IN THE CIRCUIT COURT FOR MONTGOMERY COUNTY, MARYLAND

DIANE MCDONALD-LERNER, M.D., *et al.*,	:	
	:	
Plaintiffs,	:	
	:	**Case No. 373859-V**
v.	:	
	:	
	:	
NEUROCARE ASSOCIATES, P.A., *et al.*,	:	
	:	
Defendants.	:	

MEMORANDUM AND ORDER

This court held a hearing on August 27, 2013, on the defendants' motions to dismiss the plaintiffs' first amended complaint. The federal preemption issues that swirl around a medical device manufacturer's promotion of off-label uses of medical devices approved by the federal Food and Drug Administration ("FDA") have been extensively briefed by all counsel. The only court that can definitively resolve the preemption issues presented in cases of this type is the Supreme Court. Given the volume of litigation involving the product at issue, it is quite likely that a case similar to this one will be decided by the Supreme Court at some point and the preemption questions will be finally resolved. But for now, lower courts across the country, federal and state, must wrestle with these questions. This court understands that the stakes for all concerned, legally and monetarily, are substantial.

For the reasons set forth below, the defendants' motions to dismiss are denied.

Background

On February 25, 2013, the plaintiffs, Diane L. McDonald-Lerner, M.D. and Roger J. Lerner ("the plaintiffs") sued Medtronic, Inc., Medtronic Safamor Danek, USA, Inc. ("Medtronic" or the "Medtronic defendants"), and Michael K. Rosner, M.D. and Neurocare

Associated, P.A. ("the physician defendants"). An amended complaint was filed on March 21, 2013.

The crux of the case concerns spinal surgery performed on Dr. McDonald-Lerner on January 10, 2008, by Dr. Rosner at Holy Cross Hospital in Montgomery County, Maryland. According to the amended complaint, Dr. Rosner performed a posterior approach transforaminal lumbar interbody fusion using Infuse®, which is manufactured and distributed by the Medtronic defendants. The plaintiffs allege that Dr. Rosner used only the morphogenetic protein-2 component of this medical device and performed the surgery using a posterior approach, which was contrary to the FDA mandated product label. This off-label use–using the bone protein component only and performing the surgery through a posterior approach–the plaintiffs contend, resulted in a cystic growth on the L5-S1 disc, impinging on the nerve root, and an osteophyte complex at L5-S1, all of which resulted in severe injury and recurrent pain to Dr. McDonald-Lerner.

With respect to the Medtronic defendants, the plaintiffs have alleged four causes of action: strict liability - design defect; strict liability - failure to warn; negligence; and fraud. The physician defendants have been sued for medical malpractice - lack of informed consent, and Dr. Rosner also is sued for fraud.

The FDA, through its Premarket Approval Process ("PMA"), approved Infuse® as a Class III medical device. Generally speaking, a Class III medical device is the type of medical device that presents the greatest potential risk for injury or illness to the patient. 21 U.S.C. § 360c(a)(1)(C)(ii). Among other things, the PMA application must specify the intended use of the product. 21 U.S.C. § 360e(c)(2)(A)(iv). According to the amended complaint, surgery with this Class III medical device was approved by the FDA only for a single method of use, an anterior

(through the abdomen) lumbar approach. The June 2, 2002 FDA approval letter specifically provided in this regard: "Infuse® Bone Graft/LT-Cage Devices are to be implanted via an anterior open or anterior laparoscopic approach."

The plaintiffs also contend that the FDA approved Infuse® as a medical device only when all components were used together. Infuse® has three parts: first, a recombinant human bone morphogenetic protein-2; second, an absorbable collagen sponge; and third, an interbody fusion device (the "L-T Cage"). The approval letter from the FDA expressly refers to the product as "the Infuse® Bone Graft/L-T Cage Lumbar Tapered Fusion Device" five separate times. Similarly, the 2002 FDA labeling approved by the FDA stated, in describing the use of the product: "These components must be used as a system. The Infuse® Bone Graft component must not be used without the LT-Cage Lumbar Tapered Fusion Device component." (Emphasis in original). In other words, according to the plaintiffs, as evidenced by the FDA approval letter and FDA labeling requirements, the FDA approved the Infuse® as a medical device only as a whole, not its component parts, and this device was approved only for an anterior surgical procedure.[1]

Infuse® has been the subject of considerable controversy. For example, the Department of Justice ("DOJ") took over two *qui tam* lawsuits that had been filed against Medtronic in 2002 and 2003. It was alleged in these cases that between January 1, 1998 and April 30, 2003, Medtronic was actively promoting the off-label use of Infuse® and paying physicians to do so as well. On July 18, 2006, Medtronic entered into a settlement of these cases with the DOJ, agreeing to pay $40 million to the United States Treasury to resolve claims filed against it under the federal False Claims Act, the Civil Monetary Penalties Act, and the Program Fraud Civil

[1] Subsequently, the FDA approved minor changes to the labeling requirements on July 29, 2004 and March 9, 2007. These approved changes were based on supplemental requests submitted by Medtronic, none of which are relevant to this case.

Remedies Act. As part of this settlement, Medtronic also entered into a five-year "corporate integrity agreement," which required tighter internal controls and the reporting of any payments made to physicians to promote Infuse®.

According to the amended complaint, notwithstanding this settlement with the government, Medtronic continued to actively promote the off-label use of Infuse® and continued paying physicians to promote off-label uses, as it had done in the past. As a result, it is alleged that the off-label use of Infuse® continued to increase, and, by 2011, off-label use constituted more than 90% of the total procedures using this medical device. Allegedly, Medtronic has continued to pay physicians millions of dollars to tout the benefits of off-label use of Infuse®.

In light of these events and emerging scientific data regarding adverse events from the off-label use of Infuse®, on July 1, 2008, the FDA issued a written notice to physicians warning of the serious complications that resulted from the off-label use of Infuse®. Similar reports of adverse results from the off-label use of Infuse® were published in the September 2008 edition of *The Spine Journal* and the July 2009 edition of the *Journal of the American Medical Association.* In June 2011, *The Spine Journal* published a special edition that discussed the deficiencies in Medtronic's earlier clinical trials, Medtronic's failure to report adverse events, and the increased risk of patient complications from the off-label use by Infuse®.

Medtronic Moves to Dismiss the Plaintiffs' Claims

On April 29, 2013, the Medtronic defendants moved to dismiss the amended complaint, contending that all of the plaintiffs' claims are expressly preempted by 21 U.S.C. § 360k(a), as construed by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The physician defendants joined this motion on May 16, 2013. With leave of court, the plaintiffs'

opposition to the motions to dismiss was filed on June 17, 2013. Since that time, each side has regularly updated the court as new opinions came out, for or against dismissal based on federal preemption.

The reason for this deluge of court decisions is that this lawsuit is a by-product of nationwide litigation involving what is alleged to be the tremendous off-label use of Infuse® by physicians. The plaintiffs allege that this resulted from Medtronic's own aggressive promotion of Infuse® for off-label uses, off-label promotion by physicians to whom Medtronic paid millions in "fees," and the knowing concealment of adverse results from the use of the bone protein alone.

Physicians may use FDA-approved medical devices in any way they see fit, either on-label or off-label. 21 U.S.C. § 396. This is because the states, not the federal government through the FDA, regulate the practice of medicine. *See Buckman*, 531 U.S. at 350. But, according to the amended complaint, medical device manufactures like Medtronic are prohibited by federal law from promoting off-label uses or paying physicians to tout off-label uses. Understandably, the defendants' vehemently disagree with most, if not all, of the plaintiffs' contentions.

The legal question as framed by the defendants is whether a state tort suit against a medical device manufacturer for any use of a device or any of its components, on or off-label, even if that use violates federal law, is expressly preempted by 21 U.S.C. §360k(a). This court believes that the defendants improperly framed the issue. According to the plaintiffs, and based on the allegations of the amended complaint, the real question presented is whether the Medtronic defendants, having received FDA approval of a specific medical device for a specific use under the label may nevertheless promote off-label uses, different than those approved by the

FDA, but immunize themselves via the doctrine of preemption from state tort liability. This court believes not.

Governing Legal Standards

In ruling on a motion to dismiss under Md. Rule 2-322(b), the court accepts as true all well-pled facts in the amended complaint and any reasonable inferences derived from those facts in a light most favorable to the non-moving party. Review at this juncture is cabined to the pertinent pleading and any documents attached to or incorporated into that pleading by reference. The court's objective at this point simply is to see whether relief can or cannot be granted on the basis of the facts alleged in the amended complaint as a matter of law. *Converge Servs. Grp., LLC v. Curran*, 383 Md. 462, 475 (2004); *Kendall v. Howard County*, 204 Md. App. 440, 446-47 (Md. Ct. Spec. App. 2012).

Boilerplate or conclusory allegations do not receive the benefit of this forgiving standard. *RRC Northeast,LLC, v. BAA Maryland, Inc.*, 413 Md. 638, 644 (2010). "[A]ny ambiguity or uncertainty in the allegations bearing on whether the complaint states a cause of action must be construed against the pleader." *Ronald M. Sharrow, Chtd. v. State Farm Mut. Auto. Ins. Co.*, 306 Md. 754, 768 (1986); *cf. Berman v. Karvounis*, 308 Md. 259, 265 (1987) ("what we consider are allegations of fact and inferences deducible from them, not merely conclusory charges"). A claimant still must allege sufficient facts to constitute a cause of action. *Ver Brycke v. Ver Brycke*, 379 Md. 669, 696-97 (2004); *Scott v. Jenkins,* 345 Md. 21, 27-28 (1997); *see* PAUL V. NIEMEYER & LINDA M. SCHUETT, MARYLAND RULES COMMENTARY 180 (3d ed. 2003) ("[A] pleading that fails to allege [legally sufficient] facts, or that fails to demand a particular form of relief, fails to fulfill the purposes of pleading.").

Discussion

The premarket approval process for a Class III medical device under federal law is, and is intended to be, a rigorous process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). After approval through the PMA process, the manufacturer cannot change the design, specifications, manufacturing process or labeling of the medical device without prior FDA approval. *Riegel*, 552 U.S. at 319, citing 21 U.S.C. § 360e(d)(6)(A)(i). By statute, Congress has made the policy decision to impose intense federal scrutiny on manufacturers before a medical device can enter the stream of commerce. This was, in part, in exchange for the preemption of certain types of state tort liability, if and when the device is used according to its labeling. Medical Device Amendments of 1976 ("MDA"), Pub. L. No. 94-295, 90 Stat. 539 (1976). As a consequence of this policy choice, effectuated by the FDA's pervasive regulatory authority over medical devices, Congress has decreed that no state "may establish or continue in effect" with respect to an FDA-approved medical device, any requirement "which is different from, or in addition to, any requirement applicable" under federal law. 21 U.S.C. § 360k(a).

The rules governing express preemption in medical device cases were fundamentally established by two Supreme Court cases, *Medtronic, Inc. v. Lohr* and *Riegel v. Medtronic, Inc.* In *Lohr*, the product was alleged to have been defectively manufactured in violation of the specific manufacturing standards approved by the FDA. 518 U.S. at 492-96. The plaintiffs alleged that Medtronic, in defectively manufacturing the medical device, had violated Florida law on negligence and strict liability. *Id.* at 481. The Supreme Court held that this was a parallel state law claim and, as such, was not expressly preempted by 21 U.S.C. § 360k. The Court held: "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

The Court further held that "the Lohrs' common-law claims were not pre-empted by the federal label and manufacturing requirements." *Id.* at 501.

In *Riegel*, the Supreme Court again addressed express preemption as it pertains to medical devices. In that case, the plaintiff's physician used an approved medical device in a manner contrary to the warnings on the FDA approved label. 552 U.S. at 320. The plaintiffs sued Medtronic, contending that the device was designed, labeled and manufactured in a manner that violated New York law, and that these defects caused the harm. *Id.* at 320. Medtronic argued that the suit was expressly preempted because the plaintiffs sought to impose state requirements that differed from or added to the device-specific federal requirements. *Id.* at 321.

The *Riegel* Court began its analysis by considering whether the express preemption provision of the MDA was triggered because premarket approval was "substantially informed" by the FDA's regulations. *Id.* at 322. As the Court noted, the FDA regulations in question stated that state law is preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device . . ." *Id.* at 322, quoting 21 C.F.R. § 808.1(d). Concluding that they did, the Court next addressed whether the plaintiffs' state law claims rely on any "requirement" of state law different from, or in addition to, federal law. 552 U.S. at 323. Although adhering to the *Lohr* parallel claim exception, *Id.* at 329, the Supreme Court in *Riegel* concluded that New York law added safety requirements to federal law and thus the plaintiffs' claims in *Riegel* were expressly preempted. *Id.* at 323-24.

The Supreme Court addressed implied preemption in *Buckman.* In that case, the plaintiffs sued a consulting company that had assisted the manufacturer in obtaining FDA approval for "orthopedic bone screws in the pedicles of their spine." 531 U.S. at 344. The

plaintiffs contended that this consulting company made fraudulent representations to the FDA when it assisted the manufacturer in obtaining approval. *Id.* The plaintiffs sought damages under Pennsylvania law. *Id.*

Pertinent to *Buckman*, there is an express exception to the PMA process for products already on the market before the MDA's enactment in 1976. 21 U.S.C. § 360e(b)(1)(A). It was under this exception that the manufacturer sought to bypass the PMA process. *Buckman,* 531 U.S. at 345-46. On the third try, in 1986, it was successful. *Id.* at 346. The Supreme Court held "that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348 (footnote omitted). The principle reason was that the plaintiffs' state law claims "inevitably conflict with the FDA's responsibility to police fraud" based on statements made to that agency. *Id.* at 350. This was because "the fraud claims exist solely by virtue of the FDCA disclosure requirements" and "would not be relying on traditional state tort law that had predated the federal enactments in question." *Id.* at 352-53.

In summary, express preemption requires a two-step analysis. Has the FDA established requirements applicable to the particular medical device in question? If so, do the plaintiffs' state law tort claims require the manufacturer to do something different than that which is required by federal law? If the answer to both questions is yes, the claims are expressly preempted. *Riegel*, 552 U.S. at 321-22. Section 360k, therefore, ordinarily shields a manufacturer from tort liability under state law as long as the manufacture has complied with federal law in connection with an approved medical device.[2] Further, state law claims that seek

[2] A Fourth Circuit decision, *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012), is inapposite. As the majority opinion noted: "In light of Walker's concession that the device was designed, manufactured and distributed in compliance with the terms of its premarket approval, given by the Food and Drug Administration ('FDA') as required under the MDA, however, we are compelled to affirm." 670 F.3d at 571. In this case, quite the opposite is alleged.

only to enforce federal law, without more, are impliedly preempted under *Buckman*. 531 U.S. at 352-53.

Each side in this preemption dispute has cited to the court cases which unquestionably support its positions. The defendants rely heavily on medical device cases in which they have prevailed on dismissal motions, such as *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013). The court in *Caplinger*, in dismissing the complaint without leave to amend, specifically rejected the plaintiff's argument that Medtronic's promotion of off-label uses of Infuse® was not preempted. *Id.* at 1217-18.

Reasoning similar to that of *Caplinger* has been used by a number of courts to hold that state law claims, similar to those raised in this case, are preempted. *See, e.g., Dawson v. Medtronic, Inc.*, No. 3:13-cv-663-JFA, 2013 WL 4048850, at *1 (D.S.C. Aug. 9, 2013);[3] *Houston v. Medtronic, Inc.*, No. 2:13-cv-1679-SVW-SH, 2013 WL 3927839, at *1 (C.D. Cal. July 30, 2013); *Harris v. Medtronic, Inc.*, No. RG12-636341, 2013 WL 4011624, at * 1 (Cal. Super. Ct. Aug. 1, 2013); *Wendt v. Bernstein*, No. 12L1149, 2013 WL 3199361, at *1 (Ill. Cir. Ct. June 24, 2013) (claims regarding off-label uses of Infuse® were preempted); *Lawrence v. Medtronic, Inc.*, No. 27CV131197, 2013 WL 4008821, at *1 (Minn. Dist. Ct. Aug. 7, 2013).[4]

The plaintiffs rely on cases going in the other direction, generally holding, on various grounds, that the complaints at issue in those lawsuits sufficiently alleged parallel claims under

[3] Largely following the reasoning of *Caplinger*, the court in *Dawson* also specifically held that claims arising out of Medtronic's off-label promotion of Infuse® were preempted.

[4] The defendants also cite to the decision of a member of this court, which granted their motion to dismiss. *McCormick v. Medtronic, Inc.*, No. 368532-V (Md. Cir. Ct. Apr. 19, 2013). That case currently is on appeal to the Court of Special Appeals. Respectfully, I decline to follow the trial court ruling in *McCormick*. *See Baltimore Police Dep't v. Cherkes*, 140 Md. App. 282, 300-301 (Md. Ct. Spec. App. 2001).

Riegel[5] and avoided implied preemption under *Buckman*. *See, e.g., Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc) (failure to warn claims not preempted); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (manufacturing defect claim not preempted); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009) (stating, in *dicta*, that the promotion of off-label uses by the manufacturer might escape preemption); *Howard v. Zimmer, Inc.*, 299 P.3d 463 (Okla. 2013) (negligence claims are parallel and not preempted);[6] *Cornett v. Johnson & Johnson*, 48 A.3d 1041 (N.J. 2012) (claims alleging promotion of off-label uses not preempted); *Sanda v. Medtronic, Inc.*, No. 13L000305 (Ill. Cir. Ct. July 18, 2013) (off-label promotion claims regarding Infuse® not preempted); *Messner v. Medtronic, Inc.*, 39 Misc.3d 1213(A) (N.Y. Sup. Ct. Apr. 9, 2013) (negligence in manufacturing process claim not preempted).

The most recent decision in this area is *Ramirez v. Medtronic, Inc.*, No. CV-13-00512-PHX-GMS, 2013 WL 4446913, at *1 (D. Ariz., Aug. 21, 2013). This court considers the analysis of *Ramirez* to be the most cogent of any of the cases cited by the parties or reviewed by the court. This court agrees with the decision in *Ramirez* and finds it applicable to the plaintiffs' complaint in this case.

The gist of the plaintiffs' claim is that Dr. McDonald-Lerner was injured by an off-label use of "the Infuse® Bone Graft/L-T Cage Device," and that the injuries proximately resulted from Medtronic's practice of promoting such use and making false statements about, or

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[5] The Supreme Court in *Riegel* was very careful to note that its decision in that case did not control so-called parallel claims because this argument was not properly presented for review. 552 U.S. at 330.

[6] The defendants correctly point out that the question of preemption under federal law was not presented in *Howard*, because the Tenth Circuit certified only the state law issue to the Supreme Court of Oklahoma. 299 P.3d at 465. Nevertheless, the analysis of the Supreme Court of Oklahoma in *Howard* clearly suggests that a state law negligence claim based on a violation of a state statute would not be preempted. *Id.* at 470-73. The Court stated after discussing parallel claims: "We align ourselves with those jurisdictions which would allow a negligence per se claim to proceed." *Id.* at 472-73 (footnote omitted).

concealing or minimizing, adverse results that were occasioned by that off-label use. In a sense, the plaintiffs say, the Medtronic defendants misbranded Infuse® because they advertised it in a manner inconsistent with the PMA. "The manufacturer may not tell the FDA that its device should be used only in a certain set of procedures, and then encourage physicians to use the device [or only a portion of the device] in other procedures." *Ramirez*, 2013 WL 4446913, at *9.

There is no legitimate federal concern with state judges or state juries meddling with the decisions of the FDA when the state law claims, as alleged in this case, arise "out of a use that has not been reviewed by the FDA but has been promoted by the manufacturer." *Ramirez*, 2013 WL 4446913, at *10. In other words, preemption under § 360k is not even an issue because the PMA for "the Infuse® Bone Graft/L-T Cage Device" does not establish device-specific requirements for the bone protein alone and without the LT-Cage, or the implantation of any or all of the device through a posterior approach. Further, the PMA does not allow Medtronic to actively promote a medical device or use by physicians in a manner inconsistent with the FDA's labeling requirements. In short, there is no basis for preemption under § 360k(a) under the first prong of *Riegel*. The second prong of *Riegel* also is inapplicable because there is no federal warning label to analyze regarding use of the bone protein alone. The 2002 FDA-approved label in fact says otherwise.

Even if the foregoing analysis is incorrect, the court concludes that the amended complaint alleges parallel claims sufficient to escape preemption under *Lohr* and *Riegel*. Nothing in the amended complaint would require the Medtronic defendants to do something different from or in addition to federal law. As a consequence, there is no express preemption. *See Ramirez*, 2013 WL 4446913, at *13 n.10. The permissibility of parallel claims was established in *Lohr*, 518 U.S. at 495, and reaffirmed in *Riegel*, 552 U.S. at 330.

Further, there is nothing in the amended complaint that runs afoul of *Buckman*. All of the claims pled are based on established Maryland law.[7] None turn *solely* on violations of federal law, as was the case in *Buckman*, 531 U.S. at 353; *see Riley*, 625 F. Supp. 2d at 776-77. Although a state court will have to interpret federal law in connection with assessing the plaintiffs' state law claims, such does not mean that these claims are impliedly preempted. *See Stengel*, 704 F.3d at 1232-35.

The defendants contend vehemently that there is nothing illegal or improper about off-label uses, or the promotion of off-label uses, of FDA approved medical devices. For this proposition they rely heavily on a decision by the Second Circuit, *United States v. Caronia,* 703 F.3d 149 (2d Cir. 2012). The defendants read way too much into that decision and, in any event, the court respectfully declines to follow the reasoning of the two-judge majority in that case.

The defendant in that case, Alfred Caronia, was convicted of conspiring to introduce a misbranded drug into interstate commerce in violation of 21 U.S.C. § 331(a). *Caronia*, 703 F.3d at 152. Caronia was a pharmaceutical representative of a drug manufacturer. *Id.* at 155-56. He actively promoted a drug, Xyrem, for off-label use by arranging "speakers programs" and paying the "speakers" to tout the off-label uses of Xyrem to other physicians during those programs. *Id.* at 156. The defendant did not himself answer questions or tout the off-label use of the drug, but referred interested parties to the paid physicians who he knew or expected would do so. *Id.* Although acknowledging that the government had regularly obtained convictions against both pharmaceutical companies and their representatives for misbranding based on off-label

[7] There may be an implied preemption issue as to the implied consent claim pled in count I, which is only against Dr. Rosner. The Court of Appeals did not recognize this cause of action until after the enactment of the MDA in 1976. *See Sard v. Hardy*, 281 Md. 432 (1977). There also may be a legal defense based on § 396. However, neither of these issues was discussed in Dr. Rosner's brief in support of his motion to dismiss. Ordinarily, a court is not required to address an argument that is not sufficiently set forth in a party's brief. The reasons for this are many. *See Frederick v. Corcoran*, No. 370685-V (Md. Cir. Ct. Aug. 14, 2013). The court declines to address these issues at this time.

promotion, *id.* at 154, two judges of the appellate panel concluded that this particular prosecution violated the defendant's rights under the First Amendment, based largely on how the government tried the case to the jury. *Id.* at 160-63. In a novel and unprecedented holding, the two judge panel stated: "We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs." *Id.* at 168.

As noted by the dissent, the majority's view was ill-considered and effectively would gut the FDA's labeling regulations and premarket approval process for drugs [and medical devices] for specific uses. *Id.* at 170-180 (Livingston, J., dissenting). But even if the two-judge majority is correct, its holding is limited to criminal prosecutions. Similar first amendment concerns do not apply to civil cases. *Id.* at 177.

This court agrees with the dissenting judge in *Caronia*. It is unfathomable that Congress authorized the FDA to approve and limit the sale and distribution of drugs and medical devices for specific purposes, under specific conditions, and impose stringent premarket approval and subsequent labeling requirements, setting out those purposes and other conditions of approved use, but yet allow manufacturers and their representatives to ignore those same requirements with impunity by touting off-label uses to physicians. If that is true, the federal regulatory scheme and approval process established by Congress is a complete waste of time. This court cannot fathom that this result was intended by Congress. *Cf. Lohr*, 518 U.S. at 487 (rejecting Medtronic's construction of this very statute as such would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the Judgment of Congress, needed more stringent regulation"); *Bausch*, 630 F.3d at 549-50 ("The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.").

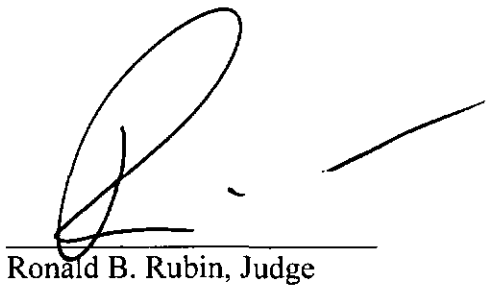
The defendants also challenge the amended complaint as being insufficiently pled in certain respects. Counts II and III of the amended complaint, allege causes of action for strict liability, both for failure to warn and for design defect. Both theories are well settled in Maryland. *See Owens-Illinois, Inc. v. Zenobia,* 325 Md. 420, 432-33 (1992); *Klein v. Sears, Roebuck & Co.* 92 Md. App. 477, 484-88 (Md. Ct. Spec. App.), *cert. denied*, 328 Md. 447 (1992), *Simpson v. Standard Container Co.*, 72 Md. App. 199, 203-04 (Md. Ct. Spec. App.), *cert. denied*, 311 Md. 286 (1987). All of the necessary elements for both theories of recovery are properly pled in the amended complaint. Further, the court is not convinced at this juncture that the Court of Appeals would apply Comment k to § 402A of the Restatement (Second) of Torts[8] ("unavoidably unsafe products") to circumstances like those alleged in this case. *See Miles Labs., Inc. v. Doe*, 315 Md. 704, 715-32 (1989) (blood products, are the quintessential type of Comment k product, which the Court of Appeals adopted in Maryland as part of our law on strict product liability). This issue is barely touched upon in the parties' briefs, which have focused on preemption. Any party is free to re-raise the issue (Comment k) if there is something new to say or there is something further for the court to consider.

The defendants also challenge the legal sufficiency of the plaintiffs' allegations of fraud in Count V. The elements of actionable fraud have been set forth many times by Maryland's appellate courts and need not be repeated. *See, e.g., Hoffman v. Stamper*, 385 Md. 1, 28 n.12 (2005); *Tufts v. Poore*, 219 Md. 1, 10-12 (1959); *Appel v. Hupfield*, 198 Md. 374, 378-79 (1951); *Bocchini v. Gorn Management Co.*, 69 Md. App. 1, 19-21 (Md. Ct. Spec. App. 1986); *Kalb v. Vega*, 56 Md. App. 653, 662 (Md. Ct. Spec. App. 1983).

[8] Generally speaking, Comment k suggests that because certain products are "unavoidably unsafe" they should not be subjected to strict liability under the rule of § 402A.

The amended complaint sufficiently alleges false factual assertions on which the Medtronic defendants intended and the plaintiffs did rely, along with specific allegations that the Medtronic defendants knowingly concealed or intentionally withheld material information about which the plaintiffs had a right to know. *See Walsh v. Edwards*, 233 Md. 552, 557 (1964); *Fowler v. Benton*, 229 Md. 571, 581-82 (1962); *Brager v. Friedenwald*, 128 Md. 8, 32 (1916). *See also Zirn v. VLI Corp.*, 681 A.2d 1050, 1053-56 (Del. 1996). Whether any of this can be proven by clear and convincing evidence remains to be seen, but the pleading is legally sufficient.[9]

For the reasons stated above, it is this 29th day of August, 2013, **ORDERED** that the defendants' motions to dismiss are denied.



Ronald B. Rubin, Judge

[9] Again, Dr. Rosner did not discuss in his brief any deficiencies in the fraud allegations that were specific to him, as opposed to those directed towards the Medtronic defendants. The court will not consider those issues in the absence of specific arguments made in the parties' written submissions.