

**IN THE UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF ILLINOIS, PEORIA DIVISION**

CHESTER JANUS, and	)	
CATHERINE ANN JANUS,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 11-CV-1183
	)	
WRIGHT MEDICAL	)	
TECHNOLOGY, INC., and	)	
WRIGHT MEDICAL GROUP, INC. ,	)	
	)	
Defendants.	)	

**OPINION**

BYRON G. CUDMORE, U.S. MAGISTRATE JUDGE:

This matter comes before the Court on Plaintiffs Chester and Catherine Ann Janus' Motion for Leave to File Amended Complaint (d/e 9) (Motion).<sup>1</sup> The Plaintiffs bring claims against Defendants Wright Medical Technology, Inc., and Wright Medical Group, Inc. (collectively Wright Medical) for injuries arising from an allegedly defective hip replacement medical device implanted into Chester Janus. Notice of Removal, Exhibit A, Tazewell County, Illinois Circuit Court Pleadings, at 26 Complaint at Law.<sup>2</sup> The Plaintiffs seek to file an Amended Complaint

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<sup>1</sup>Plaintiffs' Reply (d/e 18) is ordered stricken as it was filed in violation of Local Rule 7.1(B). The court has not considered reply (d/e 18) in rendering this Opinion.

<sup>2</sup>The Court refers to the pagination placed on the document by the Court's CMECF filing system.

alleging ten claims by Chester Janus and one claim for loss of consortium by Catherine Ann Janus. Motion, Exhibit A, Amended Complaint and Jury Demand (Amended Complaint). Wright Medical opposes the Motion because it argues that filing several of the claims would be futile. For reasons set forth below, the Motion is ALLOWED in part and DENIED in part. The Court also gives the Plaintiffs leave to replead.

Leave to amend pleadings is to be freely given when justice so requires. Fed. R. Civ. P. 15(a)(2). The Court may deny leave to file an amendment to a complaint when the amendment would be futile.

Foman v. Davis, 371 U.S. 178, 182 (1962). Wright Medical argues that filing the proposed Amended Complaint would be futile because several counts would fail to state a claim. In considering such an objection, the test is whether the proposed Amended Complaint states a claim under Federal Rule of Civil Procedure 12(b)(6). See Smart v. Local 702 International Brotherhood of Electrical Workers, 562 F.3d 798, 811 n.15 (7<sup>th</sup> Cir. 2009).

Rule 12(b)(6) requires only “a short and plain statement of the claim showing that the pleader is entitled to relief,” and allegations must be “simple, concise, and direct.” Fed. R. Civ. P. 8(a)(2) & (d)(1). The Court must accept as true all well-pleaded factual allegations and draw all inferences in the light most favorable to pleader. Hager v. City of West Peoria, 84 F.3d 865, 868-69 (7<sup>th</sup> Cir. 1996); Covington Court, Ltd. v. Village

of Oak Brook, 77 F.3d 177, 178 (7<sup>th</sup> Cir. 1996). While a complaint need not contain detailed, specific factual allegations, it must contain sufficient facts to “state a claim to relief that is plausible on its face.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is plausible if the plaintiff “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009). A claim is plausible on its face if it provides the defendant fair notice of what the claim is and the grounds upon which it rests. George v. Smith, 507 F.3d 605, 608 (7<sup>th</sup> Cir. 2007). Dismissal under Rule 12(b)(6) is appropriate when “the factual detail in a complaint [is] so sketchy that the complaint does not provide the type of notice of the claim to which the defendant is entitled under Rule 8.” Airborne Beepers & Video, Inc. v. AT & T Mobility, LLC, 499 F.3d 663, 667 (7<sup>th</sup> Cir. 2007).

In analyzing a complaint under Rule 12(b)(6), the Court does not consider matters outside the pleadings. See Rule 12(d). The Court, therefore, excludes from consideration the material outside the Amended Complaint that have been submitted by the parties.

### STATEMENT OF FACTS

The proposed Amended Complaint alleges that Wright Medical designed, manufactured, imported and distributed the Wright Medical

Profemur Hip System (System). The System is a permanent medical device designed to be implanted into a person as a hip replacement. The System was implanted into Plaintiff Chester Janus on his right side as a hip replacement on November 3, 2003. The Plaintiffs allege the System implanted into Chester Janus's right side catastrophically failed while being used in a normal and expected manner. A portion of the System identified as a modular neck fractured while in normal use. The Plaintiffs allege that Chester Janus had the defective System surgically removed on November 17, 2008.

The Plaintiffs allege that the System implanted into Chester Janus was in the same condition in all relevant respects when it left Wright Medical's control. The Plaintiffs allege that the System was unreasonably dangerous for its intended and/or reasonably foreseeable uses. The Plaintiffs allege that the modular necks in the System were known by Wright Medical to fail from fatigue fractures prior to the date the System was implanted into Chester Janus, and Wright Medical did not warn patients or surgeons of these known failures at the time. Amended Complaint ¶¶ 23(A)(10) and (11) and 23(B)(6) and (7). The Plaintiffs further allege that Wright Medical violated federal statutes and regulations governing the manufacture and distribution of medical devices such as the System, specifically 21 U.S.C. § 351 and 360j, and 21 C.F.R. §§ 820.1,

820.22, 820.30, 820.70, 820.75, and 820.90. Amended Complaint ¶¶

36-68. The Plaintiffs allege that Wright Medical misrepresented in its marketing, advertising, promotions and labeling that the System was safe and met all applicable design and manufacturing requirements. Id.

¶¶ 117-18.

Based on these allegations, the Plaintiff Chester Janus alleges products liability claims for defective manufacturing (First Cause of Action), design defect (Second Cause of Action), nonconformance with representations (Third Cause of Action), and failure to warn and instruct (Fourth Cause of Action); negligence (Fifth Cause of Action); breach of express warranty (Sixth Cause of Action); breach of implied warranty (Seventh Cause of Action); negligent misrepresentation (Eighth Cause of Action); negligence per se (Ninth Cause of Action); and punitive damages for fraud, malice or willful and wanton conduct (Eleventh Cause of Action). Plaintiff Catherine Ann Janus alleges a claim for loss of consortium (Twelfth Cause of Action).<sup>3</sup> Wright Medical argues that filing the proposed Amended Complaint would be futile because the Third, Eighth, Ninth, and Eleventh Causes of Actions fail to state a claim, and the Twelfth Cause of Action improperly refers to the Illinois Consumer Protection Act in the prayer. The Court will address each disputed Cause of Action in order.

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<sup>3</sup>There is no Tenth Cause of Action.

### Third Cause of Action

The Plaintiffs allege that when the System left Wright Medical, it did not conform to Wright Medical's representations about the System and/or applicable federal regulations. The Plaintiffs allege that Chester Janus' surgeon relied on Wright Medical's representations about the System. The Plaintiffs allege that Chester Janus suffered injuries as a result of this reliance on Wright Medical's representations about the System and/or Wright Medical's failure to comply with applicable federal regulations.

Amended Complaint ¶¶ 79-83.

Wright Medical argues that Illinois does not recognize any products liability claim for a product's nonconformance to representations or regulations. Wright Medical cites authority that a products liability claim has four elements: (1) the plaintiff's injury resulted from the condition of a product; (2) the condition of the product was unreasonably dangerous; (3) the unreasonably dangerous condition existed when the product left the defendant's control; and (4) the dangerous condition was the proximate cause of the injury. Wright Medical's Response to Plaintiffs' Motion for Leave to File Amended Complaint (d/e 17) (Response), at 7 (citing Bilski v. Scientific Atlanta, 964 F.2d 697, 699 (7<sup>th</sup> Cir. 1992)). Wright Medical argues that the allegations in the Third Cause of Action do not state these four elements.

The Court agrees that the Third Cause of Action does not state a product liability claim for defective manufacture or design. The Third Cause of Action, however, states a claim under a representational theory of products liability. The representational theory focuses on the manufacturer's representations about a products safety and efficacy for a particular use:

In those cases in which a manufacturer explicitly or implicitly represents that its product possesses certain characteristics that it does not actually possess, the representational theory would impose liability on the manufacturer for the resulting injury that reasonable use of the product causes.

Smith v. American Motors Sales Corp., 215 Ill.App.3d 951, 576 N.E.2d 146, 152 (Ill. App. 5<sup>th</sup> Dist. 1991) and authorities cited therein; see Restatement Second of Torts, § 402B. The Plaintiffs' allegations about the alleged misrepresentations are sufficient to give Wright Medical notice of the basis for the claim. The Court, therefore, finds that filing the Third Cause of Action would not be futile.

#### Eighth Cause of Action

The Eighth Cause of Action alleges that Wright Medical in the exercise of reasonable care should have known that the System "failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Wright Medical negligently misrepresented to Plaintiff Chester Janus . . . that its device was safe and

met all applicable design and manufacturing requirements.” Amended Complaint ¶ 117. The Plaintiffs further allege that Wright Medical made these misrepresentations “in their marketing, advertisements, promotions and labeling concerning these products for use in patients such as plaintiff Chester Janus.” Id. ¶ 118. The Plaintiffs allege that Chester Janus and his surgeon relied on these misrepresentations, and that the misrepresentations proximately caused Chester Janus’ injuries from the defective System implanted in his body. Id. ¶¶ 119-122.

Wright Medical argues that the Eighth Cause of Action fails to state a claim because the Plaintiffs do not allege that Wright Medical intended to induce Plaintiffs to act on its misrepresentations. Response, at 9. The elements of negligent misrepresentations are: (1) misstatement of material fact; (2) the defendant’s negligence in ascertaining the truth concerning the misstatement; (3) the defendant’s intent to induce the plaintiff to rely on the misrepresentation; (4) justifiable reliance; and (5) damages. See Sassak v. City of Park Ridge, 431 F.Supp.2d 810, 818 (N.D. Ill. 2006). Wright Medical argues that the Amended Complaint fails to allege the element of intent. The Court disagrees. The Plaintiffs allege that Wright Medical made these misrepresentations in its marketing, advertising, promotional material, and product labeling. This allegation is sufficient to put Wright Medical on notice that the Plaintiffs allege that Wright Medical made these



representations with the intent to induce potential patients and physicians to select the System for use as an implant for hip replacement. The function of advertising, marketing, and promotional material is to induce consumers to select and purchase a product. Filing the Eighth Cause of Action, therefore, would not be futile.

#### Ninth Cause of Action

The Ninth Cause of Action alleges that: (1) Wright Medical violated applicable federal statutes and regulations governing the manufacture and distribution of medical devices such as the System; (2) these statutes and regulations were intended to protect individuals such as Chester Janus from the type of injury he suffered from the defective System that was implanted into his body; and (3) Wright Medical's violations of the applicable statutes and regulations proximately caused Chester Janus' injuries. These allegations are sufficient to state a claim in Illinois for negligence per se. See Heisner ex rel Heisner v. Genzyme Corp., 2008 WL 2940811, \*6 (N.D. Ill. 2008).

Wright Medical argues that the Plaintiffs must give Wright Medical notice of the statutes and regulations that it allegedly violated. The Plaintiffs have done so. The Plaintiffs allege that Wright Medical violated 21 U.S.C. § 351 and 360j, and 21 C.F.R. §§ 820.1, 820.22, 820.30, 820.70, 820.75, and 820.90. Amended Complaint ¶¶ 36-68. This is sufficient

notice. Wright Medical relies on Heisner to support its argument of insufficient notice. In Heisner, the plaintiffs failed to state a claim because they alleged the wrong regulations in their complaint. Heisner, 2008 WL 2940811 at \*6. That did not occur here. Filing the Ninth Cause of Action would not be futile.

#### Eleventh Cause of Action

The Plaintiffs allege that Wright Medical acted with fraud, malice or in a wilful and wanton manner when it committed the allegedly wrongful conduct that forms the basis of Chester Janus' claims in the First through Ninth Causes of Actions. Based on these allegations, the Plaintiffs ask for punitive damages. These allegations state a claim for punitive damages. Punitive damages are allowed in Illinois for wrongful conduct done maliciously or in a wilful and wanton manner. Kelsay v. Motorola, Inc., 74 Ill.2d 172, 186, 384 N.E.2d 353, 360 (Ill. 1978).

Wright Medical argues that the Eleventh Cause of Action fails to state a claim for punitive damages because fraud must be pled with particularity. Wright Medical correctly states the requirements for pleading fraud; however, malice may be pled generally. Fed. R. Civ. P. 9(b). Thus, filing the Eleventh Cause of Action would be futile to the extent that the Plaintiffs attempt to allege fraud, but the Eleventh Cause of Action states a claim for punitive damages based on malice. The Court therefore denies the Motion

with respect to the Eleventh Cause of Action, but gives the Plaintiffs leave to replead the Eleventh Cause of Action without the reference to fraud.

Wright Medical also argues that Rule 11 requires the Plaintiffs to prove allegations of fraud and malice in order to secure leave to amend the Complaint to add a claim for punitive damages. Response, at 5-6. Wright Medical is incorrect. Rule 15 governs amendments to pleadings. Rule 15 does not require evidence in order to secure leave to amend. Leave to amend is to be freely given when justice so requires. Fed. R. Civ. P. 15(a)(2). Wright Medical has argued that the amendment would be futile for failure to state a claim. See Foman, 371 U.S. at 182; Smart, 562 F.3d 798, 811 n.15. In determining whether a proposed amendment would be futile for failure to state a claim, the Court assumes the allegations are true; the Court does not consider evidence outside the pleadings. Fed. R. Civ. P. 12(d); Hager, 84 F.3d at 868-69; Covington Court, Ltd., 77 F.3d at 178. Thus, the Plaintiffs are not required to prove their allegations at this stage in the proceedings.

Furthermore, Rule 11 does not require a party to present evidence before filing a pleading. Rather, Rule 11 states that the person signing a pleading certifies the propriety of the pleading. In this case, Plaintiffs' counsel has certified by signing and filing the Motion that, after reasonable inquiry under the circumstances: (1) the Motion was not presented for an

improper purpose; (2) the claims set forth in the proposed Amended Complaint are warranted under existing law or by nonfrivolous arguments for extending or modifying existing law; and (3) the factual allegations in the proposed Amended Complaint will likely have evidentiary support after a reasonable opportunity for further investigation or discovery. Fed. R. Civ. P. 11(b) (1), (2) and (3). The Court sees no basis to doubt counsel's certification.

If Wright Medical believes the Plaintiffs' counsel violated Rule 11, it must file a separate motion for sanctions in accordance with the procedures set forth in Rule 11(c)(2). Wright Medical has not done so. Rule 11, therefore, is not at issue at this time. Rather, as explained above, the Plaintiffs have been granted leave to replead the Eleventh Cause of Action without the reference to fraud.

#### Twelfth Cause of Action

Wright Medical complains that the Twelfth Cause of Action improperly refers to the Illinois Consumer Protection Act. The Court agrees. The Twelfth Cause of Action is a loss of consortium claim. The claim is based on the allegedly tortious acts committed against Catherine Ann Janus' husband Chester. Amended Complaint ¶¶ 136-137. Plaintiff Chester Janus does not allege any violation of any Illinois consumer protection

statute; thus Catherine Ann Janus' injuries are not derived from any such violation.

Filing the Twelfth Cause of Action would be futile to the extent that Catherine Ann Janus asks for relief under any Illinois consumer protection statute. The Court, therefore, denies the Motion with respect to the Twelfth Cause of Action, but grants Plaintiffs leave to replead the Twelfth Cause of Action without the reference to the Illinois Consumer Protection Act.

WHEREFORE, Plaintiffs Chester and Catherine Ann Janus' Motion for Leave to File Amended Complaint (d/e 9) is ALLOWED in part and DENIED in part. The Court denies Plaintiffs' request to amend its Complaint to add the proposed Eleventh and Twelfth Causes of Action set forth in the proposed Amended Complaint attached to the Motion, but grants the Plaintiffs leave to replead those two causes of action in accordance with this Opinion and to file a Second Amended Complaint. The Plaintiffs are directed to file the Second Amended Complaint, if any, by January 6, 2012. The Defendants are directed to file their response by January 27, 2012.

ENTER: December 20, 2011

s/ Byron G. Cudmore  
BYRON G. CUDMORE  
UNITED STATES MAGISTRATE JUDGE