IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BRADLEY COLAS,	)	
	)	
Plaintiff,	)	**No. 14 C 1452**
	)	
v.	)	**Judge Ronald A. Guzmán**
	)	
ABBVIE, INC. and ABBOTT LABORATORIES,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff sues defendants for negligence and fraud to recover for injuries he allegedly sustained after taking the generic version of a drug defendants manufacture. Defendants have moved pursuant to Federal Rule of Civil Procedure ("Rule")12(b)(6) to dismiss the complaint. For the reasons set forth below, the Court grants in part and denies in part the motion.

Facts

On February 29, 2012, plaintiff, who lives in Virginia, was diagnosed with bronchitis. (Compl. ¶¶ 2, 13-14.) His doctor prescribed Biaxin, an antibiotic designed, manufactured, labeled, and marketed by defendants, for plaintiff. (*Id.* ¶ 14.) In accordance with Virginia law, the pharmacy that filled plaintiff's prescription dispensed Clarithromycin, the generic equivalent to Biaxin, which is manufactured by Roxane Laboratories, Inc. (*Id.* ¶ 15.)

Plaintiff had no history of mental illness, but after taking the drug, he became psychotic and delusional, crashed his car and attacked the fire fighters who came to his aid. (*Id.* ¶¶ 12, 17, 34-71.) As a result, plaintiff was arrested and charged with a number of offenses, including attempted murder. (*Id.* ¶ 74.) After plaintiff spent three months in pretrial detention, and multiple psychiatrists

concluded that he was involuntarily intoxicated by Clarithromycin at the time of the offenses, the state of Virginia dismissed the charges against him. (*Id.* ¶¶ 75-78.)

Discussion

On a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded factual allegations of the complaint, drawing all reasonable inferences in plaintiff's favor. *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir. 2009). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations" but must contain "enough facts to state a claim for relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

In Count I, plaintiff alleges that defendants are liable for failing to warn doctors and consumers about the possible psychotic side effects of Biaxin and Clarithromycin.[1] (*Id.* ¶¶ 19-33, 79-84.) Under Virginia law, which the parties agree applies, a negligent failure to warn claim is governed by the Restatement of Torts, which states:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel . . . for physical harm caused by the use of the chattel . . . , if the supplier[:]
>
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

[1]Under federal law, labeling for a brand name drug must be approved by the FDA, and any generic equivalent must be labeled identically. *See PLIVA, Inc. v. Mensing*, __ U. S.__, 131 S. Ct. 2567, 2574-75 (2011) (stating that "[FDA] regulations . . . require that the warning labels of a brand-name drug and its generic copy must always be the same"); 21 C.F.R. §§ 201.50-57. Thus, though defendants did not make Clarithromycin, their labeling for Biaxin was used for it.

> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388; *see Featherall v. Firestone Tire & Rubber Co.*, 252 S.E.2d 358, 366 (Va. 1979) (adopting § 388 and stating that "[t]he duty to warn stems from the view that the manufacturer should have superior knowledge of his product").

Plaintiff admits that defendants were not the "suppliers" of the Clarithromycin he took. (Compl. ¶¶ 8-10, 14-15.) Thus, plaintiff cannot, as a matter of Virginia law, state a failure to warn claim against defendants. *See Featherall*, 252 S.E.2d at 366; *see also Baker v. Poolservice Co.*, 636 S.E.2d 360, 365 (Va. 2006) (stating that plaintiff's "reliance on *Featherall* and § 388 of the Restatement (Second) of Torts to argue [that a spa repair service] owed a duty to warn [was] . . . misplaced" because the repair service "was not the manufacturer of the spa").

In Count II, plaintiff alleges that defendants were negligent per se for violating 21 C.F.R. § 201.57, one of the federal regulations that govern drug labeling. *See Butler v. Frieden*, 158 S.E.2d 121, 122 (Va. 1967) ("Under Virginia law violation of a statute or ordinance constitutes negligence per se."); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (concluding that a violation of federal law supports a claim for negligence per se under Virginia law); *see also PLIVA, Inc. v. Mensing*, __ U.S. __, 131 S. Ct. 2567, 2576 (2011) (acknowledging that "the[] requirements [of 21 C.F.R. § 201.57] apply to generic drugs"). In *McGuire v. Hodges*, 639 S.E.2d 284 (Va. 2007), the Virginia Supreme Court said a claim for negligence per se requires proof of "the existence of a legal duty, a breach of the duty, and proximate causation resulting in damage," and that defendant's violation of a statute enacted for public safety "provides the elements of . . . duty and breach." *Id.* at 205-06 (quotation omitted). Subsequently, however, in *Steward ex rel. Steward v. Holland Family Prop., Inc.*, 726 S.E.2d 251 (Va. 2102), the court retreated from the holding in

McGuire. In the *Steward* court's view, a statute that creates "[t]he standard of care required to comply with [a] duty . . . . does not create the duty [itself]." *Id.* at 254. Thus, the *Steward* court said, a negligence per se claim requires plaintiff to show both that defendant had a common law duty of care to plaintiff *and* that he breached the duty by violating the standard of care set forth in a statute. *Id.* The *Steward* court did not acknowledge or explain the tension between its holding and that of *McGuire.* Nonetheless, the Court assumes that *Steward*, which is the more recent of the two cases, represents the Virginia Supreme Court's current view. Accordingly, plaintiff can state a claim for negligence per se only if defendants owed him a duty under Virginia law.

Apparently, no Virginia court has decided whether a company that makes a brand name drug owes a duty to consumers of a generic drug made by another company. However, the Virginia failure to warn decisions, and the weight of authority from other jurisdictions, suggest that the Virginia Supreme Court would not recognize such a duty. *See, e.g.*, *Smith v. Wyeth*, 657 F.3d 420, 424 (6th Cir. 2011) (applying Kentucky law and "reject[ing] the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company"); *Foster v. Am. Home Prods.*, 29 F.3d 165, 171 (4th Cir. 1994) (applying Maryland law and saying, "[w]e think to impose a duty [on the brand manufacturer to generic consumers] would be to stretch the concept of foreseeability too far"); *Metz v. Wyeth LLC,* 830 F. Supp. 2d 1291, 1293 (M.D. Fla. 2011) (applying Florida law, collecting cases, and stating that, "[t]he vast majority of courts . . . have consistently held that consumers may not bring claims for negligence, fraud, strict liability, misrepresentation, or breach of warranty against a brand name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties."); *see also Home Valu, Inc. v. Pep Boys*, 213 F.3d 960, 963 (7th Cir.

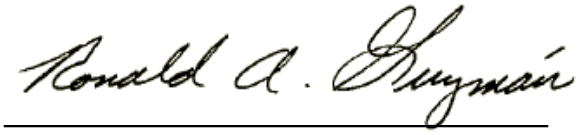
2000) ("When we are faced with two opposing and equally plausible interpretations of state law, we generally choose the narrower interpretation which restricts liability, rather than the more expansive interpretation which creates substantially more liability.") (quotation omitted). Thus, plaintiff cannot state a claim for negligence per se.

In Counts III and IV, plaintiff alleges claims for constructive fraud and fraud, respectively. To state a claim under these theories, plaintiff must allege: "a false representation of a material fact; made intentionally, in the case of actual fraud, or negligently, in the case of constructive fraud; reliance on that false representation to [his] detriment; and resulting damage." *Klaiber v. Freemason Assocs., Inc.*, 587 S.E.2d 555, 558 (Va. 2003). Plaintiff makes the requisite allegations, and despite defendants' argument to the contrary, does so with enough specificity to satisfy Rule 9(b)and Virginia's learned intermediary doctrine. (Compl. ¶¶ 98-115 (alleging that defendants negligently or intentionally "misrepresented the frequency and severity of the psychotic side effects" of Biaxin, and thus generic Clarithromycin, in the labeling it provided to plaintiff's doctor, his doctor and pharmacist reasonably relied on the misrepresentations when they prescribed Biaxin and supplied Clarithromycin to plaintiff, and plaintiff was damaged as a result)); *see Pfizer v. Jones*, 272 S.E.2d 43, 44 (Va. 1980) (characterizing as an "elementary principle[] of law," that "the duty of the [prescription] drug manufacturer is to warn the physician who prescribes the drug in question") (quotation omitted); *see also Talley v. Danek Med., Inc.*, 179 F.3d 154, 162-63 (4th Cir. 1999) ("For products requiring prescription or application by physicians, the [learned intermediary] doctrine holds that a manufacturer need only warn doctors and not consumers."). Moreover, whether the labeling is, in fact, sufficient to defeat the fraud claims, as defendants assert, is an issue that cannot be resolved on a motion to dismiss.

Conclusion

For the reasons set forth above, the Court grants in part and denies in part defendants' motion to dismiss [23]. The motion is granted as to the claims asserted in Counts I and II, which are dismissed with prejudice, and denied as to the claims asserted in Counts III and IV.

SO ORDERED. **ENTERED: June 13, 2014**



HON. RONALD A. GUZMAN
United States District Judge