THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

JAMES MACK, et al.,	*	
Plaintiffs,	*	Civil Action No.: RDB-08-688
v.	*	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	*	
Defendants.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

Plaintiffs James and Sylvia Mack, on behalf of their daughter Crystal Mack, have brought the instant products liability suit against Defendants AmerisourceBergen Drug Corporation ("AmerisourceBergen"), Centocor, Inc. ("Centocor"), and Johnson & Johnson, Inc. ("Johnson & Johnson") (collectively, "Defendants"). Plaintiffs claim that Crystal Mack died after suffering from a cardiac arrhythmia that was caused by her use of Remicade, a prescription medication primarily used to treat Crohn's disease, which is developed and manufactured by Johnson & Johnson's pharmaceutical segment, Centocor, and distributed by AmerisourceBergen.

Currently pending before this Court is Defendants' Motion for Summary Judgment (Paper No. 50). In addition, both parties have filed motions *in limine* to exclude expert witnesses. *See* Defendants' Motion in Limine to Exclude the Testimony of James T. O'Donnell, Dr. Donald H. Marks and Dr. William L. Manion (Paper No. 51); Plaintiffs' Motion in Limine to Exclude the Testimony of David Sachar, M.D., Raymond M. Cross, M.D., and Barbara Matthews, M.D., M.P.H. (Paper No. 53). Hearings were conducted on September 15 and November 2 of 2009, pursuant to *Daubert v. Merrell Dow Pharmacies, Inc.*, 509 U.S. 579

(1993), to consider the admissibility of the testimony of Plaintiffs' experts, Dr. Donald H. Marks and Dr. William L. Manion. Finally, on November 3, 2009, a hearing was convened to hear argument on the Defendants' Motion for Summary Judgment. Even with consideration of the proffered testimony of the Plaintiffs' experts Dr. Marks and Dr. Manion,[1] there is simply insufficient evidence of any defect, misrepresentation, breach of contract, or non-compliance with state licensure and permit requirements, which would create a genuine issue of material fact. Accordingly, for the reasons stated below, this Court rules that Defendants' Motion for Summary Judgment (Paper No. 50) is GRANTED.

BACKGROUND

The facts are viewed in a light most favorable to the Plaintiffs, as the non-moving party. *See Matsushita Elec. Indus. Co. Ltd v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In 2006, at the age of 25, Crystal Ann Mack was diagnosed with a severe form of Crohn's disease—an inflammatory disease affecting the gastrointestinal tract. In the autumn of 2006, Ms. Mack was hospitalized on two occasions and ultimately diagnosed with anemia, bloody diarrhea, vomiting, weight loss, leukocytosis, depression, electrolyte imbalances, and tachycardia. To alleviate the symptoms of Ms. Mack's Crohn's disease, her treating physician, Dr. Lisa Pichney, recommended that Ms. Mack undergo Remicade treatments.

On November 16, 2006, Mack received her first infusion of Remicade at the St. Joseph Medical Center's Seprick Infusion Center. In the subsequent months, she received three

[1] Plaintiffs submitted three expert witnesses: James T. O'Donnell, Dr. Donald H. Marks, and Dr. William L. Manion. Defendants have moved to exclude the testimony of these witnesses, claiming that their testimony does not comport with the standards for admissibility established in *Daubert v. Merrell Dow Pharmacies, Inc.*, 509 U.S. 579 (1993). At a hearing conducted on December 18, 2008, this Court ruled that O'Donnell was not qualified to serve as an expert in the present case and his testimony was excluded as inadmissible. Dr. Marks' testimony was ultimately deemed admissible after a *Daubert* hearing was conducted on September 15, 2009. On November 2, 2009, another *Daubert* hearing was conducted to weigh the admissibility of Dr. Manion's testimony. For purposes of ruling on Defendants' Motion for Summary Judgment, this Court assumes, without deciding, that Dr. Manion's testimony satisfies the standards of admissibility under *Daubert*.

additional infusions, in accordance with the medication's dosing instructions. Although she initially reported improvements in her health after receiving Remicade, Ms. Mack continued to require hospitalization for weakness, fatigue, and intestinal bleeding. Laboratory tests conducted in January and February of 2007 indicated that Ms. Mack was anemic and had electrolyte imbalances. In addition, her body weight remained under 80 pounds during this period.

On April 12, 2007, Ms. Mack reported to Dr. Pichney that she was bleeding from her intestines, and they scheduled another office visit. However, on April 17, 2007, before returning to Dr. Pichney, Ms. Mack fell unconscious in her home and subsequently died. Ms. Mack's body was then transported to the Office of the Medical Examiner, where an autopsy was performed by Dr. J. Laron Locke, an assistant medical examiner. Dr. Locke concluded that Ms. Mack's death resulted primarily from "intestinal hemorrhage due to Inflammatory Bowel Disease" and that diabetes mellitus was a contributing factor in her death. (Autopsy Report, p. 5, Exhibit C to Affidavit of John D. Winter ("Winter Aff.").)

Plaintiffs James and Sylvia Mack, have brought the instant products liability action to recover for the death of their daughter.[2] On March 27, 2009, Plaintiffs' First Amended Complaint was filed in this Court that set forth seven causes of action against Defendants Johnson & Johnson, Centocor, and AmerisourceBergen. Specifically, Plaintiffs bring claims for strict products liability in Count One, fraud and misrepresentation in Count Two, breach of express and implied warranty in Count Three, negligent design and manufacture in Count Four, breach of contract in Count Five, and claims for wrongful death in Counts Six and Seven. Finally, in their brief in opposition to summary judgment, Plaintiffs claim that Defendants failed

[2] Plaintiffs originally filed suit against Defendants in the Circuit Court for Baltimore City. Defendants removed the case to this Court pursuant to 28 U.S.C. § 1441 on the basis of complete diversity between the parties. Plaintiffs have also brought a lawsuit against the health care providers for Crystal Mack, which is currently pending in the Circuit Court for Baltimore County (Case No. 03-C-09-003030).

to comply with Maryland licensing and permit statutes. Plaintiffs' suit is based upon the theory that Ms. Mack died of a cardiac arrhythmia that was proximately caused by her use of Remicade, a drug that is developed and manufactured by Johnson & Johnson's pharmaceutical segment, Centocor, and distributed by AmerisourceBergen.

STANDARD OF REVIEW

Rule 56 of the Federal Rules of Civil Procedure provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A material fact is one that "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine issue over a material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* In considering a motion for summary judgment, a judge's function is limited to determining whether sufficient evidence exists on a claimed factual dispute to warrant submission of the matter to a jury for resolution at trial. *Id*. at 249.

In undertaking this inquiry, a court must consider the facts and all reasonable inferences in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). After the moving party has established the absence of a genuine issue of material fact, the nonmoving party must present evidence in the record demonstrating an issue of fact to be resolved at trial. *Pension Ben. Guar. Corp. v. Beverley*, 404 F.3d 243, 246-47 (4th Cir. 2005) (citing *Pine Ridge Coal Co. v. Local 8377, UMW*, 187 F.3d 415, 422 (4th Cir. 1999)). Summary judgment will be granted if the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case,

and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

This Court has an affirmative obligation to prevent factually unsupported claims and defenses from going to trial. *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993) (quoting *Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987)). If the evidence presented by the nonmoving party is merely colorable, or is not significantly probative, summary judgment must be granted. *Anderson*, 477 U.S. at 249-50. This Court has previously explained that a "party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences." *Shin v. Shalala*, 166 F. Supp. 2d 373, 375 (D. Md. 2001) (citations omitted).

ANALYSIS

Defendants have moved this Court to enter summary judgment against Plaintiffs on the basis that Plaintiffs have failed to present sufficient evidence to create an issue of material fact on any of their claims. This Court first addresses Plaintiffs' products liability claims before turning to their remaining causes of action for misrepresentation, breach of contract, and failure to comply with state licensing laws.

Because jurisdiction is based on diversity of citizenship, this Court applies Maryland law in deciding this Motion for Summary Judgment. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938) ("Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the State."); *Limbach Co., LLC v. Zurich Am. Ins. Co.*, 396 F.3d 358, 361 (4th Cir. 2005) ("The district court must apply the law of the forum state, including its choice of law rules.").

I. Product Liability Claims

Plaintiffs have asserted product liability claims in Counts One, Three and Four of their Amended Complaint.

Maryland law provides that "'the plaintiff in product liability litigation must satisfy three basics from an evidentiary standpoint: 1) the existence of a defect; 2) the attribution of the defect to the seller; and 3) a causal relation between the defect and the injury.'" *Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 423 (D. Md. 2002) (quoting *Jensen v. American Motors, Corp.*, 50 Md. App. 226, 234, 437 A.2d 242, 247 (Md. Ct. Spec. App. 1981)). This same evidentiary showing is required regardless of the asserted theory underlying the claim of products liability. *See Pease v. American Cyanamid Co.*, 795 F. Supp. 755, 758 n.3 (D. Md. 1992). Defendants contend that Plaintiffs' failure to make a satisfactory showing with respect to the elements of defect and causation is fatal to their claims for strict liability, negligence, and breach of warranty.

Plaintiffs' products liability claims cannot survive summary judgment because they cannot establish that Remicade is a defective product. Counsel for the Plaintiffs have made great efforts to prove specific and general causation, but they have made no showing with respect to the issue of defect. Because a showing of defect is an independent prerequisite for a products liability claim, this Court need not address whether Plaintiffs have satisfied their burden on the issue of causation.

"In order to recover on a product defect claim, a plaintiff must prove that a defect which renders the product unreasonably dangerous might arise from the design of the product, a deficiency in its manufacture, or from the absence or inadequacy of any instructions or warnings as to its safe and appropriate use." *Murphy v. Playtex Family Prods. Corp.*, 69 Fed. Appx. 140, 143 (4th Cir. June 26, 2003) (unpublished) (citing *Simpson v. Standard Container Co.*, 72 Md.

App. 199, 203, 527 A.2d 1337, 1339-40 (Md. Ct. Spec. App. 1987)). Plaintiffs have not alleged a failure to warn case.[3] Instead, their allegations focus on the contention that Remicade "was being manufactured and distributed in a defective condition." (Amend. Compl. ¶ 15.)

To prove that a product is defective, a plaintiff must establish that it is "unreasonably dangerous." *Pease*, 795 F. Supp. at 758 (citing *Phipps v. General Motors Corp.*, 278 Md. 337, 344, 363 A.2d 955, 959 (Md. 1976)). Under Maryland law, courts may apply both the "risk/utility" test and the "consumer expectation" test when evaluating the efficacy of design defect claims.[4] *Murphy v. Playtex Family Prods. Corp.*, 176 F. Supp. 2d 473, 488-89 (D. Md. 2001). The "risk/utility" test involves an assessment of "whether the benefits of a product outweigh the dangers of its design." *Tannebaum v. Yale Materials Handling Corp.*, 38 F. Supp. 2d 425, 430 (D. Md. 1999); *see also Simpson*, 527 A.2d at 1340 ("[u]nder the 'risk-utility' test, a product is defective as designed if the risk or danger of the product outweighs the product's utility"). Alternatively, a drug could be deemed unreasonably dangerous if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Phipps*, 363 A.2d at 959.

Plaintiffs' allegations of defect are not substantiated by the evidence in the record. In their brief in opposition to Defendants' motion for summary judgment, Plaintiffs merely cite the legal standards for alleging and proving defect, and reiterate the relevant allegations contained in their Amended Complaint. As a result, Plaintiffs have clearly fallen short of the standard in Federal Rule of Civil Procedure 56(e), which provides that "an opposing party may not rely

[3] During the motions hearing held on December 18, 2008, Plaintiffs' counsel conceded that their product liability actions did not include a failure to warn claim. (Transcript of December 18, 2008, 22:18-19, Exhibit J to Winter Aff.)

[4] Plaintiffs maintain that the issue of defect may only be assessed under the "consumer expectation" theory, whereas Defendants claim that only the "risk/utility" test properly applies in the present case. However, this dispute need not be addressed, as this Court finds that Plaintiffs' claims cannot pass muster under either test.

merely on the allegations or denials in its own pleading," but must instead "set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

The evidentiary deficiencies in Plaintiffs' case are glaring in light of the fact that Plaintiffs have failed to present expert testimony on the issue of defect. While the testimony of Doctors Marks and Manion largely focuses on the issue of causation, neither have contended that Remicade is unreasonably dangerous. This shortcoming is especially damaging to Plaintiffs' claims, because the issue of defect in this case "involves technical medical questions beyond the common knowledge of laypersons." *Miskin v. Baxter Healthcare Corp.*, 107 F. Supp. 2d 669, 672 (D. Md. 1999); *see also Virgil v. "Kash N' Karry" Serv. Corp.*, 61 Md. App. 23, 31, 484 A.2d 652, 656 (Md. Ct. Spec. App. 1984) (noting that expert testimony is "required when the subject of the inference is so particularly related to some science or profession that it is beyond the ken of the average layman"). Indeed, some of the expert testimony proffered by Plaintiffs instead seems to belie the allegations of defect contained in their Amended Complaint. Plaintiffs conceded at the hearing on summary judgment that Dr. Marks would not consider Remicade to be unreasonably dangerous, as he routinely oversees the administration of the medication to patients.

In the absence of any direct evidence or expert testimony on the issue of defect, Plaintiffs must rely upon circumstantial evidence. At the hearing on summary judgment on November 3, 2009, Plaintiffs' counsel proffered several miscellaneous documents, including internal corporate memoranda and correspondence from Centocor that referred to the exhibited side effects of Remicade. However, such documents do not militate for the submission of the defect issue to a jury. The fact that a drug may exhibit certain adverse side effects does not, by itself, create an

issue of material fact on whether the drug is unreasonably dangerous. This Court has previously recognized that all drugs involve risks of adverse side effects in those who take them. *See Perlov v. G.D. Searle & Co.*, 621 F. Supp. 1146, 1148 (D. Md. 1985). In *Perlov* this Court specifically observed that "[j]ust as in medical malpractice cases, where every bad result is not evidence of negligence, so too with drugs and medical devices: every side effect or adverse reaction does not indicate . . . that the product is unreasonably dangerous and defective." *Id.*

The United States Food and Drug Administration ("FDA") approved Remicade for marketing for the treatment of Crohn's disease in August of 1998, and has reaffirmed the safety and efficacy of Remicade on more than ten occasions.[5] (Affidavit of Suzanne B. Travers, M.D. ("Travers Aff."), at ¶¶ 2-4.) Remicade has also been approved for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis and plaque psoriasis. (*Id.* at ¶¶ 2-5.) In the eleven years since it was first approved for marketing, more than one million patients have received Remicade. (*Id.* at ¶ 18.) In the face of the drug's apparent advantages, Plaintiffs would need to provide a much greater evidentiary showing to establish that the medication's attendant risks outweigh its benefits—a necessary showing under the "risk/utility" test. In addition, Plaintiffs have not alleged, let alone substantiated, any claim that the Defendants failed to provide adequate warnings with respect to the risks associated with Remicade and heart failure—a showing that is often required under the "consumer expectation"

[5] Plaintiffs cite to the recent decision of the United States Supreme Court in *Wyeth v. Levine*, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009) in support of their argument that Defendants cannot rely upon FDA's risk-benefit approval test as evidence that Remicade is not unreasonably dangerous. In *Levine*, the Supreme Court assessed "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." *Levine*, 129 S. Ct. at 1193 (internal quotation omitted). The Court held that the defendant drug manufacturer was not entitled to a complete defense against a plaintiff's state law failure-to-warn claim merely because the FDA approved the drug label at issue. Thus, federal law does not preempt state common law failure-to-warn claims based on FDA-approved labeling.

Levine is distinguishable from the instant case in that Plaintiffs have not asserted a failure-to-warn claim. Moreover, to resolve Plaintiffs' product liability claims, this Court has applied Maryland law. Under Maryland law, the Plaintiff bears the burden of establishing that a drug is unreasonably dangerous, and in the present case, Plaintiffs have failed to present an issue of material fact on this issue.

test. *See Murphy*, 176 F. Supp. 2d at 487-89 (denying plaintiffs' defect claim under the "consumer expectation" test after finding that the defendant manufacturer had provided consumers with legally adequate warnings).

In sum, Plaintiffs' proffered circumstantial evidence is far too tenuous and anecdotal to create an issue of material fact as to defect, and could not permit a reasonable juror to infer that Remicade is an unreasonably dangerous drug. At the summary judgment stage, courts are obligated to enter summary judgment against claims that are not sufficiently substantiated or unduly based upon speculation and conjecture. *See Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 96 (D. Md. 1989) ("Proof of a defect in a products liability case must rise above speculation and recovery cannot be predicated on a presumption from the mere happening of an accident.") (citing *Jensen*, 437 A.2d at 245). Because Plaintiffs fail to make a showing of defect, summary judgment must be entered in favor of the Defendants on the product liability claims set forth in Counts One, Three and Four.

II. Misrepresentation Claim

In Count Two of their Amended Complaint, Plaintiffs set forth a claim of misrepresentation and fraud. Under Maryland law, to establish a claim of fraud or misrepresentation, a plaintiff must show that 1) the defendant made a false representation to the plaintiff, 2) its falsity was either known to the defendant or the representation was made with reckless indifference as to its truth, 3) the misrepresentation was made for the purpose of defrauding the plaintiff, 4) the plaintiff relied on the misrepresentation and had the right to rely upon it, and 5) the plaintiff suffered injury resulting from the misrepresentation. *See, e.g.*, *Hoffman v. Stamper*, 385 Md. 1, 28, 867 A.2d 276, 292 (Md. 2005).

In addition, Federal Rule of Civil Procedure 9(b) provides that plaintiffs must "state with particularity the circumstances constituting fraud or mistake." Towards this end, a plaintiff must provide "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999). Accordingly, "a court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Id.*

The claims of fraud and misrepresentation asserted in Count Two of the Amended Complaint have not been alleged with sufficient particularity. The language in the Amended Complaint merely states that Defendants made "false representations that the drug was safe and that [Crystal Mack] needed the Remicade treatments." (Amend. Compl. ¶ 59.) In addition, Plaintiffs allege that "Accessone, the agent[] . . . of these Defendants deceived Crystal Mack into taking unneeded treatments of Remicade to increase sales of Remicade and make profits from Medicaid patients, such as Mack." (*Id.* at ¶ 58.) Plaintiffs have not specified the time, place, and content of any particular misrepresentation. Nor have they linked any misrepresentation to any one of the Defendants. *Adams v. NVR Homes, Inc.*, 193 F.R.D 243, 250 (D. Md. 2000) ("A complaint fails to meet the particularity requirements of Rule 9(b) when a plaintiff asserts merely conclusory allegations of fraud against multiple defendants without identifying each individual defendant's participation in the alleged fraud.").

Furthermore, even assuming, *arguendo*, that Plaintiffs have properly pled actions for fraud and misrepresentation, these claims are not borne out by the evidence in the record. At his deposition, Mr. Mack conceded that Centocor did not make any misrepresentation to him and he

stated that he was not aware of any misrepresentation made to Ms. Mack. (March 10, 2009 Deposition of James Mack, 58:13-22, 56:9-58:12, 59:14-20.) Mrs. Mack only recalled viewing a video and pamphlet about Remicade. (March 10, 2009 Deposition of Sylvia Frances Stewart-Mack, 84:12-86:21; 111:12-112:20.) However Plaintiffs have not been able to identify any misrepresentation in the Remicade pamphlet and video that Ms. Mack viewed at the St. Joseph Medical Center. (Exhibit M to Winter Aff.) Finally, none of the Macks reviewed the Remicade video and pamphlet before Ms. Mack was prescribed with the drug by Dr. Pichney. Therefore, Plaintiffs cannot establish that they relied on any information provided by any of the Defendants prior to when Ms. Mack decided to begin her Remicade treatments.

Accordingly, summary judgment is entered in favor of the Defendants on the fraud and misrepresentation claim set forth in Count Two.

III. Breach of Contract

In Count Five, Plaintiffs allege that Crystal Mack entered into a contract with AccessOne, an agent of Defendants Johnson & Johnson and Centocor, which served as a "single source support for access to infusion therapy" for Remicade. (Amend. Compl. ¶¶ 7, 79.) They contend that "Defendants breached the contract by not advising Crystal Mack that she should have discontinued the treatment at 14 weeks, that therapy should be closely monitored, and that she was experiencing adverse reactions from the use of the drug at their infusion centers." (*Id.* at ¶ 81.)

Prior to receiving her first Remicade treatment, Ms. Mack signed a "Patient Authorization Form" that allowed her doctors and insurers to provide her medical information to the Lash Group, which administered AccessOne for Centocor. (Exhibit D to Winter Aff. at p. 371.) Even if it could be said that Ms. Mack entered into a contract with AccessOne and

Centocor by signing the authorization form, Plaintiffs have failed to present any evidence of breach. Plaintiffs allege that AcessOne promised to provide "assistance, guidance, counseling, and therapy follow-up regarding Remicade," Amend. Compl. ¶ 79, but such promises are not contained in the language of the authorization form. Instead the form merely provides that the Lash Group would "help find ways to pay" for Ms. Mack's Remicade treatments. (*Id.*) Moreover, the Benefit Investigation Form for Remicade and the Primary Insurance Verification of Benefits for Remicade, included explicit disclaimers noting, among other things, that the "Lash Group and Centocor make no representation or guarantee that full or partial insurance reimbursement or any other payment will be available." (Exhibit D to Winter Aff. at pp. 374, 376.) Finally, and most importantly, there can be no claim of breach because Ms. Mack was fully reimbursed for her Remicade infusions.

Accordingly, summary judgment is entered in favor of the Defendants on the breach of contract claim set forth in Count Five.

IV. Alleged Violation of Maryland Licensing and Permit Statutes

In their brief in opposition to summary judgment, Plaintiffs contend that Defendants failed to comply with Maryland licensure requirements.[6] More specifically they claim that AmerisourceBergen was not licensed to distribute Remicade in Maryland in 2006 and 2007, and that Centocor and Johnson & Johnson are operating illegally in the state because they are not registered properly to pay taxes. (Opp. Mem. at 8, 14, 16-22.)

Defendants have clearly confirmed, through evidence in the record, that they have not violated the relevant statutes and licensure requirements of the State of Maryland. AmerisourceBergen complied with The Wholesale Distributor Permitting and Prescription Drug

[6] None of the allegations in Plaintiffs' Amended Complaint refer to any violation of Maryland licensure requirements.

Integrity Act, Md. Code Ann., Health Occ. § 12-6C-03, as it held the requisite distribution permits in 2006 and 2007, when Ms. Mack received Remicade. (Affidavit of Michael Kody ("Kody Aff."), at ¶ 4.) In addition, Centocor and Johnson & Johnson are not required to register in Maryland because they do not qualify as "doing business" in the state as defined by the relevant registration codes. *See* Md. Code Ann., Corps. and Assocs. § 7-202, 203; *see also G.E.M., Inc. v. Plough, Inc.*, 118 Md. 484, 488, 180 A.2d 478, 480 (Md. 1962) (noting that a foreign drug manufacturer soliciting orders in Maryland through company representatives is not "doing business" in Maryland). Finally, even if Defendants could be said to violate the state licensure requirements, Plaintiffs' claims would still fail, as the statues requiring licensing and registration with the Board of Pharmacy and the State Department of Assessments and Taxation do not provide for a private cause of action. *See* Md. Code Ann., Health Occup. § 12-707(b); Md. Code Ann., Corps. & Assocs. § 7-301, 302.

V. Wrongful Death Claims

Plaintiffs James and Sylvia Mack have asserted wrongful death claims under Counts Six and Seven, respectively, pursuant to the Maryland Wrongful Death Statute. *See* Md. Code Ann., Cts. & Jud. Proc. § 3-904. These wrongful death claims fail because Plaintiffs have not established any independent basis upon which to impose liability on Defendants for the death of Crystal Mack.

VI. There is No Basis for Liability against Johnson & Johnson

This Court holds that Plaintiffs' claims cannot survive summary judgment because there is insufficient evidence of any product defect, misrepresentation, breach of contract, or non-compliance with Maryland licensure and permit requirements. Nevertheless, even if Plaintiffs could support a claim against Centocor or AmerisourceBergen, there would be no basis upon

which to hold Johnson & Johnson liable. Plaintiffs aim to attach liability on Johnson & Johnson solely on the grounds that it is the parent company of Centocor, which is the developer and manufacturer of Remicade.

It remains "a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation . . . is not liable for the acts of its subsidiaries." *United States v. Bestfoods*, 524 U.S. 51, 61 (1998) (internal quotation omitted). Plaintiffs have not cited any evidence showing that Johnson & Johnson participated in any conduct that allegedly caused Ms. Mack's death. In addition, Plaintiff s have provided no justification for disregarding the parent/subsidiary distinction, as they cannot show that the corporate form was being misused for some improper purpose. *Id.* at 62-63.

CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment (Paper No. 50) is GRANTED. A separate Order follows.

Date: November 24, 2009

/s/_____
Richard D. Bennett
United States District Judge