between the date of the vaccination and the onset of symptoms.<sup>65</sup> I therefore find that there is a disputed issue of material fact

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<sup>64</sup> 961 F. Supp. at 396 (emphasis omitted) (citing, *inter alia*, *Rohrbough v. Wyeth Labs., Inc.*, 916 F.2d 970, 974 (4th Cir. 1990) (stating that the doctor’s testimony merely established “that a temporal link existed in other cases between the vaccine and a reaction like that displayed by [plaintiff].” The doctor “did not testify that the literature supported a causal link between the vaccine and the reaction in other cases, much less that the vaccine caused the reaction in this particular case.”)).

<sup>65</sup> During a March 11, 2011 office visit to Dr. Itzkovitz, Ohuche reported that she broke out with a rash five times over the past two years. *See supra* Part I.C. Given the intermittent nature of her rash, it is conceivable that Ohuche first got the rash some time after March 24, 2009, when she visited Dr. Simon, and that the rash cleared up by June 19, 2009, when she visited Dr. Voll. In any event, Ohuche submitted a photograph dated March 26, 2009, which clearly shows pustules on her cheek. *See* Pl. Opp. Ex. 1. Whether this photograph is accurately dated involves an issue of credibility that this Court cannot decide on summary



as to whether the ZOSTAVAX® vaccine actually caused plaintiff's alleged injuries. Nonetheless, plaintiff's action fails given the lack of proximate cause.

## **B. Proximate Cause**

“A plaintiff proceeding under a failure-to-warn theory in New York must demonstrate that the failure to warn adequately of the dangers of a product was a proximate cause of his or her injuries.”<sup>66</sup>

Under the “learned intermediary rule” the manufacturer of a prescription drug [or vaccine] does not have a duty to warn the patient of the dangers involved of the product, but rather the duty is owed to the patient's doctor. The basis for this rule is that “[t]he doctor acts as an ‘informed intermediary’ between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use.”<sup>67</sup>

Here, the learned intermediary was Dr. Itzkovitz who testified at deposition that she was aware of the adverse reactions associated with ZOSTAVAX® despite not reading the available medical literature. And it was Dr. Itzkovitz who should have read the available medical literature surrounding

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judgment.

<sup>66</sup>  *Davids v. Novartis Pharm. Corp.*, 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012) (quoting  *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993)).


<sup>67</sup>  *Id.* (quoting  *Glucksman*, 553 N.Y.S.2d at 726) (other citations omitted).

ZOSTAVAX® before she began vaccinating patients with it. Merck, on the other hand, completely fulfilled its obligation to disclose the risks, side effects and contraindications associated with ZOSTAVAX®. To the extent that Ohuche had a viable claim, it was a malpractice claim against Dr. Itzkovitz, not a product liability claim against Merck. Accordingly, Ohuche's claims against Merck are hereby dismissed.

#### **IV. CONCLUSION**

For the foregoing reasons, defendant's motion for summary judgment is granted. The Clerk of the Court is directed to close this motion (Document # 23) and this case.

SO ORDERED:

  
Shira A. Scheindlin  
U.S.D.J.

Dated: New York, New York  
October 12, 2012

**- Appearances -**

**Plaintiff (Pro Se):**

Elizabeth Ohuche  
23 East 127th Street  
New York, NY 10035  
(212) 534-2781

**For Defendant:**

David S. Gray, Esq.  
Venable LLP  
750 E. Pratt Street, Suite 900  
Baltimore, MD 21202  
(410) 244-7400

Heather L. Maly, Esq.  
Venable LLP  
Rockefeller Center  
1270 Avenue of the Americas  
New York, NY 10020  
(212) 307-5500