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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH

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GERRY A. ADAMS,

Plaintiff,

v.

AMERICAN MEDICAL SYSTEM, INC.,  
CALDERA MEDICAL, INC. and JOHN  
DOES 1–10,

Defendants.

MEMORANDUM DECISION AND  
ORDER ON PENDING MOTIONS

Case No. 2:13-CV-604 TS

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This matter is before the Court on Defendant Caldera Medical, Inc.’s (“Caldera”) Motion to Dismiss Plaintiff’s Complaint, Defendant American Medical System Inc.’s (“AMS”) Motion to Dismiss, and AMS’s Motion for Rule 11 Sanctions.<sup>1</sup> For the reasons discussed more fully below, the Court will grant Caldera’s Motion to Dismiss, grant in part and deny in part AMS’s Motion to Dismiss, and deny AMS’s Motion for Sanctions.

### I. BACKGROUND

Plaintiff is a citizen of the State of Utah. Defendant Caldera is based out of and incorporated in California. Defendant AMS is incorporated in Delaware and has its principal place of business in Minnesota.

This suit stems from Plaintiff’s surgical implantation with a Desara Sling System (referred to hereinafter as the “Desara Sling” or the “product”) on or about July 7, 2007. The

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<sup>1</sup> Docket Nos. 18, 42, 43.

Desara Sling is a vaginal mesh sling used for the treatment of pelvic organ prolapse and stress urinary incontinence.

The Desara Sling is designed, manufactured, and marketed by Caldera. Plaintiff alleges, however, that the Desara Sling contains essential design features and technology designed and owned by AMS. These same allegations were the basis for a patent infringement suit brought by AMS against Caldera in 2005. That suit resulted in a settlement between AMS and Caldera. According to Plaintiff, AMS and Caldera entered into a royalty bearing license agreement, which allowed Caldera to continue to market the Desara Sling without threat of litigation from AMS.

On November 2, 2007, Plaintiff consulted her physician because she was in severe pain and was suffering from vaginal bleeding caused by the Desara Sling. The consulting physician found that a portion of the product had migrated out of place. The physician recommended that, “as much as possible, the sling should be excised.”<sup>2</sup> On December 28, 2007, Plaintiff underwent a second surgery where a section of the Desara Sling was removed.

Plaintiff’s second surgery removed as much of the Desara Sling as possible. However, Plaintiff’s stress urinary incontinence was worse than before implantation of the product. Plaintiff continued to experience complications from the product including infections, pain, and loss of energy. In July 2009, Plaintiff suffered from a urinary tract infection so severe that she required hospitalization. Plaintiff alleges that this infection was caused by the remaining portion of the Desara Sling.

Plaintiff’s current physician ultimately recommended that the Desara Sling be completely removed because it continued to migrate from its place of implantation, was harboring

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<sup>2</sup> Docket No. 31 Ex. B, at 1.

infections, and was adversely affecting Plaintiff's health and comfort. Plaintiff alleges that she continues to suffer from incontinence as a result of the Desara Sling.

## II. STANDARD OF REVIEW

In considering a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6), all well-pleaded factual allegations, as distinguished from conclusory allegations, are accepted as true and viewed in the light most favorable to Plaintiff as the nonmoving party.<sup>3</sup> Plaintiff must provide "enough facts to state a claim to relief that is plausible on its face,"<sup>4</sup> which requires "more than an unadorned, the-defendant-unlawfully harmed-me accusation."<sup>5</sup> "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'"<sup>6</sup>

"The court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted."<sup>7</sup> As the Court in *Iqbal* stated,

[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not show[n]—that the pleader is entitled to relief.<sup>8</sup>

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<sup>3</sup> *GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F.3d 1381, 1384 (10th Cir. 1997).

<sup>4</sup> *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007).

<sup>5</sup> *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

<sup>6</sup> *Id.* (alteration in original) (quoting *Twombly*, 550 U.S. at 557).

<sup>7</sup> *Miller v. Glanz*, 948 F.2d 1562, 1565 (10th Cir. 1991).

“An affirmative defense may be raised in a motion to dismiss for the failure to state a claim ‘if the defense appears plainly on the face of the complaint itself.’”<sup>9</sup> “[W]ith respect to a statute of limitations defense, it may be appropriately resolved on a 12(b) motion ‘when the dates given in the complaint make clear that the right sued upon has been extinguished.’”<sup>10</sup> “‘When the dates given in the complaint’ support dismissal on statute of limitations grounds, ‘the plaintiff has the burden of establishing a factual basis for tolling the statute.’”<sup>11</sup>

“If, on a motion under Rule 12(b)(6) . . . , matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56.”<sup>12</sup> Nevertheless, the Court “‘may consider documents referred to in the complaint if the documents are central to the plaintiff’s claim and the parties do not dispute the documents’ authenticity,”<sup>13</sup> without converting a motion to dismiss into one for summary judgment.

### III. DISCUSSION

Defendants move to dismiss Plaintiff’s Amended Complaint on several grounds. Caldera argues that dismissal is appropriate because Plaintiff’s claims are barred under the applicable statute of limitations. AMS also argues that dismissal is appropriate under the statute of

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<sup>8</sup> *Iqbal*, 556 U.S. at 679 (alteration in original) (citations and internal quotation marks omitted).

<sup>9</sup> *Lee v. Rocky Mountain UFCW Unions & Emp’rs Trust Pension Plan*, 13 F.3d 405, 1993 WL 482951, at \*1 (10th Cir. 1993) (unpublished table decision) (quoting *Miller v. Shell Oil Co.*, 345 F.2d 891, 893 (10th Cir. 1965)).

<sup>10</sup> *Id.* (quoting *Aldrich v. McCulloch Props., Inc.*, 627 F.2d 1036, 1041 n.4 (10th Cir. 1980)).

<sup>11</sup> *Id.* (quoting *Aldrich*, 627 F.2d at 1041 n.4).

<sup>12</sup> Fed. R. Civ. P. 12(d).

<sup>13</sup> *Alvarado v. KOB-TV, L.L.C.*, 493 F.3d 1210, 1215 (10th Cir. 2007) (quoting *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002)).

limitations and further asserts that Plaintiff's Amended Complaint fails to state a claim for relief against AMS because AMS was not involved in the manufacture or sale of the Desara Sling.

Based on this same argument, AMS moves for sanctions against Plaintiff under Federal Rule of Civil Procedure 11.

#### A. STATUTE OF LIMITATIONS

Because the Court is sitting in diversity jurisdiction, the general rule is that the substantive law of the State of Utah applies.<sup>14</sup> The parties both proceed on the assumption that Utah law should apply to the instant suit, though Caldera does note that it is conceivable that California law applies.<sup>15</sup> In any event, the parties agree that there are no significant differences between Utah and California law as to the issues before the Court. In light of the parties' agreement, the Court will apply Utah substantive law.

The relevant statute of limitations is drawn from the Utah Products Liability Act ("UPLA"), codified at Utah Code Ann. § 78B-6-700. That statute states, in relevant part, that "[a] civil action under this part shall be brought within two years from the time the individual who would be the claimant in the action discovered, or in the exercise of due diligence should have discovered, both the harm and its cause."<sup>16</sup> The Utah Supreme Court has interpreted this statute of limitations to encompass "all actions seeking money damages for injury to people or property resulting from defective products."<sup>17</sup> Each of Plaintiff's causes of action seeks money

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<sup>14</sup> *MediaNews Grp., Inc. v. McCarthy*, 494 F.3d 1254, 1260 (10th Cir. 2007) (citing *Ahrens v. Ford Motor Co.*, 340 F.3d 1142, 1145 (10th Cir. 2003)).

<sup>15</sup> See Docket Nos. 18, 41, 43.

<sup>16</sup> Utah Code Ann. § 78B-6-706.

<sup>17</sup> *Utah Local Gov. Trust v. Wheeler Mach. Co.*, 199 P.3d 949, 951 (Utah 2008).

damages for injuries she suffered as a result of the implantation of the Desara Sling. Thus, Plaintiff's claims are subject to the UPLA statute of limitations.

“By its plain language, the statute begins to run from the date the claimant discovers, or in the exercise of due diligence should have discovered, both the harm and its cause.”<sup>18</sup> The majority rule is that the determination of “when a plaintiff knew or with reasonable diligence should have known of a cause of action is a question of fact for the jury. Where the evidence is so clear that there is no genuine factual issue, however, the determination can be made as a matter of law.”<sup>19</sup> “[T]he knowledge required of a plaintiff is inquiry notice: a plaintiff need not have a ‘confirmed diagnosis’ about the causal relation to trigger the running of the statute of limitation.”<sup>20</sup> “All that is required to trigger the statute of limitations is sufficient information to put plaintiff on notice to make further inquiry if she harbors doubts or questions.”<sup>21</sup>

According to the allegations of Plaintiff's Amended Complaint, she became aware of the fact that a portion of the Desara Sling had migrated out of place by November 2, 2007. At that time, she was in severe pain and was suffering from vaginal bleeding caused by the Desara Sling. Plaintiff alleges that she underwent surgery in December 2007 to remove as much of the Desara Sling as possible. Nevertheless, Plaintiff alleges that her stress urinary incontinence was worse than before implantation of the product and that she continued to experience complications from

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<sup>18</sup> *McKinnon v. Tambrands, Inc.*, 815 F. Supp. 415, 418 (D. Utah 1993).

<sup>19</sup> *Id.* (citing *Maughan v. SW Servicing, Inc.*, 758 F.2d 1381, 1387 (10th Cir. 1985)).

<sup>20</sup> *Hansen v. Novartis Pharm. Corp.*, No. 2:08-CV-985 DB, 2011 WL 6100848, at \*3 (D. Utah Dec. 7, 2011) (citing *McKinnon*, 815 F. Supp. at 420).

<sup>21</sup> *Griffiths-Rast v. Sulzer Spine Tech*, 216 F. App'x. 790, 792–93 (10th Cir. 2007) (unpublished) (citation and internal quotation marks omitted).

the product. Plaintiff alleges that these complications went so far as to require an emergency room visit in July 2009.

From these factual allegations and the dates contained therein, the Court can only surmise that Plaintiff discovered the harm and the cause of that harm, at the latest in November 2007. At that point, Plaintiff knew that the Desara Sling had migrated out of place and that she was suffering harm as a result of that migration.

Contrary to the factual allegations of her Complaint, Plaintiff argues that she did not discover that the Desara Sling was the cause of her harm until June 10, 2013. In her briefing, Plaintiff claims that it was during a doctor's visit at that time that she was first informed that "the infections and other health complications she was experiencing were likely due to the sling system and that more of the vaginal mesh was protruding through her vaginal roof."<sup>22</sup> Nowhere in Plaintiff's Amended Complaint does she allege that she was informed for the first time on June 10, 2013, that the infections and health complication she was experiencing were due to the Desara Sling. As discussed, the allegations show that Plaintiff was aware of these issues by late 2007. Furthermore, the documents attached as exhibits to, and referenced in Plaintiff's Complaint, do not support Plaintiff's argument on this point.

In short, viewing the factual allegations in the light most favorable to Plaintiff, the Court finds that Plaintiff knew of the harm and the cause of that harm no later than November 2007 and therefore Plaintiff's claims are barred by the applicable two-year statute of limitations.

The parties do not limit their statute of limitations arguments to the factual allegations of the Amended Complaint and documents referenced therein. Included in the parties' arguments

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<sup>22</sup> Docket No. 41, at 4 (citing Docket No. 31 Ex. G, at 1).

are citations to documents from other cases, medical records, and FDA statements that the parties assert support their various positions. The Court finds that it need not convert Defendants' motions to motions for summary judgment to resolve the statute of limitations issue. But, even were the Court to convert this motion to a motion under Rule 56 and consider all of the evidence provided, it would not change the outcome in this case.

The medical records attached to Plaintiff's Amended Complaint demonstrate that Plaintiff was aware that the Desara Sling had shifted as early as November 2007.<sup>23</sup> The medical records also demonstrate that Plaintiff continued to suffer harm from that period through at least June 2013. The June 11, 2013, letter from Doctor Judith Kirstein supports that conclusion. In that letter, Dr. Kirstein states,

A few months after [the July 2007 procedure, Plaintiff] began having vaginal symptoms and her surgeon noted erosion of mesh through the vaginal wall. The mesh was trimmed, but she continued to have bouts of foul smelling vaginal discharge, suprapubic and vaginal pain. When I examined her vagina in February 2013, I could feel two pieces of mesh protruding through the vaginal roof. She had no evidence of a vaginal infection at that time, but they are intermittent. I suspect the infections are due to the mesh protruding thru her vaginal roof. The mesh needs to be removed.<sup>24</sup>

Dr. Kirstein's statement is consistent with Dr. Warshawsky's assessment in November 2007 that subsequent to the July 2007 procedure "vaginal bleeding developed associated with malodorous discharge" and Plaintiff's Desara Sling "was noted to be extruding, protruding into

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<sup>23</sup> Docket No. 31 Ex. B, at 1.

<sup>24</sup> *Id.* Ex. F, at 1.



the vaginal canal.”<sup>25</sup> Dr. Warshawsky also stated that “[u]ndoubtedly, as much as possible the sling will need to be excised.”<sup>26</sup>

Plaintiff argues that the early movement and partial removal of the Desara Sling did not put her on notice of the cause of her harm because Dr. Warshawsky did not recommend the complete removal of the Desara Sling. According to Plaintiff, it was only the opinion of Dr. Kirstein in 2013 that the “mesh needs to be removed” that alerted her to the cause of her harm. This Court, in *McKinnon v. Tambrands, Inc.*, rejected a plaintiff’s argument that “to constitute ‘discovery’ she must have received what amounts to a ‘confirmed diagnosis.’”<sup>27</sup> As in *McKinnon*, the Court is not persuaded that Dr. Warshawsky’s diagnosis was insufficient to put Plaintiff on notice of the cause of her harm. This is particularly true in light of the fact that Plaintiff continued to suffer from the same symptoms after the December 2007 surgery.

Plaintiff also cites an FDA Public Health Notification released on July 13, 2011, for the proposition that she could not have discovered the cause of her injury until that time because Utah law presumes that products approved by government entities are free from defect. Even were it convinced that Utah law’s deference to the FDA approval process ameliorated the exercise of due diligence requirement of § 78B-6-706,<sup>28</sup> the Court finds that Plaintiff’s argument would nevertheless fail because the evidence she provides does not support her assertion. On its face, the FDA Public Health Notice indicates that it issued an alert as early as October 20, 2008, warning that there are “complications associated with transvaginal placement of surgical mesh to

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<sup>25</sup> *Id.* Ex. B, at 1.

<sup>26</sup> *Id.*

<sup>27</sup> *McKinnon*, 815 F. Supp. at 419–20.

<sup>28</sup> *See Grundberg v. Upjohn Co.*, 813 P.2d 89, 96–98 (Utah 1991).

treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI).”<sup>29</sup> The notification further provides that what was released on July 13, 2011, was an “UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse.”<sup>30</sup> The FDA notice therefore supports the conclusion that Plaintiff should have been on notice of the cause of her harm, at the latest, by October 20, 2008—the date on which the FDA issued its original alert.

Based on the foregoing, the Court finds that on the evidence presented, “there is no genuine dispute as to any material fact” relating to Defendants’ statute of limitations defense “and [they are] entitled to judgment as a matter of law.”<sup>31</sup>

## B. SANCTIONS

In addition to moving to dismiss Plaintiff’s claims on statute of limitations grounds, Defendant AMS seeks dismissal for failure to state a claim under 12(b)(6). Because dismissal is appropriate on statute of limitations grounds, the remainder of AMS’s arguments for dismissal are moot. Thus, the only issue remaining before the Court is AMS’s request for sanctions.

AMS moves for sanctions pursuant to Federal Rule of Civil Procedure 11(b), arguing that certain of the factual allegations in Plaintiff’s Amended Complaint have no evidentiary support. Plaintiff contends that her factual allegations are properly supported and argues that AMS’s motion was filed for the improper purpose of seeking dismissal from this case. Both parties request an award of attorneys’ fees.

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<sup>29</sup> Docket No. 41 Ex. A, at 1.

<sup>30</sup> *Id.*

<sup>31</sup> Fed. R. Civ. P. 56(a).

Pursuant to Federal Rule of Civil Procedure 11(b), an attorney or unrepresented party who presents a pleading, written motion, or other paper to the court “certifies that to the best of the person’s knowledge, information, and belief, formed after an inquiry reasonable under the circumstances . . . the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.”<sup>32</sup> The Tenth Circuit has held that “an attorney’s action must be objectively reasonable in order to avoid Rule 11 sanctions,” and “[a] good faith belief in the merit of an argument is not sufficient; the attorney’s belief must also be in accord with what a reasonable, competent attorney would believe under the circumstances.”<sup>33</sup>

Here, AMS argues that Plaintiff violated Rule 11 because certain of the factual contentions contained in her Amended Complaint lack evidentiary support. Specifically, AMS takes issue with Plaintiff’s allegations that (1) “AMS exerted control over Caldera’s manufacturing and marketing of the Product during the negotiations of the terms of the settlement agreement entered into regarding the patent infringement case;” (2) “AMS continues to exert a measure of control over the manufacturing and marketing of the Product;” (3) “AMS, through the negotiation process regarding settlement of the patent infringement lawsuit with Caldera, exercised sufficient control over the manufacture, labeling and marketing of the defectively and improperly manufactured Product to be strictly liable;” (4) “AMS defectively and improperly manufactured the Product, rendering it unreasonably dangerous and hazardous to

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<sup>32</sup> Fed. R. Civ. P. 11(b).

<sup>33</sup> *White v. Gen. Motors Corp., Inc.*, 908 F.2d 675, 680 (10th Cir. 1990).

Ms. Adams, as a matter of law;” and (5) “[t]he Product, offered by Caldera, contained essential design features and technology designed and owned by AMS.”<sup>34</sup>

Having reviewed the foregoing allegations in the context of the remainder of Plaintiff’s Amended Complaint and considered the parties’ arguments thereon, the Court finds that Plaintiff’s counsel did not violate their obligations under Rule 11(b). The parties’ dispute with regard to these allegations centers on their differing interpretations of the effect of the settlement agreement between Caldera and AMS and the viability of conflicting legal theories. Unlike *Henry v. Black*,<sup>35</sup> relied upon heavily by AMS, the Court cannot say in this instance that Plaintiff’s allegations are wholly speculative and “fail to meet the requirements of Rule 11.”<sup>36</sup>

The Court is not persuaded, however, that AMS’s motion is frivolous, filed in bad faith, or for an improper purpose. For this reason, it will deny Plaintiff’s request for attorneys’ fees. In sum, Rule 11 sanctions are not merited in this case.

#### IV. CONCLUSION

Based on the foregoing, it is hereby

ORDERED that Defendant Caldera’s Motion to Dismiss Plaintiff’s Complaint (Docket No. 18) is GRANTED. It is further

ORDERED that Defendant AMS’s Motion to Dismiss (Docket No. 43) is GRANTED IN PART AND DENIED IN PART AS MOOT, pursuant to the terms of this Order. It is further

ORDERED that Defendant AMS’s Motion for Rule 11 Sanctions (Docket No. 42) is DENIED. The Clerk of Court is directed to close this case forthwith.

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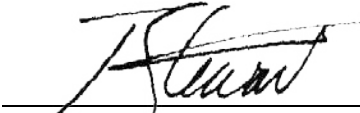
<sup>34</sup> Docket No. 31, at 3–4, 12.

<sup>35</sup> No. 2:11-CV-129 TS, 2011 WL 2938450 (D. Utah July 19, 2011).

<sup>36</sup> *Id.* at \*2.

DATED this 28th day of April, 2014.

BY THE COURT:



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TED STEWART  
United States District Judge