UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendants' Motion *in Limine* No. 1 to Exclude References to Alleged FDCA Violations or FDA Approval Status ("Mot."). As the defendants point out, see Mot. at 1, the Court has already ruled that neither the federal statutes nor the regulations cited by the plaintiffs establish a standard of care applicable in this case. See Iacangelo v. Georgetown Univ., 595 F. Supp. 2d 87, 91 (D.D.C. 2009); 580 F. Supp. 2d 111, 113, 117-19 (D.D.C. 2008). For substantially the same reasons provided by the defendants in the motion, see Mot. at 2-3, those rulings necessarily mean that the statutes and regulations in question are not relevant to Count I of plaintiffs' second amended complaint, which alleges negligence/medical malpractice. As a result, the plaintiffs may not refer to or in any way rely upon the Food, Drug, and Cosmetic Act ("FDCA") or any related regulation — or any alleged violation thereof — in an attempt to demonstrate that the defendants are liable as to Count I. This means that the plaintiffs may not argue or present evidence to the effect that defendants were negligent because (1) they did not obtain premarket approval or an investigational device

exemption ("IDE") for their use of Histoacryl, or (2) Histoacryl was "misbranded" or "adulterated."

The relationship of the laws in question to plaintiffs' lack of informed consent claim, described in in Count II of their second amended complaint, is more complicated. It is undisputed that the substances used to treat Karyn Kerris were at the time not approved by the FDA for commercial marketing. See Mot. at 5-6. The defendants point out that some courts have ruled that a drug or device's lack of FDA approval is not material information that must be revealed to a patient during the informed consent process, and so is not relevant to a claim based on lack of informed consent. See id. at 6. While a handful of state courts have so held, however, neither the United States Court of Appeals for the District of Columbia Circuit nor the District of Columbia Court of Appeals has addressed the matter. A jury may well conclude that a device's lack of FDA approval would be material information that a reasonable person would want to know before giving or declining to give consent for use of such a device in a medical procedure. The plaintiffs therefore may inform the jury that the device or devices used to treat Ms. Kerris were not FDA-approved and were not available for commercial sale in the United States. They may not, however, refer to those devices as "illegal," "misbranded," or "adulterated," as none of those terms relate to FDA-approval status, and each is inflammatory and likely to unfairly prejudice the defendants before the jury.

For the foregoing reasons, it is hereby

ORDERED that Defendants' Motion *in Limine* No. 1 to Exclude References to Alleged FDCA Violations or FDA Approval Status is GRANTED in part and DENIED in part.

SO ORDERED.

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

DATE: December 31, 2010