

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

REGINA M. GRIFFUS,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORP.,

Defendant.

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Case No. 06-10891

Honorable Nancy G. Edmunds

**ORDER GRANTING DEFENDANT'S MOTION TO DISMISS [3]**

This matter came before the Court on Defendant's Motion to Dismiss. For the reasons discussed below, Defendant's Motion is hereby GRANTED and this case is DISMISSED.

**I. Background**

Plaintiff Regina Griffus alleges that she suffered injuries as a result of her participation in a clinical research trial sponsored by Defendant Novartis Pharmaceuticals. The research trial was for the purpose of determining whether Trileptal, which is manufactured by Defendant and is FDA-approved for treatment of seizures and epilepsy, is also effective in treating pain associated with diabetic neuropathy. In her Complaint, plaintiff seeks relief on three grounds: negligence, breach of implied warranty, and breach of express warranty.

**II. Standard of Review**

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of a Complaint. In a light most favorable to Plaintiff, the Court must assume that Plaintiff's factual allegations are true and determine whether the Complaint states a valid

claim for relief. See *Albright v. Oliver*, 510 U.S. 266 (1994); *Bower v. Federal Express Corp.*, 96 F.3d 200, 203 (6th Cir. 1996); *Forest v. United States Postal Serv.*, 97 F.3d 137, 139 (6th Cir. 1996). This standard of review “requires more than the bare assertion of legal conclusions.” *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 400 (6th Cir. 1997) (quoting *Columbia Natural Resources, Inc. v. Tatum*, 58 F.3d 1101, 1109 (6th Cir. 1995)). The Complaint must include direct or indirect allegations “respecting all the material elements to sustain a recovery under some viable legal theory.” *In re DeLorean Motor Co.*, 991 F.2d 1236, 1240 (6th Cir. 1993) (citations omitted) (emphasis in original).

### III. Discussion

Defendant has brought this Motion to Dismiss on the ground that each of Plaintiff’s claims are barred by Mich. Comp. Laws § 600.2946(5), which provides in part,

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration’s approval at the time the drug left the control of the manufacturer or seller.

The Michigan Supreme Court has stated that this statute provides “*an absolute defense* to a products liability claim if the drug and its labeling were in compliance with the FDA’s approval at the time the drug left the control of the manufacturer or seller.” *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003).

Plaintiff makes two arguments in response. First, Plaintiff contends that although Trileptal was approved for treatment of seizures and epilepsy, Defendant provided her with the drug for treatment of an entirely different malady--one for which Trileptal has not been approved by the FDA. Thus, Plaintiff argues, the statute does not apply.

This argument is unpersuasive. The Michigan Legislature was certainly aware of the possibility that in some circumstances, drugs will be used for purposes besides those for which they were approved by the FDA. Nevertheless, it establishes “an absolute defense” for drug manufacturers. *Taylor*, 658 N.W.2d at 131.<sup>1</sup> Just as the statute protects drug manufacturers when a doctor prescribes a drug for a non-approved use, or when a patient overdoses on an otherwise safe medication, the statute provides an absolute defense to product liability in this case as well.

Second, Plaintiff argues that even if the statute protects Defendant from a “product liability action,” it says nothing about negligence apart from the manufacture of Trileptal. The Complaint alleges Defendant’s negligence relating to the research trial, including its failure to “warn of the potential health risks,” “evaluate Plaintiff as a proper candidate for the clinical research trial,” and “monitor the health and welfare of Plaintiff.” (Compl. at 4-5.)

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<sup>1</sup>There are two exceptions to Mich. Comp. Laws 600.2946(5):

This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 USC. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Neither of these exceptions is at issue in this case.

The problem with this argument is that the scope of the above cited defense includes "manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, *testing*, listing, certifying, *warning, instructing*, marketing, selling, advertising, packaging, or labeling." Mich. Comp. Laws § 600.2945(i) (emphasis added). Thus, the testing about which Plaintiff complains is protected by the statute.

Plaintiff's negligence and warranty claims are simply disguised product liability claims. Indeed, they are at times poorly disguised, as Plaintiff refers to Defendant's failure to properly "manufacture its product" even in her negligence claim. (Compl. at 4.) As the Michigan Legislature has established an absolute defense to lawsuits such as this, Plaintiff has failed to state a claim upon which relief may be granted.

#### **IV. Conclusion**

Being fully advised in the premises, having read the pleadings, and for the reasons set forth above, the Court hereby GRANTS Defendant's Motion to Dismiss.

s/Nancy G. Edmunds  
Nancy G. Edmunds  
United States District Judge

Dated: September 6, 2006

I hereby certify that a copy of the foregoing document was served upon counsel of record on September 6, 2006, by electronic and/or ordinary mail.

s/Carol A. Hemeyer  
Case Manager