IN THE SUPREME COURT OF THE STATE OF NEVADA

HUMBOLDT GENERAL HOSPITAL and SHARON MCINTYRE, M.D., Petitioners, v. THE SIXTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, IN AND FOR THE COUNTY OF HUMBOLDT, AND THE HONORABLE MICHAEL R. MONTERO, DISTRICT JUDGE, Respondents, and KELLI BARRETT, Real Party in Interest.	No. District Court Case No.: CV 19,460

Appendix re: Petition for Writ of Mandamus

Mark J. Lenz, Esq., NV Bar No. 4672
Margo Piscevich, NV Bar No. 0917
Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, Nevada 89509
Tel: (775) 329-0958
Fax: (775) 329-2666
Attorneys for PETITIONERS

Petitioners submit their "Appendix" in Support of their "Petition for Writ of Mandamus, pursuant to NRAP 21 as follows:

Dated this 1st day of May, 2014

PISCEVICH & FENNER

By: _____

Mark J. Lenz, Esq.
Attorneys for Petitioners

Index

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I hereby certify that I am an employee of PISCEVICH & FENNER and that on this date I caused to be served a true and correct copy of the document described herein by the method indicated below, and addressed to the following:

Document Served: **APPENDIX RE: PETITION FOR WRIT OF MANDAMUS**

Person(s) Served:

David Allen, Esq. David Allen & Associates 200 S. Virginia St., 8th Floor Reno, Nevada 89501	_____ XX _____ _____	Hand Deliver U.S. Mail Overnight Mail Facsimile
Hon. Michael R. Montero Sixth Judicial District Court Department II 50 W. Fifth St. Winnemucca, NV 89445	_____ XX _____ _____	Hand Deliver U.S. Mail Overnight Mail Facsimile

DATED this 2nd day of May, 2014.

Beverly Chambers

3350

CASE NO. CV 19,460

DEPT. NO. II

FILED

2014 APR -8 PM 3:30

TAMI RAE SPERO
DIST. COURT CLERK

IN THE SIXTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA IN AND FOR THE COUNTY OF HUMBOLDT

-o0o-

KELLI BARRETT,

Plaintiff,

vs.

ORDER

HUMBOLDT GENERAL HOSPITAL and SHARON MCINTYRE, M.D., and DOES 1 to 50, inclusive,

Defendants.

Before this Court is *Defendants' Motion to Dismiss* filed on June 3, 2013. On July 5, 2013, Plaintiff filed her opposition. Defendants filed their reply and submitted the matter to the Court for decision on July 12, 2013.

The pertinent alleged facts are as follows. On April 1, 2011, Plaintiff underwent a medical procedure whereby Dr. Sharon McIntyre, employed by Humboldt General Hospital (hereinafter "HGH"), surgically inserted a Mirena IUD. Plaintiff consented to the procedure. On or about March 6, 2012, approximately one year after the procedure,

Plaintiff was informed, through a letter dated March 2, 2012, that the Mirena IUD utilized during her procedure lacked FDA approval. Plaintiff filed her *Complaint* on March 4, 2013 alleging various claims related to Dr. McIntyre's use of a non-FDA approved Mirena IUD.

Defendants seek dismissal of Plaintiff's *Complaint* in its entirety. First, Defendants assert that Plaintiff's medical malpractice claim must be dismissed for her failure to provide a medical affidavit as required by NRS 41A.071. Second, Defendants argue that Plaintiff's battery claim should be dismissed because she consented to the insertion of the Mirena IUD. Third, Defendants allege Plaintiff has no private right of action to enforce FDA regulations through a medical malpractice claim that is void *ab inito*. Hence, according to Defendants, any claims seeking to enforce such regulations should be dismissed as well. Fourth, Defendants also argue that the *Complaint* should be dismissed because it is time-barred as Plaintiff received notice of the alleged injury on Friday, March 2, 2012, yet the *Complaint* was not filed until March 4, 2013. Lastly, Defendants assert that Plaintiff cannot maintain or allege a claim for punitive damages as HGH is a County Hospital, and Dr. McIntyre is a State employee. Accordingly, Defendants argue, Plaintiff's claim for punitive damages should also be dismissed.

On the other hand, Plaintiff asserts that her *Complaint* is not time-barred. Furthermore, Plaintiff opposes dismissal of her medical malpractice and battery claims. Plaintiff also opposes Defendants' characterization of her reliance on FDA regulations. Plaintiff does not dispute Defendants' position on punitive damages.

//

ANALYSIS

When reviewing a motion to dismiss for failure to state a claim, the Court must accept Plaintiff's factual allegations as true and draw every reasonable inference in Plaintiff's favor. *DeBoer v. Sr. Bridges of Sparks Fam. Hosp.*, 282 P.3d 727, 730 (2012). A complaint should be dismissed for failure to state a claim "only if it appears beyond a doubt that [Plaintiff] could prove no set of facts, which, if true, would entitle [her] to relief." *Buzz Stew, LLC v. City of N. Las Vegas*, 124 Nev. 224, 228 (2008).

1. Negligence Claim

Plaintiff fails to clearly articulate the basis of her "negligence" claim. Although Defendants argued in their *Motion* that the negligence claim should be analyzed as a medical malpractice claim, Plaintiff does not address the issue directly. Instead, Plaintiff cites to both medical malpractice law and simple negligence law in her analysis. Upon reviewing the alleged facts that form the basis of Plaintiff's claim, the Court construes Plaintiff's "negligence" cause of action as a medical malpractice claim. Plaintiff's factual support for her claim essentially involves allegations that Dr. Sharon McIntyre and HGH failed to use reasonable care, skill or knowledge in rendering services to her.[1] Consequently, Plaintiff's cause of action must be analyzed under medical malpractice law.

NRS 41A.071 requires the dismissal of a medical malpractice action filed without an expert affidavit. The *res ipsa loquitur* doctrine, codified in NRS 41A.100, allows medical malpractice claims to proceed, without an expert affidavit, when the Plaintiff can

[1] NRS 41A.009 defines medical malpractice as "the failure of a physician, hospital or employee of a hospital, in rendering services, to use the reasonable care, skill or knowledge ordinarily used under similar circumstances."

show that a factual situation enumerated in NRS 41A.100(1)(a)-(e) exists. *Szydel v. Markman*, 121 Nev. 453, 461 (2005). The enumerated factual situations are those where negligence can be shown without expert medical testimony, such as when a "foreign substance … was unintentionally left within the body of a patient following surgery." *Id.* at 459; NRS 41A.100(1)(a) .

Here, Plaintiff alleges that her claim constitutes negligence per se and cites to NRS 41A.100(1)(a). Specifically, Plaintiff asserts that Defendants inserted a foreign device in her body, a non-FDA approved Mirena IUD, and left it there. Accordingly, Plaintiff argues, a medical affidavit is not required to support her negligence claim; hence, dismissal of her cause of action is not warranted.

After accepting Plaintiff's allegations as true and drawing every reasonable inference in Plaintiff's favor, the Court concludes that Plaintiff fails to state a claim upon which relief can be granted. Plaintiff's allegations do not support a *res ipsa* claim. Lack of FDA approval, in and of itself, does not transform an object into a "foreign substance" as Plaintiff appears to contend. Moreover, there are no allegations in this case that the Mirena device was left in Plaintiff's body unintentionally.

Since Plaintiff's *res ipsa* claim is not viable under the factual allegations presented in this case, Plaintiff's failure to support her *Complaint* with a medical expert affidavit requires dismissal. Accordingly, Plaintiff's negligence claim, construed by this Court as a medical malpractice cause of action, is dismissed.

//

//

2. Battery

Defendants argue that the battery claim cannot survive because the entire *Complaint* is invalid for failure to comply with the medical affidavit requirement in NRS 41A.071.[2] Furthermore, Defendants assert that the claim must be construed as a medical battery claim, and should be dismissed because Plaintiff consented to the implantation of the Mirena IUD. Plaintiff, on the other hand, disputes that Plaintiff consented to the procedure. Specifically, Plaintiff contends that although she agreed to a procedure, she did not consent to the Defendants utilizing a non-FDA approved device. Plaintiff cites to common law battery elements, informed consent law, as well as NRS 41A.110 to support her claim.[3]

A person is subject to liability for battery if: (a) he acts intending to cause harmful or offensive contact with another person, and (b) harmful contact with the other person results. Restatement (Second) of Torts §13. Generally, if consent is present, plaintiff cannot maintain a successful battery claim. *Wright v. Starr*, 42 Nev. 441 (1919). In the context of a medical procedure, consent by a patient is conclusively established if the physician: 1) explains the procedure to patient in general terms, (2) explains alternative methods of treatment to patient, (3) explains to patient the risks involved, and (4) obtains the signature of patient to statement containing an explanation of procedure, alternatives, and risks involved.

---

[2] Although Defendants cite to NRS 41A.079, the Court assumes that Defendants intended to cite to NRS 41A.071 as NRS 41A.079 does not exist.

[3] Plaintiff cites to NRS 41A.100 in her opposition. The Court assumes Plaintiff intended to cite to NRS 41A.110 as NRS 41A.100 does not address the issue of consent.

Here, after accepting Plaintiff's factual allegations as true and drawing every inference in her favor, it does not appear beyond a doubt that she is not entitled to relief under the battery claim. Defendants' assertion that dismissal of the battery claim is warranted because she failed to provide a medical affidavit is not supported by legal authority. It appears that Defendants assume, without support, that any claim against a doctor or hospital, such as the battery claim here, is covered by the statutory definition of "medical malpractice" and subject to the expert affidavit requirement. The Court is not persuaded by Defendants' arguments as presented in this *Motion*.

Furthermore, Defendants assert that Plaintiff's battery claim must be analyzed as "medical battery." Subsequently, they appear to argue that if consent exists the claim is invalid because medical battery only applies if there is no consent. Defendants cite to *Gorney v. Meaney*, 214 Ariz. 226, 232 (2007) in support of their proposition. In actuality, *Gorney* provides, in a footnote, that under Arizona law a claim against medical providers sounding in battery can either be analyzed as an intentional tort or as an "informed consent" claim. *Id.* at 232 n.1. Informed consent is at issue in this case. Accordingly, the fact that Plaintiff consented to the procedure, does not, in and of itself, warrant dismissal under the law cited by Defendants.

Lastly, Plaintiff's informed consent argument is plausible. Plaintiff's allegation that she was not informed the device lacked FDA approval may possibly defeat consent. Defendants request that this Court deem Plaintiff's admission that she agreed to the implantation of a Mirena IUD valid consent as a matter of law. This conclusion is not

warranted based on the arguments and legal support before the Court at this time. As a result, Defendants' request to dismiss the battery claim is denied.

3. FDA Regulations

Defendants argue that Plaintiff cannot seek to enforce 21 CFR through a medical malpractice claim that is void as a matter of law; hence, any such claim should be dismissed. Although the Court has dismissed Plaintiff's negligence claim, analyzed as a medical malpractice claim, the battery claim survives. Accordingly, it does not appear beyond a doubt that Plaintiff could prove no set of facts that would entitle her to relief under a state law claim.

4. Timeliness of Complaint

Defendants urge the Court to interpret NRS 41A.097 as barring Plaintiff's action. NRS 41A.097 provides that an action for injury may not be commenced more than "[one] year after the plaintiff discovers or through the use of reasonable diligence should have discovered the injury, whichever occurs first." Here, Plaintiff alleges that she discovered her injury on or about March 6, 2012. The *Complaint* was filed on March 4, 2013, one year from the alleged date of discovery. Under this factual scenario, and considering that the Court must draw every reasonable inference in Plaintiff's favor, dismissal of the *Complaint* is not warranted on the statute of limitations basis.

5. Punitive Damages

Defendants argue that Plaintiff cannot claim punitive damages because HGH is a County Hospital and Dr. McIntyre is a State employee. Plaintiff does not dispute Defendants' position. Accordingly, Plaintiff's punitive damages claim is dismissed.

CONCLUSION

Based on the foregoing, *Defendants' Motion to Dismiss* is GRANTED IN PART. Plaintiff's negligence claim, analyzed as a medical malpractice claim, is dismissed. Additionally, Plaintiff's claim for punitive damages is also dismissed. Defendants' request for dismissal of Plaintiff's battery claim is denied. Defendants' request that the *Complaint* be dismissed as barred by the statute of limitations is also denied.

IT IS SO ORDERED.

DATED: April 8, 2014.

HONORABLE MICHAEL R. MONTERO
DISTRICT JUDGE

SIXTH JUDICIAL DISTRICT COURT
HUMBOLDT COUNTY • LANDER COUNTY • PERSHING COUNTY
MICHAEL R. MONTERO
DISTRICT JUDGE · DEPARTMENT II

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of the Honorable Michael R. Montero, District Court Judge, Sixth Judicial District Court and am not a party to, nor interested in, this action; and that on April 8, 2014, I caused to be served a true and correct copy of the enclosed **ORDER** upon the following parties:

David Allen, Esq.
David Allen & Associates
200 S. Virginia Street, 8th Floor
Reno, NV 89501
Via US Mail

Margo Piscevich, Esq.
Piscevich & Fenner
499 W. Plumb Lane, Suite 201
Reno, NV 89509
Via US Mail

Eliana Sandoval

Eliana Sandoval
Staff Assistant
Sixth Judicial District Court, Dept. II

DAVID ALLEN, ESQ. (SBN 2183)
DAVID ALLEN & ASSOCIATES
200 South Virginia Street, 8th Floor
Reno, NV 89501
Phone: (775) 786-1020
Facsimile: (775)786-1026

Attorney for Plaintiff,
KELLI BARRETT

IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF WASHOE

KELLI BARRETT,

Plaintiff,

v.

HUMBOLDT GENERAL HOSPITAL and SHARON McINTYRE, MD, and DOES 1 to 50, inclusive,

Defendants.

CASE NO. CV13 00460

DEPT NO: 3

COMPLAINT

Plaintiff KELLI BARRETT, ("Plaintiff" or "Plaintiff Barrett") by and through her attorney, David Allen, Esq. and the law firm of David Allen & Associates, 200 South Virginia Street, 8th Floor, Reno, Nevada, 89501, as and for causes of action against the above-named Defendants complain and allege as follows:

GENERAL ALLEGATIONS COMMON TO EACH CAUSE OF ACTION

1. Plaintiff Barrett at all times herein mentioned was a resident of the State of Nevada.

2. On information and belief, at all times mentioned herein Defendant HUMBOLDT GENERAL HOSPITAL ("Defendant Humboldt"), a business organization form unknown, is in the business of providing health care at its location commonly referred to as 118 E. Haskell Street, Winnemucca,

NV. Hereinafter "HUMBOLDT" shall designate HUMBOLDT GENERAL HOSPITAL ("Defendant Humboldt") in all forms it exists or is recognized as existing. Defendant SHARON McINTYRE, MD. ("Defendant McIntyre"), is a medical doctor licensed by the state of Nevada, and at all times relevant herein, provided medical care for Plaintiff Barrett at Defendant Humboldt's referenced medical facilities.

3. The true names and capacities, whether individual, corporate, associate, or otherwise, of other Defendants, identified herein as DOES 1 to 50 are unknown to Plaintiff Barrett, who therefore will seek leave of court to amend this Complaint to show their true names and capacities when the same have been ascertained. Plaintiff Barrett is informed and believes and thereon alleges that each of said DOES 1 through 50 are responsible, in whole or in part, independently or in connection with the other named defendants for the events and injuries and damages sustained by Plaintiff Barrett as alleged in this Complaint.

4. At all times mentioned herein, the agents and or employees for defendants Humboldt, McIntyre and DOES 1 to 50 were acting within the course and scope of their agency and employment for said named defendants and said defendants Humboldt and McIntyre and DOES 1 to 50 ratified and approved the acts of their agents and or employees.

5. On or about April 1, 2011, Plaintiff Barrett sought medical treatment from defendants Humboldt and McIntyre and agreed to have a medical device, a Mirenda intrauterine device "IUD", implanted in her body as a result of medical difficulties with oral contraceptives. Plaintiff Barrett had the IUD surgically implanted on said date by defendant McIntyre at defendant Humboldt's medical hospital.

6. After the surgical insertion of the IUD, Plaintiff Barrett commenced to have moderate to severe pain almost constantly from the time of the insertion of said IUD. Plaintiff Barrett experienced other pain in other parts of her body in addition to the pelvic pain developing after said IUD insertion. Further, after said IUD insertion Plaintiff experienced pain while engaging in usual and customary activities which prior to said IUD insertion never produced pain.

7. These medical issues, *infra*, forced Plaintiff Barrett to return to her medical providers without any relief from aforesaid problems.

8. Subsequently, on or about March 6, 2012, Plaintiff Barrett received a letter from Defendant Humboldt informing her that said IUD implanted in Plaintiff at Defendant Humboldt's medical facility was a devise purchased in violation of law. It was ordered from Canada and not approved

by the federal Food and Drug Administration ("FDA"). Said correspondence advised Plaintiff to discuss this "problem" with her physician and evaluate removal of said IUD.

9. Plaintiff Barrett was shocked and completely dismayed at receiving the information that said IUD implanted in her body was a product not approved by the FDA. She reasonably feared that her ongoing physical pain was caused by the use of a product implanted in violation of law. Plaintiff sustained serious personal injuries as a direct and proximate result of the acts of defendants herein. Plaintiff's aforesaid injuries caused Plaintiff to suffer extreme and continuing pain and suffering and also forced her to immediately have an emergency medical procedure to remove said IUD.

FIRST CAUSE OF ACTION

(NEGLIGENCE)

10. Plaintiff Barrett refers to and incorporates by reference as if fully set forth the allegations of Paragraphs 1 through 13, inclusive, of this Complaint as if fully set forth herein.

11. On or about April 1, 2011, Defendants Humboldt and DOES 1 to 20, and each of them, owned, operated and had a duty to maintain said hospital in a manner that would not create a dangerous or hazardous condition for patients of said hospital. Defendant McIntyre and Does 21 through 50, and each of them had a duty to provide Plaintiff with care, treatment, medications and medical devices consistent with state and federal law.

12. Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them, knew or should have known of the existence of a dangerous condition of using and implanting in Plaintiff Barrett said IUD obtained in violation of FDA rules and law, as well as the likelihood of harm caused by the dangerous condition of said IUD obtained in violation of law.

13. By permitting said purchase and use of said IUD, defendants unreasonably subjected Plaintiff to a dangerous condition without warning to Plaintiff. Defendants Humboldt and DOES 1 to 20, and each of them failed to exercise due care in the ownership, operation and maintenance of their hospital to ensure that patients such as Plaintiff Barrett were not unreasonably exposed to risk of harm by use of said IUD in violation of federal law. Defendant McIntyre and DOES 21 through 50 failed to exercise due care in placing said IUD in Plaintiff's body.

14. As a direct and proximate result of the negligence of Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them, Plaintiff Barrett suffered continuing injury to her body and shock and injury to Plaintiff's nervous system and person, all of which have caused and continue to cause

Plaintiff great physical and mental pain and suffering. On information and belief, Plaintiff alleges that said injuries will result in some permanent disability to Plaintiff. The continuing injury to the body of Plaintiff, the shock to Plaintiff and continuing disability to Plaintiff all constitute general damages inflected in an amount in excess of ten thousand dollars ($10,000).

15. As a further direct and proximate result of the negligence of Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them Plaintiff also incurred related medical expenses in an amount which shall be shown according to proof at the time of trial.

16. As a further direct and proximate result of the negligence of Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them, Plaintiff Barrett suffered a loss of earnings and impaired earning capacity in an amount which shall be shown according to proof at the time of trial

17. As a further direct and proximate result of the negligence of Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them, suffered fear, anxiety, humiliation, physical pain, discomfort, and emotional distress, all to Plaintiff's damage in an amount exceeding the sum of ten thousand dollars ($10,000.00).

SECOND CAUSE OF ACTION

(BATTERY)

18. Plaintiff Barrett refers to and incorporates by reference as if fully set forth the allegations of Paragraphs 1 through 11, inclusive, and Paragraph 15 of this Complaint as if fully set forth herein.

19. Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them, knew or should have known of the existence of a dangerous condition of using and implanting in Plaintiff Barrett said IUD obtained in violation of FDA rules and law, as well as the likelihood of harm caused by the dangerous condition of implanting said IUD obtained in violation of law.

20. Defendants Humboldt, McIntyre and DOES 1 to 50, knew or reasonably should have known that Plaintiff Barrett did not consent to the implantation in Plaintiff's body of said IUD which lacked FDA approval for medical use. Despite the lack of Plaintiff's consent, defendants unreasonably touched Plaintiff Barrett by implanting said IUD. This subjected Plaintiff to the unreasonable exposure to risk harm by use of by a non FDA approved IUD.

21. On information and belief, the conduct of Defendants Humboldt, McIntyre and DOES 1 to 50, and each of them, was committed with intent to cause, or with the substantial certainty it would cause, harm, injury and damage to Plaintiff Barrett without obtaining the consent of Plaintiff.

22. As a direct and proximate result of said intentional conduct, or conduct conducted with the substantial certainty by defendants, Plaintiff suffered continuing injury to her body and shock and injury to Plaintiff's nervous system and person, all of which caused and continue to cause Plaintiff great physical and mental pain and suffering. The continuing injury to the body of Plaintiff, the shock to Plaintiff and continuing disability to Plaintiff all constitute general damages to Plaintiff in an amount in excess of ten thousand dollars ($10,000).

23. On information and belief, the actions of defendants, and each of them were wilful, wanton, oppressive, malicious, and done with a conscious disregard for the rights and safety of Plaintiff Barrett. Defendants' actions were done with the intention to harm, injure, annoy, vex and harass Plaintiff, within the meaning of Nevada RS 42.005. Plaintiff is therefore entitled to an award of exemplary or punitive damages against defendants and each of them, to make an example of said defendants and to deter such reprehensible conduct.

WHEREFORE PLAINTIFF PRAYS FOR JUDGMENT AGAINST DEFENDANTS AND EACH OF THEM AS FOLLOWS:

1. For general Damages in a sum in excess of Ten Thousand Dollars ($10,000.00) ;
2. For all medical and incidental expenses according to proof;
3. For all loss of earnings and earnings capacity according to proof;
4. For punitive and exemplary damages according to proof ;
5. For pre-judgment interest on all general and special damages;
6. For costs of suit herein;
7. For such further relief as the Court deems just.

DATED: March 4, 2013

DAVID ALLEN & ASSOCIATES

DAVID ALLEN
Attorney for Plaintiff
KELLI BARRETT

AFFIRMATION
Pursuant to NRS 239B.030

The undersigned does hereby affirm that the COMPLAINT filed in the instant case does not contain the social security number of any person.

DATED: March 4 , 2013

DAVID ALLEN & ASSOCIATES

DAVID ALLEN
Attorney for Plaintiff
KELLI BARRETT

filed 6/3/13

MARGO PISCEVICH
Nevada State Bar No. 000917
MARK J. LENZ
Nevada State Bar No. 004672
PISCEVICH & FENNER
499 West Plumb Lane, Suite 201
Reno, Nevada 89509
775-329-0958
Attorneys for Defendant
HUMBOLDT GENERAL HOSPITAL

IN THE SIXTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF HUMBOLDT

KELLI BARRETT,

Plaintiff,

vs.

HUMBOLDT GENERAL HOSPITAL and SHARON McINTYRE, M.D., and DOES 1 to 50, inclusive,

Defendants.
_____/

CASE NO. 19460

DEPT. NO. 2

DEFENDANTS' MOTION TO DISMISS

Defendants Humboldt District Hospital dba Humboldt General Hospital (hereinafter referred to as HGH) and Sharon McIntyre, M.D., by and through their counsel of record, Piscevich & Fenner, move the Court pursuant to NRCP 12(b), NRS 41A.071, NRS 41A.097 and NRS 41.035 for an order dismissing Plaintiff's Complaint on the grounds the Complaint fails to state a claim against Defendants on which relief may be granted as a matter of law, is not in compliance with the requirements of the medical malpractice statutes, and is time-barred.

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

This Motion is made and based on the Memorandum of Points and Authorities in Support, and on all the records, papers and pleadings on file in this action.

Notice of Motion

TO: Plaintiff, and her counsel of record, David Allen, of David Allen & Associates, 200 S. Virginia St., 8th Floor, Reno, NV 89501;

PLEASE TAKE NOTICE: That on May 31, 2013, Defendants sent to the Court for filing their "Motion to Dismiss" in the above-captioned action. The Motion will be set for hearing on _____, 2013, or on such other date as the court deems convenient for court and counsel.

Dated this 31st day of May, 2013

PISCEVICH & FENNER

By: _____
Mark J Lenz
Attorneys for Defendants

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

Memorandum of Points and Authorities

I. Nature of the Case

Although Plaintiff has attempted to disguise this action as a simple negligence case, it is first a medical malpractice case, and second, an unlawful attempt to enforce a federal regulation. Plaintiff alleges that Defendants, a hospital and a doctor, provided negligent medical treatment in relation to the surgical implantation of an intrauterine device. Plaintiff failed to attach the requisite affidavit of a medical expert. The court is therefore obligated as a matter of law to dismiss the Complaint, without prejudice, but without leave to amend. In addition, to the extent Plaintiff is attempting to enforce an FDA regulation or claim violation of such, she has no private right of action under federal law. And finally, Plaintiff's Complaint was untimely.

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

II. Standard of Review

NRCP 12(b) provides in part:

> Every defense, in law or fact, to a claim for relief in any pleading, whether a claim, counterclaim, cross-claim, or third-party claim, shall be asserted in the responsive pleading thereto if one is required, except that the following defenses may at the option of the pleader be made by motion: (1) lack of jurisdiction over the subject matter, ...(5) failure to state a claim upon which relief can be granted.... A motion making any of these defenses shall be made before pleading if a further pleading is permitted. No defense or objection is waived by being joined with one or more other defenses or objections in a responsive pleading or motion. If a pleading sets forth a claim for relief to which the adverse party is not required to serve a responsive pleading, the adverse party may assert at the trial any defense in law or fact to that claim for relief. If, on a motion asserting the defense numbered (5) to dismiss for failure of the pleading to state a claim upon which relief can be granted, matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.
>
> "A motion to dismiss under Rule 12(b) (1)... may be utilized when a lack of jurisdiction over the subject matter appears on the face of the pleading."

Girola v. Roussile, 81 Nev. 661, 663, 408 P.2d 918 (1965).

Motions to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) may be based upon either a facial or factual attack. *See, e.g., United States v. Ritchie,* 15 F.3d 592, 598 (6th Cir. 1994) *cert. denied*, 513 U.S.868 (1994).

> A facial attack challenges the sufficiency of the pleading itself, and requires the Court to take all of the material allegations in the complaint as true and construe them in the light most favorable to the non-moving party. *Ritchie*, 15 F.3d at 598 (citing *Scheuer v. Rhodes*, 416 U.S. 232, 235-37 (1974)). In contrast, a factual attack challenges the factual existence of subject matter jurisdiction, *Ohio Hosp. Ass'n v.Shalala*, 978 F.Supp. 735, 739 (N.D. Ohio 1997), and requires a court to "weigh the conflicting evidence to arrive at the factual predicate that subject-matter [jurisdiction] does or does not exist." *Gentek Bldg. Prods. v. Sherwin-Williams Co.*, 491 F.3d 320, 330 (6th Cir. 2007). Thus, whereas a facial attack requires the Court to accept Plaintiff's allegations as true, a factual attack precludes any assumption of truthfulness and allows the Court to weigh the evidence.

Bramberger v. Toledo Hospital, (N.D. Ohio 9-24-2012).

> Once a party has moved to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the opposing party bears the burden of establishing the Court's jurisdiction. *See Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994); *Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1122 (9th Cir. 2010); *St. Clair v. City of Chico*, 880 F.2d 199, 201 (9th Cir. 1989).

Full Circle Sales v. Organic Alliance (N.D.Cal. 10-29-2012).

Rule 12(b)(1) is a proper vehicle for challenging subject matter jurisdiction where a statute of limitation bars the action:

> Courts have recognized a variety of ... defenses that one normally would not think of as raising subject matter jurisdiction questions when considering a Rule 12(b)(1) motion, including claims that the plaintiff's suit is barred by the governing statute of limitations.

Aeons Centro de Administracao de Empresas v. Central Bank Of Nigeria (D.Md. 7-3-2012).

Motions to dismiss for failure to state a claim are governed by a standard of reasonable plausibility. *See, e.g., Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) ("a complaint requires a plausible set of facts; 'the no set of facts' language has been questioned, criticized, and explained away long enough by courts and commentators, and is best forgotten as an incomplete, negative gloss on an accepted pleading standard ..."). Although the plausible allegations in the complaint "must be accepted as true," *Hynds Plumbing & Heating Co. v. Clark County Sch. Dist.,* 94 Nev. 776, 585 P.2d 1331 (1978), and the court must "draw every fair intendment in favor of the plaintiff," *Capital Mortgage Holding v. Hahn,* 101 Nev. 3134, 705 P.2d 126 (1985), "a court need not 'blindly accept as true all allegations, nor must it draw all inferences from them in plaintiff's favor unless they are reasonable inferences.'" *Big Lots Stores, Inc. v. Bain Capital Fund VII,* [C.A. No. 1081-N, Court of Chancery of Delaware, 2006). Also, "in ruling on a motion to dismiss for failure to state a claim, the court may take into account any exhibits attached to the complaint and matters in the record." *Schmidt v. Washoe County,* 123 Nev. 128, 159 P.3d 1099 (2007). Under the standards set forth in *Twombly*, the Court should dismiss Plaintiff's Complaint.

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

III. Statement of Facts

Taking the plausible allegations in the Complaint as true, the court will accept that HGH is a County hospital that employs Dr. Sharon McIntyre. Plaintiff "sought medical treatment from defendants," and "agreed to have a medical device, a Mirena intrauterine device ("IUD") implanted in her body...," [Complaint ¶5], and agreed to have Dr. McIntyre perform the procedure. [*Id.*]. Plaintiff signed a consent form permitting the procedure to go forward. [**Exhibit "3"**]. On April 1, 2011, Dr. McIntyre performed the surgical procedure to implant the IUD in Plaintiff at HGH, using the Mirena device. [Complaint, ¶5]. Plaintiff allegedly experienced "moderate to severe pain almost constantly from the time of the insertion of said IUD." [Complaint, ¶6]. She also claims she "experienced pain in other parts of her body, ... even while engaging in usual and customary activities which prior to the IUD insertion never produced pain." [*Id.*].

On or about March 2, 2012, HGH informed Plaintiff by letter [copy attached hereto as **Exhibit "1"**] that it had discovered that the Mirena devices the Hospital had purchased lacked FDA approval, solely because they had been ordered from a Canadian distributor, rather than a U.S. distributor, even though the devices were all made at the same factory in Finland. Dr. McIntyre had ordered the Mirena IUDs for her patients from Canada as they are substantially less expensive. Unbeknownst to Dr. McIntyre, hospitals are required to purchase FDA approved IUDs, while individuals are not.

The Mirena brand IUDs are manufactured in Finland and imported and distributed in the United States by Bayer Schering Pharmacy (Bayer). The IUDs when imported and distributed by Bayer are FDA approved as Class III devices bearing National Drug Code Number (NDC)

50419-421-01. When the same Mirena devices, manufactured in the same facility are imported through a Canadian pharmacy, those devices lack the NDC number assigned by the FDA.

Plaintiff now asserts the "device was purchased in violation of law" [Complaint, ¶8]. She alleges that the implanted IUD caused severe pain and pelvic pain [Complaint, ¶6], is dangerous and hazardous for patients of the hospital [Complaint, ¶11] and believes the insertion of the IUD will cause her permanent disability [Complaint, ¶14].

The Court may, and is requested to, take judicial notice that IUDs are medical devices covered by regulations promulgated and enforced by the U.S. Food & Drug Administration. As noted below, any proceeding involving such devices may be brought only in the name of the United States. The regulations do not create a private right of action.

In addition, assessing the need for, and the surgical procedure for insertion of an IUD requires appropriate medical decision-making. Any alleged breach is a standard of care issue, and determining whether the IUD caused Plaintiff any harm is also a medical determination. Plaintiff's Complaint does not have attached to it any affidavit or declaration of any medical expert, although the Complaint unequivocally sounds in medical malpractice. Plaintiff's counsel tacitly admits the medical malpractice nature of the Complaint. He sent HGH and Dr. McIntyre a "Notice of Medical Malpractice Claim and Intent to Sue" dated June 28, 2012, with the date of loss of March 8, 2012 [See **Exhibit "2"** hereto].

IV. Argument

A. The Court must dismiss Plaintiff's Complaint.

Although the Complaint avoids using the term "medical malpractice," it unequivocally alleges that Plaintiff "sought medical treatment;" that defendants, a hospital and a doctor, are healthcare professionals; that they "had a duty to provide Plaintiff with care, treatment,

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

medications and medical devices…;" and that they "failed to exercise due care in placing said IUD in Plaintiff's body." [Complaint, ¶¶11-13].

NRS 41A.009 defines "medical malpractice" to mean "the failure of a physician, hospital or employee of a hospital, in rendering services, to use the reasonable care, skill or knowledge ordinarily used under similar circumstances." Nothing in Plaintiff's Complaint removes it from its category of "medical malpractice." It is therefore subject to the requirements of NRS Chapter 41A.

NRS 41A.071 provides:

> If an action for medical malpractice or dental malpractice is filed in the district court, the district court shall dismiss the action, without prejudice, if the action is filed without an affidavit, supporting the allegations contained in the action, submitted by a medical expert who practices or has practiced in an area that is substantially similar to the type of practice engaged in at the time of the alleged malpractice.

In *Borger v. Eighth Judicial District Court*, 120 Nev.Adv.Op. No. 102, 42128, 102 P.3d 600 (2004), the Nevada Supreme Court held:

> [W] conclude that NRS 41A.071 clearly mandates dismissal, ***without leave to amend,*** for Complete failure to attach an affidavit to the complaint.

(Emphasis added).

Similarly, in *Washoe Medical Center, Inc. v. State*, 122 Nev. 1298, 148 P.3d 790 (2006), the Court affirmed *Borger* and noted that "a complaint defective under NRS 41A.071 is void and cannot be amended." *Id.* At 1304. Finally, the affidavit requirement applies in cases alleging medical malpractice against a hospital or physician. *See, Fierle v. Perez*, 125 Nev.Adv.Op. No. 54, 219 P.3d 906 (2009). The Court's latest pronouncement, in *Egan v. Chambers*,, 129 Nev.Adv.Op. No. 25, __P.3d __ (2013), holding that NRS 41A.071 applies only to "medical malpractice or dental malpractice claims, not professional negligence actions," does not affect this action, which clearly sounds in medical malpractice. Accordingly, because the Complaint

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

lacks an affidavit of any kind, the Court is obligated to dismiss it, without prejudice, but without leave to amend.

B. Plaintiff's "battery" claim fails.

Plaintiff's Complaint purports to allege a claim for "battery." [Complaint, ¶¶ 18-23]. In actuality, her claim appears to be one for "medical battery," arising out of Defendants' alleged failure to obtain her consent to implant the Mirena IUD. [*See,* Complaint, ¶20 ("Plaintiff ... did not consent to the implantation in Plaintiff's body of said IUD....")]. The consent form attached hereto as Exhibit "3" negates the battery claim in its entirety.

Medical battery occurs "where the provider performs a medical procedure to which the patient has not consented...." *Gorney v. Meaney*, 214 Ariz. 226, 232, 150 P.3d 799 (2007). Here, Plaintiff consented, specifically, to the implantation of a Mirena IUD. [*See,* Exhibit "3"]. Plaintiff admits that a Mirena IUD was implanted. She therefore did not suffer any medical "battery" as a matter of law.

C. 21 CFR does not provide Plaintiff with a private right of action to enforce FDA regulations.

The Mirena device is a "contraceptive IUD" that incorporates a drug activity function. It is as noted a Class III device governed under the regulations for "new drugs," i.e. 21 CFR §310.502, rather than §894.5360, which defines IUDs. Plaintiff's Complaint, in addition to its failed attempt to state a claim for medical malpractice, is also attempting to allege, and punish, a claimed violation of the Food & Drug Administration Rules and Regulations based upon HGH's ordering of Canadian IUDs, which were not FDA approved. 21 CFR does not create or permit any private right of action to enforce an FDA regulation or violation.

21 U.S.C. §337(a) provides in part:

Except as provided in subsection (b) of this section, all such proceedings for the

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

enforcement or the restraint of violations of this chapter shall be by and in the name of the United States. . ..

Subsection (b) allows the state to bring such an action after giving a thirty (30) day notice to the Secretary of Health and Human Services.

In *Stengel v. Medtronic Inc.*, 676 F.3d 1159 (9th Cir. 2012), plaintiff brought an action for injuries sustained from the plaintiff's use of a pain pump manufactured by Medtronic. The medical device infuses medication through a catheter into the intrathecal space of the spine for pain control. On review, the Court discussed the 1976 amendment to the Food, Drug and Cosmetic Act i.e., the Medical Device Amendment of 1976, and the pre-market approval process. The Court affirmed that plaintiff's complaint failed because the claims were impliedly preempted under *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 121 S.Ct. 1012 (2001). *Buckman* in turn held that the federal government, rather than any private litigant, is authorized to file suit for noncompliance with the medical device provisions, and there is no private right of action to enforce the FDCA. The Court also found that a purported state law fraud-on-the-FDA claim conflicts with the FDA's responsibility to police fraud. The Court concluded that plaintiff's failure to warn claim and fraud on the FDA claim were impliedly preempted.

Accordingly, even if Plaintiff somehow managed to avoid dismissal for failure to attach an expert affidavit, and for failure to allege a cognizable theory of medical battery, she simply cannot assert a legal claim based upon the lack of FDA approval of an IUD from Canada. Any such claim is impliedly preempted as a matter of law.

D. Plaintiff's Complaint is time-barred.

NRS 41A.097 provides in relevant part:

2. Except as otherwise provided in subsection 3, an action for injury or death against a provider of health care may not be commenced more than 3 years after the date of injury

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

or 1 year after the plaintiff discovers or through the use of reasonable diligence should have discovered the injury, whichever occurs first, for:
(a) Injury to or the wrongful death of a person occurring on or after October 1, 2002, based upon alleged professional negligence of the provider of health care;
(b) Injury to or the wrongful death of a person occurring on or after October 1, 2002, from professional services rendered without consent; or
(c) Injury to or the wrongful death of a person occurring on or after October 1, 2002, from error or omission in practice by the provider of health care.

As noted above, HGH provided Plaintiff with written notice that her Mirena IUD lacked FDA approval. That notice was delivered to Plaintiff on Friday, March 2, 2012, although Plaintiff asserts she received notice "on or about March 6, 2012." Plaintiff's Complaint was filed on March 4, 2013, which is more than one year after Plaintiff's discovery or through the use of reasonable diligence should have discovered the alleged injury involving the IUD. Notice was given to Plaintiff on March 2, 2012.

Plaintiff alleges she received notice "on or about March 6, 2012." The notice / letter is dated March 2, 2012, and Plaintiff would have received it on March 3, 2012. It is relatively unlikely that she received it as late as March 4, 2012, (which was a Sunday). Accordingly, the Complaint was untimely. As a practical matter, the Complaint fails even without the statute of limitations defense.

E. Plaintiff may not claim punitive damages.

Plaintiff may not make a claim for an award of punitive damages.

HGH is a County Hospital, i.e., a "political subdivision" of the State, and Dr. McIntyre is a "State" employee. NRS 41.035 limits an award of damages in tort actions to $100,000, and states "An award may not include any amount as exemplary or punitive damages." Accordingly, Plaintiff cannot maintain or allege a claim for punitive damages.

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

V. Conclusion

The Court should dismiss Plaintiff's Complaint for failure to state a claim on which relief can be granted as a matter of law. This is a medical malpractice action and yet Plaintiff failed to provide any expert affidavit or declaration with the Complaint. The Complaint therefore fails to meet the statutory requirements for a medical malpractice claim. In addition, Plaintiff has no standing to enforce a federal regulation, and her claim is barred by the applicable statute of limitations contained in NRS 41A.097. Finally, Plaintiff cannot assert a claim for punitive damages against a County facility or its employees based upon NRS 41.035.

WHEREFORE, Defendants respectfully request relief as follows:

1. For an Order dismissing Plaintiff's Complain, without prejudice, but without leave to amend;

2. For costs of suit and reasonable attorney's fees as allowed by law; and

3. For such other and further relief as the Court may deem appropriate in the circumstances.

AFFIRMATION

The undersigned does hereby affirm that the preceding document **DOES NOT** contain the social security number of any person.

DATED this 31st day of May, 2013.

PISCEVICH & FENNER

By: _____
Mark J Lenz
Attorneys for Defendants

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I hereby certify that I am an employee of PISCEVICH & FENNER and that on this date I caused to be served a true and correct copy of the document described herein by the method indicated below, and addressed to the following:

Document Served: MOTION TO DISMISS

Person(s) Served:

David Allen
David Allen & Associates
200 South Virginia Street, 8th Floor
Reno, Nevada 89501

_____	Electronic Filing
_____	Hand Deliver
___X_____	U.S. Mail
_____	Overnight Mail
_____	Facsimile (775)

DATED this 31st day of May, 2013.

Beverly Chambers

Beverly Chambers

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

EXHIBIT LIST

Exhibit "1" - March 2, 2012 letter to Plaintiff

Exhibit "2" - Notice of Medical Malpractice Claim

Exhibit "3" - Signed consent form

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

EXHIBIT "1"

EXHIBIT "1"

Humboldt General
HOSPITAL

March 2, 2012

Kelli J Barrett
6330 Sandi Drive
Winnemucca, NV 89445

Dear Ms. Barrett:

It has come to Humboldt General Hospital's attention that the birth control device or intrauterine device (IUD) that you had inserted at the clinic may have been purchased in violation of law.

Hopefully, you have not had any problems with your IUD, and if that is the case, there may be no reason for concern. The IUD that was inserted was ordered from Canada and is known as a Mirena IUD.

Bayer Pharmaceuticals is the distributor for the Mirena IUD and all Mirena IUDs are manufactured at the same place and location in Finland. The IUDs are then forwarded to the United States or Canada. However, the FDA requires that IUDs that are sent to the United States be approved by the FDA. The IUDs ordered through the Canadian pharmacy, while they are exactly the same IUDs, are not approved by the FDA.

You may choose to schedule an appointment with your physician to discuss the options available to you: (1) if your IUD has already been removed, you do not need to do anything; or, (2) if you still use the IUD from Canada, you should discuss options with your physician. These options would include doing nothing; having your IUD removed and replaced at no cost to you; or having your IUD removed and select another method of birth control.

Your physician may wish to do an examination and test before discussing the above options with you. There will be no cost to you for any of the choices you select and your physician can work with you to decide what is the best option for you.

I regret any inconvenience that this may cause you. Thank you for your prompt attention to this matter. Please respond prior to June 30, 2012.

Sincerely,

Humboldt General Hospital

By: James G. Parrish, Administrator

HGH

118 E. Haskell Street ▪ Winnemucca, Nevada 89445 ▪ 775.623.5222 ▪ fax: 775.623-5904 ▪ www.hghospital.ws

EXHIBIT "2"

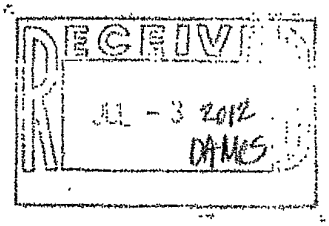
EXHIBIT "2"

DAVID ALLEN & ASSOCIATES ATTORNEYS

5230 Folsom Blvd
Sacramento, California 95819
(916) 456-4800
www.davidallenlaw.com
Personal Injury Fax: (916) 451-5687
Social Security Fax: (916) 451-5897

June 28, 2012

Sharon McIntyre, M.D.
Humboldt General Hospital
118 East Haskell St.
Winnemucca, NV 89445



Our Client: Kelli Barrett
Our File #: 228397
Date of Loss: 3/6/2012

NOTICE OF MEDICAL MALPRACTICE CLAIM AND INTENT TO SUE

Greetings:

Please be advised that this office represents Kelli Barrett in an effort to obtain reimbursement for the personal injuries arising from medical negligence which occurred around April 2011.

Pursuant to California Code of Civil Procedure §364, this letter is to advise you of Kelli Barrett's intent to bring suit against you:

"No particular form of notice is required, but it shall notify the defendant of the legal basis of the claim and the type of loss sustained, including with specificity the nature of the injuries suffered." California Code of Civil Procedure §364(b)

The legal basis of Kelli Barrett's claim is due to the negligent implantation of an IUD that was not FDA approved at Humboldt General Hospital by Dr. Sharon McIntyre. In April of 2011, Ms. Barrett Immediately began to feel moderate to severe pain immediately after the procedure. During the first week in March Ms. Barrett received a letter from Humbolt General Hospital notifying her that the IUD that had been implanted was from Canada and was not approved by the FDA.

Our investigation reveals that you are one of the parties responsible for this injury. Accordingly, we ask that you place your insurance carrier on notice. In the event you are not insured for matters of this nature, please contact our office directly.

Please preserve all evidence related to this incident, including but not limited to, photographs, video surveillance, accident reports, or other physical evidence. Failure to preserve evidence may result in sanctions for spoliation or destruction of evidence. If there all any costs involved in the preservation of evidence, please contact this office so that arrangements may be made.

We ask that you acknowledge receipt of this letter, again, please address your correspondence to EDUARDO GONZALEZ via phone or email at egonzalez@davidallenlaw.com. Your cooperation will be appreciated.

Very truly yours,

DAVID ALLEN & ASSOCIATES

EDUARDO GONZALEZ
Attorney at Law
egonzalez@davidallenlaw.com

FAG/jw

EXHIBIT "3"

EXHIBIT "3"

CONSENT FOR MIRENA IUD

Please put your initials next to each statement you agree with, after asking any questions you may have.

KB I understand that a Mirena IUD will be inserted into my uterus to prevent pregnancy for up to 5 years.

KB I understand that when the IUD is inserted I will feel some cramping and may have some bleeding. The discomfort may continue after insertion. I may have bleeding, spotting, or no periods at all while using this IUD.

KB I understand that it is uncommon for the IUD to be inserted into or through the wall of the uterus, but that it may occur. I would then need surgery to remove it.

KB I understand that my uterus may expel the IUD and that I should check for the strings on a monthly basis to be sure the IUD is in place.

KB I understand that the Mirena does not protect me from getting HIV or any other sexually transmitted infection and that I will need to use a condom if I feel I am at risk.

KB I understand that pregnancy is rare when the Mirena is in place. If I should become pregnant, it is more likely to be outside of the uterus. There may be serious risks with a pregnancy that occurs in the uterus or outside the uterus and I would need to get medical care as soon as possible.

KB I have been given information on follow-up care and have been told when the IUD should be removed.

KB I understand that the IUD can be removed by a medical provider at any time I want it removed.

Someone talked with me and gave me written information about the Mirena. I understand that information and choose to use this method of birth control.

Signature Kelli Barrett Date 3/11/11

Witness [signature] Date 3/11/11

As the parent/guardian of _____, I give my permission for the insertion of a Mirena intrauterine device.

Signature _____ Date _____

P:\CLINIC\Clinical Forms\Consents\Mirena consent.doc

5350

DAVID ALLEN, ESQ. (SBN 2183)
DAVID ALLEN & ASSOCIATES
200 South Virginia Street, 8th Floor
Reno, NV 89501
Phone: (775) 786-1020
Facsimile: (775)786-1026
DAllen@DavidAllenLaw.com

Attorneys for Plaintiff,
KELLI BARRETT

IN THE SIXTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF HUMBOLDT

KELLI BARRETT, Plaintiff, v. **HUMBOLDT GENERAL HOSPITAL and SHARON McINTYRE, MD, and DOES 1 to 50, inclusive,** Defendants.	**CASE NO. CV 13-00460** **DEPT NO: 8** **PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITY IN OPPOSITION TO THE MOTION TO DISMISS BROUGHT BY DEFENDANTS HUMBOLDT GENERAL HOSPITAL AND SHARON McINTYRE, M.D.**

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

Plaintiff Kelli Barrett ("Plaintiff Barrett" or "Plaintiff") submits the following opposition to the Motion to Dismiss brought by Humboldt General Hospital and Sharon McIntyre, M.D. pursuant to *NRCP 12(b), NRS 41A.071, NRS 41A.097.* Plaintiff submits that her negligence and battery claims premised upon Defendants' insertion of a non-FDA approved Mirenda intrauterine device ("IUD") constitute viable claims for negligence and battery.

Essentially, Plaintiff alleges that Defendants' insertion of the non-FDA approved IUD constitutes a rebuttable presumption of negligence (*Nev. Rev. Stat. Ann. Sect. 41A.100).* Defendants' acts also constituted battery since Plaintiff was not informed of this non-FDA approval and Plaintiff did not consent to surgical insertion of a device purchased and used in violation of federal law.

Finally, the Complaint (filed March 4, 2013) explicitly avers that Plaintiff received notice from defendant Humboldt General that the IUD placed in Plaintiff's body was purchased in violation of law since it was not approved by the FDA. This notice was provided "on or about March 6, 2012." (*Complaint, para. 8 at p. 2:26-28.)* Plaintiff's complaint was filed March 4, 2013.

Plaintiff respectfully submits the motion of Defendants should be denied in its entirety.

I. FACTS

Plaintiff Barrett's action is based on injuries suffered after Defendant doctor Sharon McIntyre implanted a non-FDA approved Mirenda IUD in Plaintiff's body at Defendant Humboldt General Hospital on April 1, 2011. (*Complaint, para. 5 at p. 2:16-19.)* Plaintiff experienced mental and physical difficulties and hardships as a result of the IUD. *(Complaint, para. 6 to 7 at p. 2:20-25.*)

On or about March 6, 2012, Plaintiff received notice from Defendant Humboldt admitting the IUD implanted in Plaintiff's body was a device purchased in violation of law. The device was ordered by Defendants from Canada. The device was never approved for use in the United States by the FDA approval. *(Complaint, para. 8 at p. 2:27- p.3: 2.)* Plaintiff experienced shock upon learning the IUD was an unapproved product. This caused Plaintiff anguish and distress. *Complaint, para. 9 at p. 3:3-7.)*

Plaintiff's two causes of action for negligence and battery are stated in her Complaint.

II. ARGUMENT

A. Complaint's allegations must be liberally construed.

NRCP 12(b) governs a party's motion to dismiss for failure to state a claim. A trial court

considering such a motion is required to construe the complaint liberally, drawing "every fair intendment in favor of the plaintiff." *See Capital Mortgage Holding v. Hahn, 101 Nev. 314, 315, 705 P.2d 126, 126 (1985.)* Further, the Court is required to accept all factual allegations of the Complaint as true. *See Hal Roach Studios, Inc. v. Richard Feiner & Co., 896 F.2d 1542, 1550 (9th Cir. 1990.)*

Here, Plaintiff's Complaint sets forth a "plausible set of facts" which support her claim for negligence. Additionally, since Defendants failed to inform Plaintiff of the crucial fact the IUD was never approved by the FDA, she was never able to provide consent. Her "consent" was premised on the reasonable and good faith assumption the IUD was approved for use in the United States. Since a crucial fact was concealed she was never able to provide informed consent. These facts support a valid battery claim.

B. No medical affidavit is required when rebuttable presumption of negligence appears.

NRS 41A.100 1.(a) permits a personal injury action premised on negligence by a medical care provider, and a rebuttable presumption arises that the injury was caused by negligence where evidence shows "...a foreign substance other than medication...was unintentionally left with the body of a patient following surgery." *Id.*

Here, defendant violated the FDA statutes and rules requiring a Mirenda IUD device be pre-approved by the FDA. The foreign device inserted by defendants was left in the body of plaintiff. This resulted in harm to Plaintiff. As such the conduct of defendants constitute *negligence per se*.

As explained in *Vega v. Eastern Courtyard Associates, LLP 117 Nev. 436, 24 P3d. 219; 2001 Nev. Lexis 40 (2001)* , "we have consistently held that the violation of a statute constitutes negligence per se if the injured party belongs to the class of persons that the statute was intended to protect, and the injury suffered was of the type the statute was designed to prevent." *Vega, supra, 117 Nev. at 440.*

Under these circumstances, Plaintiff submits the Complaint states valid causes of action for negligence per se in addition to battery for insertion of this unapproved IUD device.

C. The Complaint sets forth a valid claim for battery.

A claim for battery requires a showing the "actor (1) intended to cause harmful or offensive contact, and (2) such contact did occur." *Burns v. Mayer 175 F. Supp. 2d 1259; 2001 U.S. Dist. Lexis 20370 (2001)*.

N.R.S. 41A100 establishes a patient's consent is conclusively established if the doctor explained to the patient the procedure to be undertaken, alternative methods of treatment and risks. *Id.* However, a patient is entitled to receive from the physician "the information necessary for him [or her] to give his [or her] informed consent to a procedure or treatment." *Id.*

For example, in *Smith v. Cotter 107 Nev. 267; 810 P.2d 1204; 1991 Nev. Lexis 45 (1991)* the court affirmed a judgment in favor of a patient where the doctor was found negligent for failing to obtain informed consent - failing to inform the patient of the significant medical risks prior to obtaining consent. *Smith, supra. 107 Nev. at 272.*

Defendants failed to provide Plaintiff with the information necessary to obtain informed consent. Defendants concealed from Plaintiff they were going to implant in her body a medical device that was not approved by the FDA. In addition they failed to advise Plaintiff of the of the risks she would confront through the use of the unapproved IUD.

Plaintiff clearly set out in the Complaint the basis for a battery claim.

D. The State damage claims of Plaintiff are not pre-empted by federal law (MDA.)

Defendant incorrectly asserts that Plaintiff' complaint is barred claiming that *21 CFR* doesn't provide a right of action to enforce an FDA regulation or violation. (*Defendant's Motion at p. 8:24-26.)*

First, Plaintiff is not seeking "enforcement or restrain of violations" which are left solely to the federal government. *See 21 U.S.C. section 337* (which only permits a State to bring an action to enforce or restrain violation after notice to the Secretary of Health and Human Services.)

As stated by the U.S. Supreme Court in *Riegel v. Medtronic 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892; 2008 U.S. LEXIS 2013 (2008)* "State requirements are pre-empted under

the MDA [Medical Device Amendment of 1976] only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. *§ 360k(a)(1).* **Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulation. The state duties in such a case 'parallel,' rather than add to, federal requirements.** *Lohr, 518 U.S., at 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700; see also id., at 513, 116 S. Ct. 2240, 135 L. Ed. 2d 700* (O'Connor, J., concurring in part and dissenting in part)." (Emphasis added.) *Riegel, supra, 552 U.S. at 322-323.*

In *Riegel, supra,* the Court examined the MDA and its pre-emption provision regarding common law claims challenging the safety and effectiveness of a medical device given pre-market approval by the FDA. The case arose from a claim brought when a catheter, a Class III device, ruptured in the patient's coronary artery during surgery. The *Riegel* Court noted that the catheter had been subject to a rigorous pre-market approval process which effectively precluded the *Riegel* plaintiffs's negligence and strict liability claims that differed or were in addition to federal FDA requirements. *Riegel, supra,* 552 U.S. at 319-322.

Here, Defendants placed Plaintiff in jeopardy by circumventing FDA requirements. They then compounded this error by failing to inform Plaintiff that this foreign object (the Mirenda non-FDA approved IUD) was to be implanted in Plaintiff's body. No additional or "different" state law requirements are implicated in this action. Thus *§ 360k(a)* does not prevent Plaintiff's State law claims. Even though premised on a violations of FDA laws and regulations, the claims "parallel" instead add to federal requirements. *Riegel, supra, 552 U.S. at 330.*

Defendant's reliance on *Stengel v. Medtronic Inc. 676 F.3d 1159 (9th Cir. 2012)* [see Defendant's Motion to Dismiss, page 9:5-18] is similarly misplaced. Defendants fail to acknowledge the decision in *Stengel* was ***vacated***. The Court granted a rehearing en banc in *Stengel v. Medtronic Inc. 686 F.3d 1121; 2012 U.S. App. Lexis 13579 (9th Cir. 2012)*, with the earlier opinion not to be cited as precedent.

E. Plaintiff's Complaint was clearly timely-filed.

Plaintiff's Complaint clearly alleges that on or about March 6, 2012, she learned the IUD

implanted in her body was a device purchased in violation of law. (*See Complaint, paragraph 8 at p. 2:26-26.)* The Complaint filed in this action bears a filing date of March 4, 2013. Plaintiff's complaint complies with the provisions of *NRS 41A.097.2.*, which requires filing of the complaint within one year "... after the plaintiff discovers or through the use of reasonable diligence should have discovered the injury."

III. CONCLUSION

Plaintiff timely filled claims for negligence per se and for battery which are validly stated. Plaintiff's claims in this action "parallel" the federal requirements implicated by *§ 360k(a).* It is therefore appropriate to dismiss in its entirety the Motion to Dismiss brought Defendants.

Respectfully submitted,

Dated: July3, 2013

DAVID ALLEN
Attorney for Plaintiff
KELLI BARRETT

AFFIRMATION

The undersigned does hereby affirm that the preceding document ***does not*** contain the social security number of any person.

DAVID ALLEN
Attorney for Plaintiff
KELLI BARRETT

Barrett v. Humboldt General Hospital, et al.
County of Humboldt, Case No.: CV 13-00460

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I hereby certify that I am an employee of DAVID ALLEN & ASSOCIATES and that on this date I caused to be served a true and correct copy of the document described herein by the method indicated below and addressed to the following:

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITY IN OPPOSITION TO THE MOTION TO DISMISS BROUGHT BY DEFENDANTS HUMBOLDT GENERAL HOSPITAL AND SHARON MCINTYRE, M.D.

☐ **BY FAX:** by transmitting via facsimile the document(s) listed above to the fax number(s) set forth below on this date before 5:00 p.m.

☐ **BY HAND:** by personally delivering the document(s) listed above to the person(s) at the address(es) set forth below.

☐ **BY MAIL:** by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Stockton, California addressed as set forth below.

☒ **BY OVERNIGHT MAIL:** by causing document(s) to be picked up by an overnight delivery service company for delivery to the addressee(s) on the next business day.

☐ **BY PERSONAL DELIVERY:** by causing personal delivery by _____ of the document(s) listed above to the person(s) at the address(es) set forth below.

Margo Piscevich
Mark J. Lenz
PESCEVICH & FENNER
499 West Plumb Lane, Suite 201
Reno, NV 89509

I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with an overnight delivery service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on July 3, 2013, at Sacramento, California.

Anita Estioko

5350

MARGO PISCEVICH
Nevada State Bar No. 000917
MARK J. LENZ
Nevada State Bar No. 004672
PISCEVICH & FENNER
499 West Plumb Lane, Suite 201
Reno, Nevada 89509
775-329-0958
Attorneys for Defendant
HUMBOLDT GENERAL HOSPITAL

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

IN THE SIXTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF HUMBOLDT

KELLI BARRETT,

Plaintiff,

vs.

HUMBOLDT GENERAL HOSPITAL and SHARON McINTYRE, M.D., and DOES 1 to 50, inclusive,

Defendants.
_____/

CASE NO. 19460

DEPT. NO. 2

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS

Defendants Humboldt District Hospital dba Humboldt General Hospital (hereinafter referred to as HGH) and Sharon McIntyre, M.D., by and through their counsel of record, Piscevich & Fenner, submit their Memorandum of Points and Authorities in support of their "Motion to Dismiss," filed on or about May 31, 2013, as follows:

purchased through the other vendor. Plaintiff was informed of the risks of, and consented to, the implantation of a Mirena device. No medical battery can be found in this circumstance.

Plaintiff's citation to *Smith v. Cotter*, 107 Nev. 267, 810 P.2d 1204 (1991) is unavailing and inapposite. *Smith v. Cotter* did not involve implantation of any medical device, but rather undisclosed ***medical*** risks associated with a thyroidectomy. No such risks were associated with the Mirena device implanted in this case.

C. Plaintiff has no private right of action to enforce FDA regulations.

Plaintiff argues correctly that state law requirements are "preempted only to the extent that they are different from or in addition to' the requirements imposed by federal law." [Opp. p. 5, lns. 1-3]. However, Defendants did not suggest that 21 CFR §337 should preclude a legitimate medical malpractice claim. Instead, Defendants asserted that Plaintiff could not seek to enforce the federal regulation by means of a medical malpractice claim, especially where such a claim is void *ab initio* as a matter of law.

D. Plaintiff's Complaint is time-barred.

As noted in Defendants' Motion, HGH provided Plaintiff with written notice that her Mirena IUD lacked FDA approval. That notice was delivered to Plaintiff on Friday, March 2, 2012.

Plaintiff continues to assert she received notice "on or about March 6, 2012." The notice / letter is dated March 2, 2012, and Plaintiff would have received it on March 3, 2012. It is relatively unlikely that she received it as late as March 4, 2012, (which was a Sunday). Accordingly, the Complaint was untimely. As a practical matter, the Complaint fails even without the statute of limitations defense.

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

E. Plaintiff may not claim punitive damages.

As noted in the Motion, HGH is a County Hospital, i.e., a "political subdivision" of the State, and Dr. McIntyre is a "State" employee. NRS 41.035 limits an award of damages in tort actions to $100,000, and states "An award may not include any amount as exemplary or punitive damages." Accordingly, Plaintiff cannot maintain or allege a claim for punitive damages. Plaintiff offers no argument to the contrary.

IV. Conclusion

Plaintiff failed to provide any expert affidavit or declaration with the Complaint. The Complaint therefore fails to meet the statutory requirements for a medical malpractice claim. In addition, Plaintiff has no standing to enforce a federal regulation, and her claim is barred by the applicable statute of limitations contained in NRS 41A.097. Finally, Plaintiff cannot assert a claim for punitive damages against a County facility or its employees based upon NRS 41.035.

WHEREFORE, Defendants respectfully request relief as set forth in their Motion to Dismiss, and such other and further relief as the Court may deem appropriate in the circumstances.

AFFIRMATION

The undersigned does hereby affirm that the preceding document **DOES NOT** contain the Social Security number of any person.

DATED this 11th day of July, 2013.

PISCEVICH & FENNER

By: _____
Margo Piscevich
Attorneys for Defendants

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I hereby certify that I am an employee of PISCEVICH & FENNER, and that on this date I caused to be served a true and correct copy of the document described herein by the method indicated below, and addressed to the following:

Document Served: **Defendants' Reply in Support of Motion to Dismiss**

Person(s) Served:

David Allen
David Allen & Associates
200 South Virginia Street, 8th Floor
Reno, Nevada 89501

_____	Electronic Filing
_____	Hand Deliver
X	U.S. Mail
_____	Overnight Mail
_____	Facsimile (775)

DATED this 11th day of July, 2013.

Beverly Chambers

Piscevich & Fenner
499 West Plumb Lane, Suite 201
Reno, NV 89509 775.329.0958