IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

JEFFREY T. TIERNEY, Plaintiff, v. AGA MEDICAL CORPORATION, Defendant.	)	4:11CV3098 MEMORANDUM AND ORDER

The defendant, AGA Medical Corporation ("AGA"), has moved to dismiss this product liability action for failure to state a claim that is not preempted by federal law. The plaintiff, Jeffrey T. Tierney ("Tierney"), argues that AGA's motion is premature and requests that he be allowed to conduct discovery and then amend his complaint to allege an actionable claim. For the reasons discussed below, the motion to dismiss will be granted and judgment will be entered dismissing the action with prejudice.

I. BACKGROUND

A. Plaintiff's Claims

In his complaint,[1] Tierney alleges that in May 2005 an AMPLATZER® Septal Occluder ("ASO") device designed, manufactured, and sold by AGA was medically inserted in his heart to plug a hole. Tierney claims he subsequently experienced severe headaches, transient ischemic attacks, seizure disorders, memory issues, osteoporosis, and tachycardia, which were diagnosed in April 2008 as being symptoms of a nickel

[1]Tierney's complaint was filed in June 2011 in the District Court of Douglas County, Nebraska, but AGA promptly removed the action to this court based on diversity jurisdiction. *See* 28 U.S.C. §§ 1332, 1441.

allergy and attributed to the implanted ASO device. Tierney states the ASO device was medically removed from his heart in October 2008.

The complaint contains two counts: negligence and strict liability. Tierney claims AGA was negligent in "failing to exercise ordinary care in the circumstances," "failing to adequately test this ASO before it was put into the stream of commerce," "failing to warn [him] of the nickel content of this ASO," "failing to have issue[d] adequate warnings concerning the hazards to patients including [Tierney] that it's[sic] ASO could be inserted in patients with nickel allergies," "failing to design an ASO without nickel content," "failing to manufacture an ASO without nickel content," "selling [this] ASO when it knew same was defective with its nickel content, "failing to properly research and test this ASO to determine it was hazardous to patients with a nickel allergy," "failing to warn doctors not to insert this ASO in patients with nickel allergy," "failing to remove the nickel content of this ASO," "failing to recall this ASO from its market," "designing, producing, manufacturing, distributing, selling and placing this ASO into the stream of commerce," "failing to perform, it [sic] continuing non-delegable duty in respect to this ASO, that is, to withdraw it from the market for use due to the unreasonable dangers of this ASO because of its nickel content," and "failing to warn patients, including [Tierney], of the ASO's nickel content." (Filing 1 at 5.) For his strict liability claim, Tierney additionally alleges AGA "designed, produced, manufactured, distributed, marketed and sold this ASO in a defective condition which made it unreasonably dangerous to the patients receiving same including [him]." (Filing 1 at 7.)

B. FDA Approval of the ASO Device

In support of its motion to dismiss, AGA has filed three exhibits[2] which are available online at the official web site of the Food and Drug Administration ("FDA"):

[2]AGA's index of evidence (filing 9) lists a fourth exhibit, a notice published in the Federal Register (available online at the official web site of the Government Printing Office), but it was not filed.

(1) a "brief overview of information related to the FDA's approval to market [AGA's AMPLATZER® Septal Occluder]"[3] (filing 9-1 at 1-2), including a link to the ASO "approval letter"[4] (filing 9-1 at 3-9)[5]; (2) a "premarket approval (PMA)"[6] for the ASO device (filing 9-2)[7]; and (3) a "device classification"[8] information sheet (filing 9-3). Tierney has not objected to the court's consideration of these exhibits,[9] which establish that the FDA granted premarket approval to the ASO device in 2001.

II. DISCUSSION

A. Rule 12(b)(6) Standard

Under Federal Rule of Civil Procedure 12(b)(6), "[d]ismissal is proper where the plaintiff's complaint fails to state a claim upon which relief can be granted."

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[3]http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083978.htm

[4]http://www.accessdata.fda.gov/cdrh_docs/pdf/P000039a.pdf

[5]AGA's evidence index (filing 9) also references links to the agency's "Summary of Safety and Effectiveness" and "Instructions for Use," but these documents are not included in the filed exhibits.

[6]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=1631

[7]The filed exhibit is incomplete and web page listed on the exhibit is outdated.

[8]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

[9]"In addressing a motion to dismiss, '[t]he court may consider the pleadings themselves, materials embraced by the pleadings, exhibits attached to the pleadings, and matters of public record.'" *Illig v. Union Elec. Co.*, 652 F.3d 971, 976 (8th Cir. 2011) (quoting *Mills v. City of Grand Forks*, 614 F.3d 495, 498 (8th Cir. 2010)). I find that AGA's exhibits are properly considered as matters of public record. *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (district court took appropriate judicial notice of publicly available FDA documents).

Northstar Indus., Inc. v. Merrill Lynch & Co., 576 F.3d 827, 831-32 (8th Cir.2009). "To survive a motion to dismiss, the factual allegations in a complaint, assumed true, must suffice 'to state a claim to relief that is plausible on its face.'" *Id.* at 832 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Thus, "although a complaint need not include detailed factual allegations, 'a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *C.N. v. Willmar Pub. Sch., Indep. Sch. Dist. No. 347*, 591 F.3d 624, 629-30 (8th Cir. 2010) (quoting *Twombly*, 550 U.S. at 555).

B. Medical Device Amendments of 1976

"In the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ('MDA'), Congress authorized the Food and Drug Administration ('FDA') to regulate the safety and effectiveness of medical devices." *In re Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010). "Transcatheter septal occluder" devices, including AGA's product, are highly regulated as Class III devices under the MDA because while they may be "use[ful] in supporting or sustaining human life or in preventing impairment of human health," they also "present a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). "Before a new Class III device may be marketed, the manufacturer must assure the FDA through a rigorous Pre-Market Approval ('PMA') process that the device is safe and effective." *In re Medtronic, Inc.*, 623 F.3d at 1203. "Once the product is approved, the manufacturer may not change its design, manufacturing process, labeling, or other attributes that would affect safety or effectiveness without filing a PMA Supplement . . . [which] is reviewed using the same standard as the original PMA." *Id.*

The MDA contains an express preemption provision which prohibits states and political subdivisions from imposing any requirement "which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device or to any other matter included in

a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). The Supreme Court has construed this statutory provision to mean that common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA are barred. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

C. Preemption of Plaintiff's Claims

"[P]reemption is an affirmative defense." *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 886 (8th Cir. 2005). "If an affirmative defense . . . is apparent on the face of the complaint, however, . . . [it] can provide the basis for dismissal under Rule 12(b)(6)." *Noble Systems Corp. v. Alorica Central, LLC*, 543 F.3d 978, 983 (8th Cir. 2008). "[T]his means simply that the district court is limited to the materials properly before it on a motion to dismiss, which may include public records and materials embraced by the complaint." *Id.*

Tierney does not dispute that the negligence and strict liability claims alleged in his complaint are preempted by the MDA, but suggests he should be permitted to amend the complaint to add claims alleging that "[t]he design of the ASO failed to comply with the FDA's specifications as contained in the Premarket Approval assessment" and that "[t]he ASO was manufactured in a manner that failed to comply with the FDA's specifications as contained in the Premarket Approval assessment." (Filing 11 at 1.) Apparently recognizing that these allegations are also insufficient to withstand a motion to dismiss, Tierney "requests time to conduct discovery for the purpose of obtaining access to Defendant's PMA files in order to state his amended complaint with more specificity." (Filing 11 at 1.)

Tierney's prospective claims rely on the Supreme Court's qualifying statement in *Riegel* that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 330. The discovery request is based on the Court of Appeals' observation in *In re Medtronic, Inc.*, that

"in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit," it could be argued with "considerable force" that stringent application of the *Twombly* rule would impose an "impossible pleading standard." 623 F.3d at 1206.

D. Plaintiff's Request for Discovery and Leave to Amend

Importantly, Tierney has not filed a separate motion for leave to amend his complaint. Instead, he has concluded his opposing brief by "ask[ing] this Court to deny Defendant's motion to dismiss as premature, and to permit him 180 days in which to conduct discovery and amend his Complaint." (Filing 11 at 3.) This request will be denied.

"A request for a court order must be made by motion . . . [which] must . . . state with particularity the grounds for seeking the order . . . and . . . state the relief sought." Fed. R. Civ. P. 7(b)(1). In addition, under our local rules, "[a] party who moves for leave to amend a pleading . . . must file as an attachment to the motion an unsigned copy of the proposed amended pleading that clearly identifies the proposed amendments." NECivR 15.1(a).

> "Although Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend 'shall be freely given when justice so requires,' there is no absolute or automatic right to amend one's complaint." *Deutsche Fin. Servs. Corp. v. BCS Ins. Co.*, 299 F.3d 692, 700 (8th Cir.2002). . . . "A district court does not abuse its discretion in failing to invite an amended complaint when plaintiff has not moved to amend and submitted a proposed amended pleading." *Carlson v. Hyundai Motor Co.*, 164 F.3d 1160, 1162 (8th Cir.1999); *see also Clayton v. White Hall Sch. Dist.*, 778 F.2d 457, 460 (8th Cir.1985) (finding no abuse of discretion where plaintiff merely sought leave to amend at the conclusion of her response to the motion to dismiss and saying, "in order to preserve the right to amend the complaint, a party must submit the proposed amendment along with its motion."). All civil

> litigants are required to follow applicable procedural rules. *See* *Beck v. Skon*, 253 F.3d 330, 333 (8th Cir.2001).

Meehan v. United Consumers Club Franchising Corp. 312 F.3d 909, 913-14 (8th Cir. 2002). *See also* *O'Neil v. Simplicity, Inc.*, 574 F.3d 501, 505 (8th Cir. 2009) ("A district court does not abuse its discretion in denying leave to amend where a plaintiff has not followed applicable procedural rules."); *Drobnak v. Andersen Corp.*, 561 F.3d 778, 788 (8th Cir.2009) ("We have previously affirmed orders denying a plaintiff's conditional request for leave to amend in cases in which the substance of the proposed amendment was unclear and the local rules were not followed.").

Tierney has expressed a desire to amend his complaint to allege that the ASO device was not designed and manufactured in accordance with FDA specifications, but "legal conclusions, without any supporting factual allegations, are insufficient to survive a motion to dismiss." *Walker v. Barrett*, 650 F.3d 1198, 1209 (8th Cir. 2011) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009)). Tierney must allege sufficient facts to show that AGA "violated a federal requirement specific to the FDA's PMA approval of this Class III device." *In re Medtronic, Inc.*, 623 F.3d at 1207. While "courts must exercise [care] in applying *Riegel*'s parallel claim principle at the pleading stage, particularly to manufacturing defect claims," *id.*, "a plaintiff must offer sufficient factual allegations to show that he or she is not merely engaged in a fishing expedition . . .." *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 597 (8th Cir. 2009).

Tierney has only alleged that had an allergic reaction to the implanted ASO device because of its nickel content. Although he has asserted in his brief that he "requires time for discovery in order to determine the extent to which the Defendant failed to comply with the specific requirements imposed upon it by the FDA" and "requires information regarding the methods of manufacturing the specific device which injured him" (filing 11 at 3), Tierney has not demonstrated any actual need for gaining access to PMA file documents that are not already publicly available. *See* 21 C.F.R. § 814.9 (providing for public disclosure of certain PMA file documents).

Despite AGA's failure to file printed copies of the "Summary of Safety and Effectiveness [Data]" and "Instructions for Use" documents which are specifically referenced in AGA's index of evidence (filing 9), I will take judicial notice of these documents because they are public records which are available on the FDA's web site[10] and which are linked directly to AGA's Exhibits "A" and "C" (filings 9-1, 9-2). The "Summary of Safety and Effectiveness Data"[11] document specifies (on page 2) that "[t]he AMPLATZER® Septal Occluder is a self-expandable, double disc device made from a Nitinol wire mesh" and explains (on page 11) that Nitinol is "a nickel-titanium alloy." The document also states (on page 11) that "[s]ufficient information from the literature exists to demonstrate biocompatability of the Nitinol for use in an implantable device." Significantly, however, the "Instructions for Use"[12] of the ASO device, which are dated June 14, 2002, warn (on page 2) that "[p]atients allergic to nickel may suffer an allergic reaction to this device."

III. CONCLUSION

In summary, AGA's motion to dismiss is not premature. The uncontroverted evidence establishes, and Tierney implicitly concedes, that the complaint fails to state a claim upon which relief can be granted because the claims alleged merely challenge the safety of an inherently dangerous Class III medical device that received premarket approval from the FDA. Consequently, it is appropriate that the plaintiff's action be dismissed with prejudice pursuant to Rule 12(b)(6). *See In re Medtronic, Inc.*, 623 F.3d at 1205-07.

However, this judgment will not preclude Plaintiff from bringing an action predicated upon a factually supported claim that "[t]he design of the ASO failed to

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[10] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P000039

[11] http://www.accessdata.fda.gov/cdrh_docs/pdf/P000039b.pdf

[12] http://www.accessdata.fda.gov/cdrh_docs/pdf/P000039c.pdf

comply with the FDA's specifications as contained in the Premarket Approval assessment" or predicated upon a factually supported claim that "[t]he ASO was manufactured in a manner that failed to comply with the FDA's specifications as contained in the Premarket Approval assessment" *providing* that such an action complies with Rule 11 of the Federal Rules of Civil Procedure.

Accordingly,

IT IS ORDERED:

1. Defendant's motion to dismiss (filing 7) is granted.

2. Plaintiff's informal requests for discovery and for leave to amend are denied.

3. Final judgment shall be entered by separate document.

November 18, 2011. BY THE COURT:

Richard G. Kopf
United States District Judge

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*This opinion may contain hyperlinks to other documents or Web sites. The U.S. District Court for the District of Nebraska does not endorse, recommend, approve, or guarantee any third parties or the services or products they provide on their Web sites. Likewise, the court has no agreements with any of these third parties or their Web sites. The court accepts no responsibility for the availability or functionality of any hyperlink. Thus, the fact that a hyperlink ceases to work or directs the user to some other site does not affect the opinion of the court.