UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

KEVIN DRAKE AND LORI DRAKE, individually and as next friend of J.D.,	:	
Plaintiffs,	:	
v.	:	Case No. 2:13-cv-234
ALLERGAN, INC.,	:	
Defendant.	:	

OPINION AND ORDER

Plaintiffs Kevin and Lori Drake bring this products liability action, individually and as next friend of their son J.D., claiming J.D. suffered injuries after receiving Botox injections to treat lower-limb spasticity. The Drakes allege that J.D. received an overdose of Botox after manufacturer Allergan, Inc. ("Allergan") failed to warn about proper dosages for children, and that he now suffers from seizures as a result. Before the Court is Allergan's motion for partial summary judgment on the Drakes' claims of strict liability/failure to warn, negligence, and violations of the Vermont Consumer Fraud Act. For the reasons set forth below, the motion for partial summary judgment is DENIED.

Factual Background

J.D. was born in 2006 with mild cerebral palsy. He is cognitively normal, walks and engages in extra-curricular activities, and attends regular school. At various times, J.D.

has experienced mild to moderate spasticity or tightness in his legs.

When J.D. was two years old, his parents took him to see Dr. Scott Benjamin at Fletcher Allen Health Care ("Fletcher Allen"). Dr. Benjamin is a doctor of physical medicine and rehabilitation, also known as a physiatrist. He specializes in assisting patients improve mobility, and in particular children with cerebral palsy. Dr. Benjamin's treatment recommendations for J.D. included Botox injections for lower limb spasticity. Botox is an injectable pharmaceutical that consists of the neurotoxin botulinum toxin type A. When injected into muscle, Botox temporarily blocks the nerve impulses that trigger muscle contractions. The Food and Drug Administration ("FDA") has not approved Botox as a treatment for pediatric spasticity. Accordingly, the administration of Botox for that purpose is known as an "off-label" use.[1]

Dr. Benjamin first treated J.D. with Botox on April 22, 2010, when J.D. was three-and-a-half years old. At that time, he injected a dose of approximately 6 units per kilogram of body weight (u/kg) into J.D.'s calves. The treatment resulted in some improvement in J.D.'s flat-footedness.

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[1] "[O]ff-label drug usage is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways." *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012).

On April 25, 2012, when J.D. was almost five-and-a-half years old, Dr. Benjamin suggested additional Botox injections at a higher dose. J.D.'s parents agreed to the treatment, and on May 24, 2012 Dr. Benjamin injected J.D. with 100 units into each calf, a dose of approximately 12.33 u/kg.

The next day, J.D.'s mother noticed swelling in his face. J.D. also experienced slurred speech, respiratory difficulties, increased secretions from his mouth, and vomiting. The Drakes took J.D. to his pediatrician's office, where doctors administered an EpiPen injection. J.D.'s symptoms immediately got worse, and he was transported by ambulance to Fletcher Allen. Once at Fletcher Allen, J.D. was admitted, treated with steroids, and kept overnight for observation. The attending physician at Fletcher Allen believed the episode was an anaphylactic (allergic) reaction to the Botox.

J.D. experienced similar episodes in the months following the May 2012 injections. In February 2013, Dr. Jennifer Hanowell of Dartmouth-Hitchcock Medical Center noted that "[i]n light of repeated events and abnormal EEG, [I] suspect epilepsy as [the] etiology rather than anaphylaxis." ECF No. 94-19 at 4. Accordingly, Dr. Hanowell prescribed anti-seizure medication. J.D. continues to be on seizure watch and to take anti-epileptic medication.

At the time of J.D.'s second Botox injection, the package

insert for Botox contained the following "black box" warning:

> Warning: Distant Spread of Toxin Effect
>
> Postmarketing reports indicate that the effects of Botox and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include ashenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

ECF No. 94-4 at 3.[2] The insert also warned that the "[s]afety and effectiveness of Botox have not been established for the treatment of upper limb spasticity in pediatric patients, and for the treatment of lower limb spasticity in adult and pediatric patients." *Id.* at 2.

Prior to J.D.'s treatment, Allergan stated in its Core Data Sheet that the maximum cumulative dose for children "should generally not exceed 8.0 Units/kg body weight." ECF No. 106-9 at

[2] Allergan represents in its memorandum that "using the average human's weight of 70kg, the BOTOX package insert describes dosing for cervical dystonia at between 2.8 u/kg and 4.3 u/kg." ECF No. 94-1 at 9 n.1. The insert states that for cervical dystonia, "in general, no more than 50 units per site should be administered." ECF No. 94-4 at 8.

7. This warning, Plaintiffs contend, has never been shared with the medical community or the public. However, when Allergan reported adverse events to the Food and Drug Administration ("FDA"), it characterized any pediatric dose greater than 8 u/kg as an "overdose." ECF No. 106-10 at 13. Consistent with this practice, when Dr. Benjamin reported J.D.'s reaction to Allergan, Allergan's report to the FDA characterized the dosage as exceeding the recommended maximum, ECF No. 106-37 at 16, and in internal documentation referred to it as an "overdose." ECF No. 106-39 at 9.

Plaintiffs filed suit on September 3, 2013. The Complaint consists of four counts: (I) strict liability/failure to warn/breach of implied warranties; (II) negligence; (III) strict liability/design defect/breach of implied warranties; and (IV) a cause of action under the Vermont Consumer Fraud Act. Allergan now moves for summary judgment on Counts I, II, and IV, arguing that Plaintiffs cannot prove proximate cause. Specifically, Allergan argues that Dr. Benjamin would not have used a different dose even if Allergan had warned about dosages over 8 u/kg. Allergan also contends that its labeling was adequate with regard to many of J.D.'s post-Botox symptoms, that different labeling would not have altered the parents' reliance on their doctor, and that its efforts to promote off-label uses had no causal relationship to J.D.'s injuries.

Dr. Benjamin testified that he has been using Botox to treat children with cerebral palsy for 14 years, that he has provided the treatment to hundreds of patients, and that Botox has been one of the standards of care for treating pediatric spasticity for over 20 years. He routinely uses doses "between 10 and 15 [u/kg]" to treat juvenile cerebral palsy patients, and bases his dosages upon his own clinical experience and conversations with colleagues. Dr. Benjamin also testified that "it is not at all uncommon that what is considered maximum dosing for medications are exceeded in clinical practice safely, based on the doctor's breadth of experience and their own clinical practice." Benjamin Dep. at 31:15-19.

Allergan thus contends that Dr. Benjamin based his dosage decision upon his own experience, and not upon Allergan's warnings. Allergan similarly submits that even if it had warned Dr. Benjamin not to provide a dose of over 8 u/kg to children, he would not have heeded the warning. When asked the potential impact of a graph indicating adverse effects in a majority of cases where the dosage was higher than 8 u/kg, Dr. Benjamin testified as follows:

> The information would be interesting to me, yes. What I will say is that you're talking about a study with 30 cases, where clinically I've done thousands of cases using similar doses and have never had a reaction that comes anywhere close to this, routinely using between 10 and 15 units per kilogram.
>
> So you can pick a small number of cases and show that

> it was all because it was over 8 units per kilogram; but then in the clinical world of doing this for 12 years, hundreds of patients, thousands of times, in that dosing schedule, that I have not seen this type of response to the medication at those doses.

Benjamin Dep. at 30:2-14.

Plaintiffs have submitted evidence to show that Allergan representatives spoke with Dr. Benjamin in the years prior to J.D.'s treatment. The call notes reflect that those discussions included "hi-dose BTX." Although Dr. Benjamin testified that he did not discuss pediatric Botox dosages with Allergan sales representatives, he conceded in his deposition that it was possible such discussions occurred and he does not recall them. *Id.* at 168:2-7.

Plaintiffs also note that Dr. Benjamin did not explicitly state whether, had he been warned about a maximum safe dosage of 8 u/kg, he would have treated J.D. differently. He did testify, however, that he did not communicate any such maximum dosage to the Drakes, nor could he have since Allergan did not provide a specific dosage warning. Dr. Benjamin also testified that if he had been informed of a maximum safe dose, and planned to exceed that dose, he would have included that fact in the information provided to the parents prior to their consent. *Id.* at 31.[3]

[3] Dr. Benjamin was asked in his deposition: "If you're planning on exceeding the maximum safe dose with a medication that's a lethal neurotoxin, would you at least let the parents know about it so that they can consent to that?" *Id.* He responded that he would "include that in my information to them, sure," and subsequently agreed that

Allergan further contends that the Drakes relied entirely upon Dr. Benjamin's advice, and that any labeling or marketing by Allergan either did not, or would not have, altered their decision-making. The summary judgment record belies this contention, as Lori Drake testified in her deposition that if Dr. Benjamin had informed them "that he was going to give our son an overdose of Botox . . . we would not have moved forward with that." L. Drake Dep. at 106:22-25. As she explains in a subsequent declaration,

> [m]y son's spasticity was not severe or life-threatening in any way. In fact, it has been manageable since May 2012 without the need for Botox injections, surgery or other invasive procedures. There would have been no reason to expose my son to the risks, including seizures, of an overdose of botulinum toxin in order to treat this mild spasticity.

ECF No. 106-31 at 2.[4] Had the Drakes declined treatment, Dr. Benjamin would have acceded to their wishes. Benjamin Dep. at 66:16-20.

Discussion

I. Summary Judgment Standard

Summary judgment may only be granted where, construing the evidence in the light most favorable to the non-movant, "there is

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Botox is a neurotoxin. *Id.* at 31-32.

[4] In its reply memorandum, Allergan contends that Lori Drake's declaration is inconsistent with her deposition testimony and should not be considered. Although Ms. Drake testified that she and her husband trusted Dr. Benjamin, she also testified that a warning about a maximum safe dose would have changed their mind about treatment.

no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Redd v. N.Y. Div. of Parole*, 678 F.3d 166, 173–74 (2d Cir. 2012). A dispute is "genuine" when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material where it is legally relevant such that it "might affect the outcome of the suit under the governing law." *Id.* In determining whether there are genuine disputes of material fact, the court must "resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought." *Terry v. Ashcroft*, 336 F.3d 128, 137 (2d Cir. 2003) (citation and quotation omitted).

This standard imposes the initial burden on the moving party to demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has met this burden, the party opposing summary judgment must identify specific facts and affirmative evidence that contradict those offered by the moving party to demonstrate that there is a genuine issue for trial. *Id.* at 324; *see also Anderson*, 477 U.S. at 256–57. The nonmoving party "may not rely on mere conclusory allegations nor speculation, but instead must offer some hard evidence showing that its version of the events is not wholly fanciful." *D'Amico v. City of N.Y.*, 132 F.3d 145,

149 (2d Cir. 1998). "Summary judgment is appropriate only '[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party.'" *Donnelly v. Greenburgh Cent. Sch. Dist. No.* 7, 691 F.3d 134, 141 (2d Cir. 2012) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)).

II. Choice of Law

The Court has jurisdiction in this case on the basis of diversity of the parties' citizenship: the Drakes reside in New York, and Allergan is a Delaware corporation with a principal place of business in California. "A federal trial court sitting in diversity jurisdiction must apply the law of the forum state to determine choice-of-law." *Fieger v. Pitney Bowes Credit Corp.*, 251 F.3d 386, 393 (2d Cir. 2001). The Vermont Supreme Court has adopted the Restatement (Second) of Conflicts for choice-of-law questions in tort cases, including cases alleging strict liability. *See McKinnon v. F.H. Morgan & Co.*, 750 A.2d 1026, 1028 (Vt. 2000) (citing *Amiot v. Ames*, 693 A.2d 675, 677-78 (Vt. 1997)). "Under § 146 of the Restatement, the 'law of the state where the injury occurred determines the rights and liabilities of the parties' in an action for personal injury unless another jurisdiction has a more significant relationship to the occurrence and the parties under the general principles stated in § 6." *Id.* Here, J.D.'s alleged injuries occurred in

Vermont, and the Court finds that no other jurisdiction has a more significant relationship to the case. The Court therefore applies Vermont law.

III. Failure To Warn

The Plaintiffs' first claim is that Allergan is strictly liable for its failure to provide an adequate product warning. Under Vermont law,

> A manufacturer [] has a duty to warn users and consumers when it knows or has reason to know of dangers inherent in the product at the time the product is sold, Restatement (Second) of Torts § 402A cmt. k, or when the product is dangerous to an extent beyond that which would be contemplated by an ordinary consumer. *Menard v. Newhall*, 135 Vt. 53, 55, 373 A.2d 505, 507 (1977). To establish strict liability for an inadequate warning, a plaintiff must prove that the inadequate warning made the product unreasonably dangerous and was the proximate cause of the injury. *Id.* at 54, 373 A.2d at 506.

Webb v. Navistar Intn'l Transp. Corp., 692 A.2d 343, 347 (Vt. 1996). Accordingly, to withstand summary judgment the Drakes must put forth admissible evidence that (1) Allergan had a duty to warn; (2) the lack of an adequate warning made the product unreasonably dangerous, and therefore defective; and (3) the lack of an adequate warning was a proximate cause of the injury. *Id.* (citations omitted). Allegan's primary focus at summary judgment is proximate cause, as it argues that Dr. Benjamin's decision-making was based upon his own clinical experience, and was independent of any warning that might have been provided. Allergan also argues that the Drakes relied entirely upon Dr.

Benjamin's expertise.

A. Duty to Warn and The Learned Intermediary Doctrine

With respect to its duty to warn, Allergan invites the Court to first consider the "learned intermediary doctrine." Under this doctrine, a manufacturer of prescription drugs has a duty to warn a patient's doctor, and not the patient himself. *See Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993).

> The learned intermediary doctrine provides that "adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment."

Vitanza v. Upjohn Co., 778 A.2d 829 (Ct. 2001) (quoting *Vitanza v. Upjohn Co.*, 48 F. Supp. 2d 124, 127 (D. Conn. 1999)); *see Wright ex rel. Trust Co. of Kansas v. Abbott Labs., Inc.*, 259 F.3d 1226, 1233 (10th Cir. 2001) ("The 'learned intermediary doctrine' states that once a manufacturer warns a doctor about a drug's inherent dangers, it has fulfilled its legal duty to provide a warning," applying Kansas law). While the doctrine is widely accepted, "[s]ome jurisdictions have rejected or recognized exceptions to the learned intermediary doctrine." *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 700 (D. Vt. 2010) (citing cases). The learned intermediary doctrine has not been accepted

or rejected by the Vermont Supreme Court.

Allergan contends that the doctrine should apply here because J.D.'s mother, Lori Drake, testified that she relied upon Dr. Benjamin's judgment when he recommended Botox treatment. Plaintiffs submit that it is not necessary to determine whether Vermont would adopt the doctrine, as the warnings to Dr. Benjamin were inadequate. As set forth below, the primary disputes are whether the warning to Dr. Benjamin was adequate, and if that warning had been communicated to the Drakes, whether J.D.'s treatment would have been different. Accordingly, the Court need not predict at this time whether the Vermont Supreme Court would adopt the learned intermediary doctrine. *See Kellogg*, 762 F. Supp. at 700.

B. Proximate Cause

In Vermont, proximate cause in a failure to warn case "is typically shown by means of a presumption. If a plaintiff can demonstrate that the manufacturer had a duty to warn and failed to provide an adequate warning, a causal presumption arises that had an adequate warning been provided, the user would have read and heeded the warning. . . ." *Town of Bridport v. Sterling Clark Lurton Corp.*, 693 A.2d 701, 704 (Vt. 1997). "A defendant may, of course, present evidence to overcome the presumption." *Id.* (citing *Menard v. Newhall*, 373 A.2d 505, 506-07 (Vt. 1977)); *see also Davids v. Novartis Pharm. Corp.*, 857 F. Supp. 2d 267,

286 (E.D.N.Y. 2012) ("The Defendant may rebut this presumption by introducing specific facts that the warning would have been futile.") (citation omitted).

The Drakes allege that Allergan was aware of toxicology studies demonstrating that doses above 8 u/kg are not safe. The Drakes also cite Allergan's Confidential Core Data Sheet for Botox stating that 8 u/kg is the maximum safe dose for children. This information has allegedly never been communicated to the medical community.

Dr. Benjamin testified that additional information about dosage, and specifically about a maximum safe dose, "would be interesting," but that he also had significant clinical experience with Botox treatment. Dr. Benjamin did not testify whether, had he been given a specific dosage warning, he would have done anything different with respect to J.D. Indeed, as Plaintiffs note in their summary judgment memorandum, "[n]either side asked Dr. Benjamin at his deposition whether he would have done anything differently had he received an adequate warning regarding the maximum safe dose." ECF No. 106-1 at 15. Accordingly, and viewing the facts in a light most favorable to the non-moving party, the summary judgment record is inconclusive with respect to the effect a specific dosage warning would have had on Dr. Benjamin.

Allergan also notes that Dr. Benjamin has not changed his

practice since learning about the facts of this case and the Plaintiffs' labeling claim. Dr. Benjamin testified in his deposition, however, that "this event in general gives me just a moment of pause," and that he now warns families of J.D.'s "unusual allergic reaction that may or may not have been seizure activity." Benjamin Dep. at 159:24-160:2. Dr. Benjamin further testified that if had been informed of a maximum dose, and if he planned to exceed that dose, he would have informed the parents. *Id.* at 31:20-32:1.

Vermont law presumes that if an adequate warning is provided, the warning will be read and heeded. The record in this case is not sufficiently clear that such a warning would not have been both read and heeded, or that the information would not have been passed on to the Drakes for their consent. As Lori Drake makes clear in her testimony, notice of an overdose would have caused the Plaintiffs to decline treatment. The Court therefore finds that, given this record, a reasonable jury could conclude that Allergan's failure to warn was a proximate cause of J.D.'s injuries.

C. Adequacy of the Botox Warning

Allergan next contends that its Botox label was adequate as a matter of law because "many" of J.D.'s symptoms were discussed in the package insert. The black box warning stated that "the effect of Botox and all botulinum toxin products may spread from

the area of injection to produce symptoms consistent with botulinum toxin effects." The warning also stated that "[s]wallowing and breathing difficulties can be life threatening," and that "[t]he risk of symptoms is probably greatest in children treated for spasticity." Allergan thus argues that summary judgment is warranted on Plaintiffs' claims that (1) Allergan failed to warn that Botox "migrates out of the muscle into which it is injected," and (2) that Botox "causes life-threatening systemic side effects." ECF No. 94-1 at 24 (citing Compl. ¶ 19).

Plaintiffs respond that their "primary 'adverse effect' . . . claim in this case is the seizure disorder that J.D. developed as a result of his Botox overdose." ECF No. 106-1 at 23. To the extent that Allergan warned of a possible migration out of the muscle, Plaintiffs contend that this warning was inadequate given that "the maximum dose of 8 u/kg is a bright line boundary beyond which the risks and hazards of Botox are exponentially greater." *Id.* at 24. Plaintiffs also note that on page 15 of the package insert, Allergan warned that new onset seizures have been reported, but that "[t]he exact relationship of these events to [Botox] has not been established." ECF No. 106-41 at 15. This language, they argue, was not sufficiently highlighted and was thus inadequate under Vermont law. *See Town of Bridport*, 693 A.2d at 703 (concluding that "one factor in determining the

adequacy of a warning is its conspicuousness on a label").

The question at summary judgment is whether a reasonable jury could find that the labeling was insufficient. That question is commonly left to the jury. *See Kellogg*, 762 F. Supp. at 701 (quoting *McCullock v. H.B. Fuller Co.*, 981 F.2d 656, 658 (2d Cir. 1992); *Town of Bridport*, 693 A.2d at 705 ("where a warning has been provided by a manufacturer, ordinarily the sufficiency of that warning is a question for the jury"). Here, there are disputed questions of material fact concerning the adequacy of the warning, and whether the provided warnings were specific and obvious enough to put Dr. Benjamin and the Drakes on notice of a known danger of Botox. Furthermore, while Allergan may have warned about some of the specific symptoms suffered by J.D., a reasonable jury could find that it did not adequately address the danger of seizures. Summary judgment with respect to the adequacy of Allergan's warning is therefore DENIED.

IV. Negligence

In addition to their strict liability claims, Plaintiffs allege that Allergan's marketing of Botox was negligent. Specifically, they claim that Allergan illegally promoted the off-label use of Botox to treat pediatric spasticity at unsafe doses, and that Botox is a dangerous and defective drug. Allergan again argues that these claims fail for lack of proximate cause.

Under Vermont law,

> [t]he elements required for a cause of action in common law negligence are: (1) the defendant must owe a legal duty to conform to a certain standard of conduct so as to protect the plaintiff from an unreasonable risk of harm; (2) the defendant must have committed a breach of this duty by failing to conform to the standard of conduct required; (3) the defendant's conduct must be the proximate cause of the plaintiff's injury; and (4) the plaintiff must have suffered actual loss or damage.

Langle v. Kurkul, 510 A.2d 1301, 1304 (Vt. 1986) (emphases omitted). "The law of proximate cause 'calls for a causal connection between the act for which the defendant is claimed to be responsible and which is alleged to be negligent and the resulting flow of injurious consequences.'" *Lussier v. Bessette*, 16 A.3d 580, 585 (Vt. 2010)(quoting *Rivers v. State*, 328 A.2d 398, 400 (Vt. 1974)).

Allergan contends that its marketing had no impact on Dr. Benjamin's decision to treat J.D. with Botox at a particular dosage. Allergan also submits that its promotional materials did not affect the Drakes' decision to consent to Botox treatment for J.D. Both parents testified that they did not communicate with Allergan directly, and that they did not recall ever seeing advertisements or other promotional materials regarding the use of Botox to treat pediatric spasticity.

Plaintiffs have submitted evidence of Allergan marketing plans directed at off-label use of Botox to treat pediatric spasticity. Plaintiffs contend that Allergan not only marketed

Botox as a spasticity treatment, but also encouraged physicians to treat children with high doses. Viewing the facts in a light most favorable to the Plaintiffs, the record suggests that Dr. Benjamin was a target of Allergan's marketing efforts. The evidence indicates that during Dr. Benjamin's medical residency and fellowship, Allergan marketed Botox to young physicians so that they would incorporate the drug into their clinical practices. Allergan sales call notes also indicate that Dr. Benjamin discussed his use of Botox with Allergan sales representatives, and "hi-dose BTX" with Allergan's Regional Scientific Services representative. While Dr. Benjamin does not recall speaking with anyone from Allergan about Botox dosages for pediatric spasticity, he conceded that it was "possible" such conversations took place. Given this record, the Court finds that there are genuine issues of material fact as to whether Dr. Benjamin was influenced by Allergan's promotion of Botox as a treatment for pediatric spasticity. The motion for summary judgment as to the claim of negligent promotion is therefore DENIED.

V. The Vermont Consumer Fraud Act

The Vermont Consumer Fraud Act (VCFA) prohibits "unfair or deceptive acts or practices in commerce." 9 V.S.A. § 2453(a). To establish a "deceptive act or practice" under the CFA requires three elements: "(1) there must be a representation, omission, or

practice likely to mislead consumers; (2) the consumer must be interpreting the message reasonably under the circumstances; and (3) the misleading effects must be material, that is, likely to affect the consumer's conduct or decision regarding the product." *Carter v. Gugliuzzi*, 716 A.2d 17, 23 (Vt. 1998). "Deception is measured by an objective standard, looking to whether the representation or omission had the 'capacity or tendency to deceive' a reasonable consumer; actual injury need not be shown." *Id.* (quoting *Bisson v. Ward*, 628 A.2d 1256, 1261 (Vt. 1993)). The VCFA "does not require a showing of intent to mislead, but only an intent to publish the statement challenged." *Winton v. Johnson & Dix Fuel Corp.*, 515 A.2d 371, 376 (Vt. 1986). Whether an act is "unfair" is guided by consideration of several factors, including (1) whether the act offends public policy, (2) whether it is "'immoral, unethical, oppressive or unscrupulous,'" and (3) "'whether it causes substantial injury to consumers.'" *Christie v. Dalmig, Inc.*, 396 A.2d 1385, 1388 (Vt. 1979) (quoting *FTC v. Sperry Hutchinson Co.*, 405 U.S. 233, 244 n.5 (1972)).

To bring a private claim under the VCFA, the plaintiff must be a consumer who "contracts for goods or services in reliance upon false or fraudulent representations or practices prohibited by section 2453" or "who sustains damages or injury as a result of any false or fraudulent representations or practices prohibited by section 2453 . . . or prohibited by any rule of

regulation made pursuant to section 2453." 9 V.S.A. § 2461(b); *see also Dernier v. Mortgage Network, Inc.*, 87 A.3d 465, 481 (Vt. 2013). The VCFA does not require privity between the consumer and the seller. *See Elkins v. Microsoft Corp.*, 817 A.2d 9, 12-13 (Vt. 2002).

Allergan again contends that J.D. did not suffer injury as a result of any alleged representations or practices. Allergan argues that, instead, Dr. Benjamin provided Botox based upon his own experience, and the Drakes relied entirely upon his recommendations. Plaintiffs respond that Allergan made material representations and omissions, that Dr. Benjamin was impacted by both those representations and omissions, and that a proper warning would have been communicated to the Drakes who, in turn, would have declined Botox treatment. For the reasons set forth above, there are genuine issues of material fact with respect to causation, and the Court declines to grant summary judgment on that basis.

Allergan also argues that the Plaintiffs may not recast their failure to warn and negligence claims as VCFA claims. For support, Allergan cites *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, 951 F. Supp. 2d 592 (D. Vt. 2012), in which the plaintiff sued Fletcher Allen and a medical device manufacturer for injuries allegedly caused by a spinal infusion device. This Court concluded in *Otis-Wisher* that a VCFA claim against Fletcher

Allen "was not meant to provide a second method to plead a malpractice or negligence claim." 951 F. Supp. 2d at 603.[5] *Otis-Wisher* relied upon *Webb v. Leclair*, 933 A.2d 177, 183 (Vt. 2007), which held that a legal opinion did not constitute a misrepresentation and was therefore not actionable under the VCFA. *See id.* (concluding that "[a]s other courts have found, opinions generally do not give rise to misrepresentation"). *Webb* does not apply to Allergan's alleged failure to warn, as a failure to warn presents an issue of fact rather than opinion. This Court's *Otis-Wisher* conclusion with regard to Fletcher Allen's alleged malpractice is similarly inapposite. The motion for summary judgment on the Plaintiffs' VCFA claim is therefore DENIED.

Conclusion

For the reasons set forth above, Allergan's motion for partial summary judgment (ECF No. 94) is DENIED.

Dated at Burlington, this 31st day of October, 2014.

/s/ William K. Sessions III
William K. Sessions III
District Court Judge

[5] Allergan's briefing does not rely upon the *Otis-Wisher* holding with respect to the device manufacturer.