UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

FELICE I. IACANGELO and CICILY IACANGELO, Guardians of the Person and Property of KARYN A. KERRIS, *et al.*, Plaintiffs,	)	
v.	)	Civil Action No. 05-2086 (PLF/AK)
GEORGETOWN UNIVERSITY, *et al.,* Defendants.	)	

MEMORANDUM OPINION

Pending before this Court is Defendants' Emergency Motion to Extend the Deadlines for Defendants' Fed. R. Civ. P. 26(a)(2) Expert Disclosures and to Strike Plaintiffs' Expert Reports for Plaintiffs' Failure to Comply with Fed. R. Civ. P. 26(a)(2)(B) ("Motion") [87]; Plaintiffs' opposition to the Motion ("Opposition") [89]; Defendants' reply to the Opposition ("Reply") [92]; Plaintiffs' Surreply to the Reply ("Surrreply") [96]; and Defendants' response to the Surreply ("Response") [98]. Defendants' Motion is twofold; Defendants first move to extend the January 31, 2008 deadline for disclosure of their Expert Disclosures to a date five weeks after the Plaintiffs provide all required Rule 26(a)(2)(B) information considered by their 13 named experts. Second, Defendants move to strike Plaintiffs' designated legal experts and experts who provide legal opinions and ask the Court to impose a limit on the number of experts who can testify. The Court held a hearing on this Motion on February 27, 2008. A separate Order accompanies this Memorandum Opinion.

I. Background

This case involves claims brought by the parents of an incapacitated adult, Karyn Kerris ("Kerris"), against Georgetown University and Dr. Vance Watson for medical malpractice, breach

of fiduciary duty, and failure to adequately warn. Plaintiffs, guardians of Kerris's person and property, allege that Defendants willfully and wantonly defrauded their daughter by failing to inform her that the devices to be used in her medical treatment were not FDA-approved. Plaintiffs claim that Defendants breached an alleged guaranteed rate of success of the medical procedure employed by Defendants. Plaintiffs also include negligence *per se* claims based on Defendants' alleged violations of the Food, Drug & Cosmetic Act ("FDCA").

II. Legal Standard

Pursuant to Rule 26(a)(2)(B), expert disclosures shall be "accompanied by a written report prepared and signed by the witness [and such] [r]eport shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor; *the data or other information considered by the witness in forming the opinions;* any exhibits to be used . . .; the qualifications of the witness, . . .; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified . . . ." (Emphasis Added.)

Federal Rule of Evidence 403 provides for the exclusion of relevant evidence on grounds of prejudice, confusion or waste of time.[1] Federal Rule of Evidence 702, relating to expert testimony, states that:

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied

[1]Defendants rely on Rule 403 to support their claim for excluding cumulative or duplicative expert testimony. Plaintiffs also cite Fed. R. Civ. P. 26(b), providing for court-imposed limitations on discovery if "the burden or expense of the proposed discovery outweighs its likely benefit, ..." Fed. R. Civ. P. 26(b)(2)(C)(iii).

the principles and methods reliably to the facts of the case.

Federal Rule of Evidence 704 generally allows "testimony in the form of an opinion or inference otherwise admissible" even where it "embraces an ultimate issue to be decided by the trier of fact."

III. Analysis
A. Production of Supplemental Information

The first part of Defendants' Motion addresses alleged insufficiencies in the expert reports provided by Plaintiffs. Attached to the Motion at Exhibit 8 is a letter dated January 7, 2008, wherein counsel for Defendants sets forth questions regarding certain expert reports and requests for additional documentation in support of those reports. The expert reports are identified by name and date. During the hearing on the Motion, the parties were diametrically opposed in their views as to whether the expert reports were complete. Counsel for Defendants argued that some data and documents relied upon by the experts have not yet been produced while Plaintiffs' counsel countered that numerous documents have been produced or identified and expert production is complete.[2] This Court, having completed its review of the expert reports in the context of the Defendants' January 7, 2008 letter, will address them in the order in which they appear in that correspondence:[3]

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[2]Plaintiffs' counsel gave an example to illustrate the overreaching nature of the Defendants' requests, noting that during Dr. Van Woert's deposition, Defendants indicated that they would like copies of certain IRB documents that he might have looked at during his employment at Mount Sinai Hospital. Plaintiffs claim that such documents are extraneous and further, they contest production of medical records that were generated by Defendants, which are being demanded by Defendants.

[3]Some of the complaints raised in Defendants' January 7, 2008 correspondence are moot in light of Plaintiffs' supplemental production of information post-dating that letter [*see* documents attached to Motion at Exhibit 9] but the Court is uncertain whether any other supplemental

1. Dr. Kaufman- Supplemental documentation was produced to Defendants in response to the January 7, 2008 letter.

2. Dr. Gerald Debrun- Dr. Debrun should specify which films he considered.

3. Julia Gabis, Esq.- Supplemental documentation was produced to Defendants in response to the January 7, 2008 letter.

4. Dr. Basil Harris- Documents entitled "Violation Code translation"- Detentions for OASIS for Canada and the "Import Alert (FDA) for Class III Device" were produced in connection with the Kaufman supplementation. If the documents referenced by Defendants in connection with Dr. Harris are not the same documents that were produced by Plaintiffs regarding Dr. Kaufman, additional documents should be produced A schedule of fees for Dr. Harris has also been produced by Plaintiffs.

5. Robert Kamm- Plaintiffs should produce a copy of the "Patients letter to Yucan Medical Systems" noted in the Defendants' January 7, 2008 letter.

6. Dr. Richard Latchaw - Plaintiffs should identify the multiple imaging examinations referenced in his October 15, 2007 Report. Defendants request that Dr. Latchaw provide notes from his conversation with counsel, referenced in his October 28, 2007 Report, prior to provision of his final report. During the deposition of Dr. Latchaw, Defendants may explore what Dr. Latchaw learned from Plaintiffs' counsel that caused him to change his report. Defendants may also question Dr. Latchaw about his statement indicating a 5 to 7% complication rate.

7. Dr. Lichtblau- Defendants request that Plaintiffs provide copies of notes of Dr. Lichblau's conversations with Drs. Delaney and Musselman, and with Manish at Capital Home Care. Notes of Dr. Lichtblau's conversations with these persons have already been provided to Defendants and are included in the packet of documents provided to chambers. Plaintiffs should however provide Defendants with a copy of Dr. Delaney's medical records from 2006 through the present, if these records have not been produced. Defendants further note [without providing a specific reference to the records] that Dr. Lichtblau had a conversation with Mr. Lurito, but the Court finds no reference to this conversation in the Lichtblau records. If such conversation did occur and Dr. Lichtblau relied upon the discussion in formulating his expert opinion, he should provide any notes of the conversation. Alternatively, the Defendants may explore this topic with Dr. Lichtblau at his deposition, and they may also question this witness about the basis for his opinion that Kerris's life span has decreased by 10%.

8. Richard Lurito, Ph.D.- Defendants request a copy of Mr. Lurito's fee schedule, which should be provided by Plaintiffs. Defendants note that Lurito spoke with Dr. Lichtblau (see above) but Mr. Lurito's report does not state that he spoke with Lichtblau; instead, he may have relied upon

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documentation has been given to the Defendants.

Lichtblau's written opinions. Consistent with the above discussion of Dr. Lichtblau, if Lurito and Lichtblau did discuss Plaintiff's condition and prognosis, the notes of such discussion should be produced. Lurito should also indicate the materials on which he relied to prepare his report.

9. Dr. Sheldon Margulies : Defendants requested a fee schedule for Margulies, which has been produced. Defendants request information regarding the "literature searches" performed by Margulies on October 15, 2007 and December 15, 2007, and identification of such information should be provided.

10. Dr. S.J. Peerless: Defendants request that Plaintiffs provide a fee schedule for Peerless and a list of the radiographic studies he reviewed. Plaintiffs should provide these items to the Defendants. The January 7, 2008 letter also notes Defendants' assumption that Peerless only "considered the records as bate stamped and listed by [counsel] in [the] letter dated January 4, 2008" unless Defendants are informed otherwise.

11. Donald Sherwin, Esq.: Defendants request three documents, which may have already been produced in connection with the Kaufman supplementation. If these are not the same documents that Sherwin reviewed, the three documents should be produced to the Plaintiffs.

12. Dr. Melvin Van Woert: Defendants again assert that they presume the only records provided to the experts are those listed in a January 4, 2008 letter. The referenced "Investigational Device Exemptions Manual" should be produced along with the "IRB information sheets," if these documents have not already been produced in connection with the deposition.

The Defendants do not mention any deficiencies regarding expert witness William H. Damaska in their January 7, 2008 letter.[4] At the hearing on the Motion, counsel indicated that Defendants have deposed 4 of Plaintiffs' 13 prospective experts: Dr. Debrun, Mr. Damaska, Dr. Van Woert, and Dr. Kaufman.

The supplemental information to be provided by Plaintiffs should be made available to the Defendants within ten days from the date of this Memorandum Opinion and Defendants' Expert Disclosures will be due four weeks thereafter.[5]

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[4]The copy of the Damaska report attached as Reply, Exh. 10 appears to be incomplete.

[5]Supplementation of expert disclosures for all noted prospective experts is to be provided to the Defendants, in light of the fact that the trial court is the final arbiter on the issue of expert witnesses.

B. Cumulative or Duplicative Testimony

Defendants move to limit the number of expert witnesses designated by Plaintiffs on grounds that there is significant overlap in the trial testimony to be proffered by several of Plaintiffs' prospective expert witnesses, which will unduly prejudice the Defendants and increase their costs in terms of deposing the witnesses and obtaining rebuttal experts. "This court has discretion to limit the number of expert witnesses when their testimony would be cumulative, a waste of time, or present a danger of unfair prejudice." *Washington v. Greenfield*, 1986 WL 15758 (D.D.C. Oct. 15, 1986).

Plaintiffs argue that they must be allowed to present testimony from each of their named experts to assist the jury and the Court, even if there is some overlap in testimony, because the issues in this case are very complex. Plaintiffs further contend that, pursuant to Fed. R. Evid. 403, which provides for a balancing test, the probative value of such expert testimony outweighs the prejudice, if any, to the Defendants.

At the hearing, counsel for Plaintiffs indicated that Plaintiffs are willing to limit their proposed expert witnesses in the following manner: 1) Plaintiffs request two interventional neuroradiologists, Drs. Debrun [deposed] and Latchaw [not deposed], on grounds that these two experts have very different backgrounds and experience, and medical malpractice [glue embolization] is a critical issue in this case; 2) Plaintiffs will use Dr. Kaufman as an expert regarding hospital administration; 3) Plaintiffs are willing to use only one of the two designated neurosurgeons, either Dr. Peerless or Dr. Harris [neither deposed] to testify about alternative treatments and Plaintiff's condition; 4) Plaintiffs intend to use Mr. Damaska [deposed] as their FDA expert as well as a fact witness; 5) Plaintiffs can limit their legal experts to two instead of

three, probably using Ms. Gabis, an attorney and healthcare consultant, instead of Mr. Sherwin, and Mr. Kamm, an FDA liaison; 6) Dr. Van Woert [deposed] will testify regarding IRB research protocol; 7) Dr. Lichtblau will testify as a life care planner damages expert; 8) Mr. Lurito, an economist, will testify about the present value of Plaintiff's life care plan; and 9) Dr. Margulies' testimony about Plaintiff's competence may not be necessary if Plaintiffs call a treating physician instead. Excluding the Margulies' testimony brings the total number of Plaintiffs' experts to ten, instead of thirteen.[6] The Court will use Plaintiffs' designation of these ten experts as a starting point for its analysis of Defendants' Motion.

C. Legal Experts

Plaintiffs allege that Defendant Georgetown University was negligent not only through Dr. Watson but also through its in-house counsel and counsel for Defendant Georgetown's IRB, Sheila Zimmet, who did not require IRB approval of Defendant Watson's use of Histoacryl. Plaintiffs propose to use two of three legal experts to show that Zimmet did not meet the applicable "National Standard of Care." Defendants note that Zimmet is neither a defendant in this case nor have Plaintiffs asserted a legal malpractice claim in their Complaint.

Defendants indicate that Gabis will testify "that Defendant Georgetown's in-house counsel violated the national standard of care by condoning and allowing the use and continued use of illegal, unapproved Class III devices without both an IDE and IRB approval." (Opposition at 5.) Sherwin will testify that "it is a violation of the national standard of care to not use an IRB

[6]At the hearing, Defendants noted that the testimony of Ms. Gabis regarding IRB issues overlaps with Dr. Van Woert's testimony. In their Reply, Defendants proposed that Plaintiffs be limited to offering expert testimony by one or two experts on the medical and FDA issues in addition to an economist and life care planner.

to review the treatment and develop consent for Histoacryl . . . [and] that it is the attorney for the IRB's duty to advise Defendant Watson that IRB oversight was needed." (Opposition at 6.) Kamm will testify "to the required due diligence that was not performed and the interactions that should have taken place, which, if done, would have uncovered the fact that the device was illegal, was being used in derogation of the relevant statutes, and was the subject of an Import Act." (Opposition at 7.) This Court's review of the expert reports by Kamm, Gabis and Sherwin indicates that these three experts have made sweeping legal [and in some cases medical] conclusions in their reports.[7]

Plaintiffs argue that they need to produce expert opinion on national "legal" standards of care involving Georgetown's in-house counsel because "inextricably intertwined in this medical malpractice litigation is a 'legal malpractice' issue." (Opposition at 8.) Plaintiffs contend that Sheila Zimmet was negligent and such negligence proximately caused the [Class III] device to be used at Georgetown, which provided Dr. Watson with the ability to commit medical malpractice.

Defendants contend that expert testimony on legal issues is improper and inadmissible. (Memorandum at 15.) *See Mossey v. Pal-Tech*, 231 F.Supp.2d 94, 98 (D.D.C. 2002) ("It is

[7]For example, Kamm's report states that it is his opinion that "to a reasonable degree of legal probability Ms. Zimmet failed to meet the National Standard of Care for a reasonabl[ly] prudent minimally competent attorney in the opinions she provided in regard to the use of the product in question" and "to a reasonable degree of legal probability that the failure of Dr. Watson and Georgetown University Hospital to follow the Federal Law and receive and use an unapproved device was the proximate cause of the injuries sustained by Ms. Kerris." (Reply, Exh. 8.) Sherwin's report states his opinion that "if the defendants had complied with [the] national standard of care and perf[or]med the necessary IRB review, Histoacryl would not have been injected into Karyn Kerris." (Defendants' Tab 7.) Gabis's report states "Ms. Zimmet's failure to act with reasonable diligence and/or to exercise independent professional judgment and render candid advice, . . ., was the proximate cause of Dr. Watson's use of the device histoacryl in treating Karyn Kerris without an IDE and IRB approval, including the requisite informed consent." (Defendants' Tab 2.)

established, however, that expert testimony consisting of legal conclusions will not be permitted because such testimony merely states what result should be reached, thereby improperly influencing the decisions of the trier of fact and impinging upon the responsibilities of the court.") *See also Burkhart v. Washington Metropolitan Area Transit Authority*, 112 F.3d 1207, 1212-13 (D. C. Cir. 1997) ("[An expert] may not testify as to whether the legal standard has been satisfied.")

Plaintiffs cite several cases for the proposition that "[i]t is black-letter law that expert testimony is required to establish a claim for legal malpractice." (Opposition at 9, citations omitted.) The Court notes, however, that while Plaintiffs' complaint has recently been amended, Plaintiffs have never asserted a claim for legal malpractice nor is Zimmet named as a party in this action. Plaintiffs also rely upon *Halcomb v. Washington Metropolitan Area Transit Authority*, 526 F.Supp.2d 24 (D.D.C. 2007), a case involving an arrestee who filed a Section 1983 suit against a police officer and the District of Columbia, alleging false arrest and assault and battery. (Surreply at 4.) The *Halcomb* court found that Rules 702 and 704 permit expert testimony "about applicable professional standards and defendants' performance in light of those standards." *Halcomb*, 526 F.Supp.2d at 27 (citing *Richman v. Sheahan*, 415 F.Supp.2d 929, 945 (N.D. Ill. 2006)). The *Halcomb* court did however impose certain limits on expert testimony, as follows: "To the degree that [the expert's] opinions . . . verge into impermissible legal conclusions, however, they must be excluded." *Id.* at 27. The expert's opinions in *Halcomb* were excluded "to the extent that they [were] 'phrased in terms of inadequately explored legal criteria' or otherwise '[told] the jury what result to reach.'" *Id.* (citing Fed. R. Evid 704, Advisory Committee's Note.)

Plaintiffs in the instant case imply that there is a "National Standard of Care" applicable to

attorney advisors who provide hospitals with legal advice on utilization of Class III devices. They contend that they need legal experts to testify about breach of this standard of care but Plaintiffs provide no statutory or case law support for imposition of such standard in this case, particularly where there is no claim for legal malpractice or any supporting legal theory that a patient can sue her physician's lawyer for legal malpractice. Even if Plaintiffs could assert legal malpractice against Ms. Zimmet, the legal expert reports contain numerous "impermissible legal conclusions" and the prejudice in allowing such experts to testify clearly outweighs any probative value of their testimony, particularly where there are other experts [Van Woert, Kaufman and Damaska] who may provide testimony regarding IRB research protocol, hospital administration, and the FDA regulations, respectively. In attempting to use legal experts to prove that liability and causation have been established and to interpret statutory language, Plaintiffs would effectively usurp the function of the trier of fact in this case. Accordingly, this Court finds that the Gabis and Kamm expert reports should be stricken and their testimony should be excluded from the Plaintiffs' list of prospective expert witnesses.[8]

D. Other Legal Testimony

Defendants not only contest the use of legal experts to testify about the existence of a national standard of legal care applicable to Georgetown's counsel, but more broadly, Defendants contest the permissibility of expert testimony [by any of Plaintiffs' experts] stating legal conclusions that Defendants violated a national "legal" standard of care by violating federal law. By way of example, Defendants note that the Plaintiffs' experts "lift language from the FDCA and its regulations or overtly cit[e] them." (Memorandum in support of Motion ("Memorandum") at

[8]The Sherwin expert report and testimony would also be excluded on these grounds.

12). Defendants provide several specific examples of contested expert statements in their Memorandum at 12-14. Defendants note that Damaska states: "[i]t is my opinion that Georgetown University and Vance Watson, M.D., violated the national standard of care by violating the following statutes: 21 U.S.C. §331c . . . §351(f)(1)(B)(1). . . 21 C.F.R.§812.20(a) . . ., by using Histoacryl and its combination Lipiodol in the treatment of Karyn Kerris." (Reply, Exh. 10.) Latchaw states: "[i]t is my opinion to a reasonable degree of medical certainty, in fact, to a high degree of certainty *that the aforesaid negligence* and violations of the national standards of care by Dr. Watson, and the national statutes regulating the use of a non-approved device . . ." (Reply, Exh. 3.) (emphasis added).

Plaintiffs argue that their negligence *per se* claim involves a violation of statutes proving a deviation from the national standard of care and Plaintiffs must have the opportunity to demonstrate that to the jury or they would be left to speculate about the nature, purpose and application of statutes and regulations at issue here. Plaintiffs rely on *McNeil Pharmaceutical v. Hawkins*, 686 A.2d 567, 582 (D.C. 1996) ("Where the statutes and regulations are admitted as the basis for a finding of negligence per se, or as evidence of negligence, the plaintiff must also prove a deviation from the standard of care, i.e., that the statutes were in fact violated.") (citation omitted.) Plaintiffs cite *McNeil*, 686 A.2d at 583 for the proposition that "expert testimony [is required] to explain the applicability of statutes where the statute is relied upon as establishing the standard of care."

Defendants assert that bringing a claim for negligence *per se* does not allow use of experts to demonstrate statutory violations; instead, the Court must determine whether the FDCA provisions support a negligence *per se* claim, and then, the jury determines whether a statutory

violation has occurred and if that constitutes a breach of the standard of care. *See generally Burkhart*, 112 F.3d at 1212-13 ("An expert may offer his opinion as to facts that, if found, would support a conclusion that the legal standard at issue was satisfied, but he may not testify as to whether the legal standard has been satisfied.") The *Burkhart* court further noted that "[e]ach courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards." *Id.* at 1213 (citation omitted.) *See also Mossey*, 231 F.Supp.2d at 98 (striking an expert's report, which lifted language from federal regulations to explain certain conclusions, in part because the report included impermissible legal opinions) and *Halcomb*, 526 F.Supp.2d at 27 (D.D.C. 2007) (prohibiting expert testimony that draws legal conclusions.)[9]

Defendants dispute that *McNeil* stands for the proposition that "paid legal opinions are allowed." (Reply at 7.) According to Defendants:

> *McNeil* did not address whether the FDCA set forth a standard of care (although it questioned whether it could, *id.* at 580); rather, the Court held that the lower court erred in admitting FDCA regulations without first determining that the FDCA stated a standard of care and also erred in failing to determine whether the statutes were sufficiently clear for a jury, and lastly, the trial court was directed to then determine whether and what expert testimony might help the jury understand the admitted provisions - by discussing the FDCA in terms of the facts of the case- not to opine that the FDCA was violated.

Reply at 7 (*see McNeil* at 581.)

Defendants also cite *Steele v. D.C. Tiger Market,* 854 A.2d 175 (D.C. 2004) ("Rather than being helpful, expert testimony purporting to state or apply the governing law risks

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[9]Plaintiffs argue that the reasoning in *Halcomb* is not applicable to a negligence *per se* case but Defendants employ that case in support of a general proposition that is not confined to civil rights cases. Similarly, Plaintiffs try to distinguish *Burkhart* [a decision in a criminal case not involving negligence *per se*] on factual grounds but that case is also cited to support a general principle that experts cannot instruct the jury on legal issues.

misinterpreting that law and confusing or misleading the jury.") Defendants contend that statutory interpretation is a question of law for the court. (Reply at 8 & n.11 (containing string cite of cases)). In the instant case, the expert reports are replete with examples of impermissible legal conclusions; i.e., opinions that a statute imposing a certain "standard of care" was violated. Plaintiffs' proposed experts also state impermissible opinions on Defendants' state of mind.[10] (Reply at 9; *see generally Lohrenz v. Donnelly*, 225 F.Supp.2d 25, 36 (D.D.C. 2002) ("courts have generally disfavored expert testimony in determining actual malice, which is essentially a determination of defendants' subjective state of mind") and *S.E.C. v. Johnson*, 525 F.Supp.2d 70, 78 (D.D.C. 2007) (excluding opinions as to intent because "[d]eterminations of individuals' intent is a quintessential jury question.")

This Court finds that Mr. Damaska's **expert** testimony should be excluded on grounds that he has also been named as a fact witness and the statements in his expert report set forth numerous facts, drawn from his experience as a former Director of Compliance for the FDA and drafter of import alerts. His conclusion that "Georgetown University and Vance Watson, M.D., violated the national standard of care by violating the following statutes [listing several statutory cites], by using Histoacryl and its combination with Lipiodol in the treatment of Karyn Kerris," (Exh. 10), is a legal conclusion, and it involves issues for the jury. This Court finds that many of Plaintiffs' expert reports contain impermissible legal conclusions and opinions about state of

[10]Defendants provide several examples of proposed testimony on state of mind: Van Woert Report at 3 (stating that Dr. Watson "knowingly participated in the illegal importation of a Class III medical device") (Exh. 9); Kaufman Report. at 2 (stating that "willful and wanton misbehavior" is not permitted. (Exh. 11.)

mind. Exclusion of all such testimony from the expert reports would require such reports to be revised and perhaps rewritten because such legal conclusions and state of mind opinions are commingled with permissible expert medical testimony. Alternatively, in the interest of judicial efficiency and economy, this Court suggests that imposing actual limitations on the scope of expert testimony be addressed in the form of a motion *in limine* immediately prior to trial, after Defendants' pending dispositive motion has been ruled upon by the trial court and after Plaintiffs have determined whether they will use Dr. Peerless or Dr. Harris.

DATED: June 17, 2008

_____/s/_____
ALAN KAY
UNITED STATES MAGISTRATE JUDGE