UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FELICE I. IACANGELO, *et al.*, Plaintiffs, v. GEORGETOWN UNIVERSITY, *et al.*, Defendants.	)	Civil Action No. 05-2086 (PLF)

MEMORANDUM OPINION AND ORDER

This matter is before the Court on defendants' objections to Magistrate Judge Alan Kay's report and recommendation of September 17, 2008 ("Report").[1]

I. BACKGROUND

In this diversity action, plaintiffs assert claims based on medical treatment provided to Karyn Kerris. Plaintiffs' allegations center on three embolization procedures performed on Ms. Kerris between 1998 and 1999 by Dr. Vance Watson at Georgetown University Hospital. Those procedures involved two substances – Histoacryl and Lipiodol – which were injected into Ms. Kerris' brain to treat a defect known as arteriovenous malformation. Plaintiffs claim that after the third embolization, Ms. Kerris "became very

[1] The papers submitted in connection with this matter include: Defendants' Objections to the Magistrate Judge's Proposed Findings and Recommendations ("Defs. Obj."); Plaintiffs' Opposition to Defendants' Objections to Magistrate Judge Kay's September 17, 2008 Report and Recommendation ("Pls. Opp."); defendants' reply; and plaintiffs' sur-reply. Plaintiffs' objections to Magistrate Judge Kay's report and recommendation are not discussed because, as explained below, the Court addressed plaintiffs' objections in a prior opinion.

lethargic and then stopped eating, communicating or showing signs of being awake . . . [and] ultimately became and remains catatonic." Pls. Opp. at 2 (internal quotation marks omitted).

Plaintiffs brought suit on October 24, 2005. According to defendants,

> [p]laintiffs have two basic theories of liability. First, Plaintiffs allege that embolization itself should not have been attempted at all. . . . Plaintiffs [also] assert that it was . . . negligence *per se* for Dr. Watson to use Histoacryl and Lipiodol, because [those substances] were not FDA approved (Counts VII and VIII) and Georgetown allegedly should have submitted an investigation device exemption (IDE) application to the FDA before using them (Count IX).

Defs. Obj. at 5.

On February 14, 2008, defendants filed a motion (1) seeking judgment on the pleadings or dismissal with respect to Counts VI, VII, VIII and IX of plaintiffs' Second Amended Complaint, and (2) asking the Court to strike certain allegations in the Second Amended Complaint. The undersigned referred that motion to Magistrate Judge Alan Kay for a report and recommendation pursuant to Local Civil Rule 72.3(a). On September 17, 2008, Magistrate Judge Kay recommended that this Court grant defendants' motion for judgment on the pleadings with respect to Count VI (a free-standing claim for punitive damages), Count VII (a negligence *per se* claim based on violations of 21 U.S.C. § 360c, a provision of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"), and 21 C.F.R. § 812.20, a regulation intended to implement the investigational device exemption of the FDCA) and Count IX (a negligence *per se* claim based on violations of 21 C.F.R. § 812.20). Magistrate Judge Kay further recommended that this Court deny without prejudice defendants' motion with respect to Count VIII (a negligence *per se* claim based on violations of 21 U.S.C. § 331, another provision of the FDCA)

and deny without prejudice defendants' motion to strike.

On September 27, 2008, plaintiffs filed objections to the Report.[2] Three days later, the Court issued a Memorandum Opinion rejecting all of plaintiffs' objections and adopting and approving Magistrate Judge Kay's Report. In that Memorandum Opinion, the Court observed that "[d]efendants have not, at this writing, filed objections to the Report, and their time to do so has expired. . . . The Court therefore assumes that they accept Magistrate Judge Kay's recommendations [including his recommendation not to dismiss Count VIII]." Iacangelo v. Georgetown Univ., Civil Action No. 05-2086, Memorandum Opinion at 2 n.2 (D.D.C. Sept. 30, 2008). On October 1, 2008, defendants filed a motion for reconsideration of the Court's September 30, 2008 Memorandum Opinion, arguing that it was issued prematurely because defendants' time to object to the Report had not yet expired. See Defendants' Motion for Reconsideration of the September 30, 2008 Memorandum Opinion Adopting and Approving Report and Recommendation of Magistrate Judge Kay at 1. Defendants simultaneously filed their objections to Magistrate Judge Kay's Report, in which they objected only to Magistrate Judge Kay's recommendation to retain Count VIII.

On October 10, 2008, the Court acknowledged that it had issued the September 30, 2008 decision prematurely. See Iacangelo v. Georgetown Univ., Civil Action No. 05-2086, Memorandum Opinion and Order at 3 (D.D.C. Oct. 10, 2008). The Court therefore announced that it would consider defendants' objections to Magistrate Judge Kay's Report (and plaintiffs'

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[2] Plaintiffs objected to Magistrate Judge Kay's recommendation to dismiss Count VI and Count VII. See generally Plaintiffs' Objections to Magistrate Judge Kay's September 17, 2008 Report and Recommendation. They also disagreed with Magistrate Judge Kay's recommendation to dismiss Count IX, but offered no separate argument respecting that count.

responses thereto) and, if necessary, modify its September 30, 2008 decision accordingly. Those objections, plaintiffs' opposition to them, defendants' reply, and plaintiffs' sur-reply are now before the Court.

When a party files written objections to any part of the magistrate judge's recommendation with respect to a dispositive motion, the Court considers *de novo* those portions of the recommendation to which objections have been made, and "may accept, reject, or modify the recommended disposition." FED. R. CIV. P. 72(b)(3).

II. DISCUSSION

As noted above, Count VIII of plaintiffs' Second Amended Complaint sets forth a claim of negligence *per se* based on certain provisions of the FDCA. See Second Amended Complaint ¶¶ 60-68. Count VIII hinges on the idea that defendants acted negligently – *i.e.*, violated a substantive standard of care – by obtaining and using devices that the FDCA defines as "adulterated" or "misbranded." Plaintiffs point to the following specific provisions of the FDCA as the basis for their negligence *per se* claim in Count VIII:

> The following acts and the causing thereof are prohibited:
>
> > (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
> >
> > (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
> >
> > (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * *

> (g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

21 U.S.C. § 331(a), (b), (c), (g) and (k). According to plaintiffs, defendants violated these provisions, and thereby committed negligence *per se*, because they

> (a) introduced and or caused introduction of, Histoacryl and Lipiodol, both adulterated and misbranded devices, into interstate commerce,
>
> (b) adulterated both Histoacryl and Lipiodol by mixing and/or compounding the two devices together,
>
> (c) received a misbranded and adulterated device,
>
> (d) manufactured a "new" Class III adulterated and misbranded device when they mixed Histoacryl with Lipiodol,
>
> (e) ignored the warnings and/or destroyed the labeling on the Class III device Histoacryl.

Second Amended Complaint ¶ 65.

Relying principally on Cabiroy v. Scipione, 767 A.2d 1078, 1080-81 (Pa. Sup. Ct. 2001), Magistrate Judge Kay concluded that the cited provisions of 21 U.S.C. § 331 could support plaintiffs' negligence *per se* claim in Count VIII because those provisions set forth a discernible standard of care. See Report at 13. Having reviewed the papers considered by

Magistrate Judge Kay, Magistrate Judge Kay's Report, both parties' objections to Magistrate Judge Kay's Report, all of the filings by the parties relating to defendants' objections, and the relevant case law, the Court concludes that it must reject Magistrate Judge Kay's conclusion with respect to Count VIII. The provisions of Section 331 on which plaintiffs base Count VIII cannot support a negligence *per se* claim for two reasons: (1) those provisions do not set forth a substantive standard of care the violation of which amounts to the violation of a duty in tort, and (2) plaintiffs cannot demonstrate a causal relationship between the unapproved status of Histoacryl and Lipiodol and Ms. Kerris' injuries.

A. Negligence Per Se

"As a general rule, the plaintiff in a negligence action bears the burden of proving the applicable standard of care, a deviation from that standard by the defendant, and a causal relationship between that deviation and the plaintiff's injury." McNeil Pharmaceutical v. Hawkins, 686 A.2d 567, 577 (D.C. 1996) (citation and internal quotation marks omitted). The doctrine of negligence *per se* represents a "slight variation[] on this general rule." Id. at 578. In some cases, that doctrine permits a plaintiff to "rely on a statute or regulation as proof of the applicable standard of care." Id. In the District of Columbia,

> [t]he "general [negligence *per se*] rule" . . . is that "where a particular statutory or regulatory standard is enacted to protect persons in the plaintiff's position or to prevent the type of accident that occurred, and the plaintiff can establish his relationship to the statute, unexplained violation of that standard renders the defendant negligent as a matter of law." Richardson v. Gregory, 281 F.2d 626, 629 (D.C. Cir. 1960). . . . If a party charged with statutory or regulatory negligence produces competent evidence tending to explain or excuse his or her violation of the statutory or regulatory standard, the jury is properly instructed, upon proper

> request of the party, that the violation is evidence of negligence but not negligence as a matter of law.

Ceco Corp. v. Coleman, 441 A.2d 940, 945 (D.C. 1982) (some citations omitted); see also Joy v. Bell Helicopter Textron, Inc., 999 F.2d 549, 557 (D.C. Cir. 1993) (same). In addition, the statute or regulation in question must impose specific duties on the defendant. See id. at 558. Ultimately, "[t]he decision to adopt from a statute a standard of care to be applied in determining common law negligence is purely a judicial one, for the court to make." McNeil Pharmaceutical v. Hawkins, 686 A.2d at 579; see also Rong Yao Zhou v. Jennifer Mall Restaurant, Inc., 534 A.2d 1268, 1274 (D.C. 1987).

B. No Substantive Standard of Care

Plaintiffs argue that Section 331 sets forth a substantive standard of care and therefore supports Count VIII because Section 331 "obviously governs behavior." Pls. Opp. at 7. The question before the Court, however, is not whether Section 331 "governs behavior." It surely does – as does almost every statute and regulation. The question before the Court is whether Section 331 embodies "a legislative judgment as to the standard of care" applicable to this case, and thus whether the violation of the cited provisions of Section 331 amounts to the violation of a duty giving rise to an action in tort. Talley v. Danek Medical, Inc., 179 F.3d 154, 161 (4th Cir. 1999). The Court concludes that the answer to that question is "no."

The principal problem with plaintiffs' attempt to base claims of negligence *per se* on Section 331 is that Section 331 simply sets forth – in prohibitory terms – "the basic requirement [of the FDCA and its implementing regulations] that FDA approval is required for commercial distribution [and use of Class III medical devices like Histoacryl and Lipiodol]."

Defs. Obj. at 7.[3] That basic requirement does not embody a *substantive standard of care*, but rather an *administrative requirement* aimed at furthering the FDCA's regulatory goals. In other words:

> The administrative requirement that a given device be approved by the FDA before being marketed – as opposed to a specific substantive requirement that a device be safe and effective – is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care, the breach of which could form the basis of a negligence *per se* claim.

Talley v. Danek Medical, Inc., 179 F.3d at 161. See also King v. Danek Medical, Inc., 37 S.W. 3d 429, 456-60 (Tenn. Ct. App. 2000) (same); Morton v. George Washington Univ., No. 99-4599, Order at 9 (D.C. Sup. Ct. Nov. 30, 2001) (rejecting negligence *per se* claims for use of unapproved devices based on 21 U.S.C. § 331, 21 U.S.C. § 360c and 21 C.F.R. § 812.20; characterizing those provisions as "administrative in nature" and concluding that they do not "set

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[3] The FDCA classifies devices as Class I, II or III devices.

> A Class III device is subject to the statutory requirement of pre-market approval. . . . A Class III device that is introduced, or delivered for introduction, into interstate commerce without such approval violates the statute because it is ["adulterated" under 21 U.S.C. § 351 and "misbranded" under 21 U.S.C. § 352] . . . .
>
> The status of a device as unapproved and uncleared . . . does not necessarily mean that the device is unsafe, defective, or unreasonably dangerous. It means simply that the FDA has not yet concluded that the device should be approved or cleared. Many lawfully marketed medical products have "off-labeled uses" (unapproved and uncleared) that the medical community is satisfied are safe and effective and to which the FDA has no objection.

Baker v. Smith & Nephew Richards, Inc., No. 95-58737, 1999 WL 811334, at *6 (Tex. D. Ct. 1999).

forth a standard of conduct, the breach of which would constitute negligence *per se*"). Thus, Count VIII must be dismissed because 21 U.S.C. § 331 reflects an administrative requirement – not a substantive standard of care that can support plaintiffs' negligence *per se* claim.

C. No Causal Relationship

Plaintiffs' attempt to base negligence *per se* claims on alleged violations of 21 U.S.C. § 331 suffers from another flaw. An essential element of any negligence claim is proof that the alleged breach of duty at issue proximately caused the harm at issue. Thus, to succeed on negligence *per se* claims, "plaintiffs must prove that *the statutory violation* was the proximate cause of their injuries." Rong Yao Zhou v. Jennifer Mall Restaurant, Inc., 534 A.2d at 1277 (emphasis added). Here, the statutory violation at issue is the use of "adulterated" and/or "misbranded" devices. Plaintiffs therefore would have to show that the mere fact that defendants used "adulterated" and/or "misbranded" devices contributed to Ms. Kerris' injuries. This they cannot do. As plaintiffs acknowledge, Histoacryl and Lipiodol were deemed "adulterated" and/or "misbranded" not because of any affirmative determination of dangerousness or impropriety, but merely because they lacked FDA approval. As a result, it is no more logical to infer a causal connection between Histoacryl's and Lipiodol's unapproved status and Ms. Kerris' injuries than it is to infer a causal connection between a driver's lack of a drivers license and injuries he causes while driving. See KEETON ET AL., PROSSER & KEETON ON TORTS § 36, at 223-24 (5th ed. 1984) (observing that "[w]hen a car is driven without a license, the act of driving the car certainly causes a collision; the absence of the license, or the existence of the statute, of course does not"). In short, plaintiffs have not shown and cannot show "that the breach of the

FDA approval requirement proximately caused" the injuries to Ms. Kerris. Talley v. Danek Medical, Inc., 179 F.3d at 161; see also id. ("If the quality or proper labeling of the device, rather than its formal approval, were at issue, then causation might [be] a question of fact. But that [is] not the circumstances here."). Accordingly, it is hereby

ORDERED that the Court's Memorandum Opinion of September 30, 2008 is modified in the manner set forth in this Memorandum Opinion and its Order of Judgment of September 30, 2008 is amended to provide that Count VIII of plaintiff's Second Amended Complaint is DISMISSED.

SO ORDERED.

/s/_____
PAUL L. FRIEDMAN
United States District Judge

DATE: February 3, 2009