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**UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA**

**Lori Spellman,**  
**Plaintiff,**  
**vs.**  
**Smith & Nephew, Inc.,**  
**Defendant.**

**3:16-cv-08080 JWS**  
**ORDER AND OPINION**  
**[Re: Motion at Docket 16]**

**I. MOTION PRESENTED**

At docket 16, defendant Smith & Nephew, Inc. (“S&N”) moves pursuant to Federal Rule of Civil Procedure 12(b)(6) for an order dismissing the complaint of plaintiff Lori Spellman (“Spellman”). Spellman opposes at docket 21. S&N replies at docket 22. Oral argument was requested but would not assist the court.

**II. BACKGROUND**

Spellman’s complaint alleges she was injured by the Birmingham Hip Resurfacing (“BHR”) system, a metal-on-metal hip resurfacing prosthesis manufactured by S&N that was implanted in her hips in 2009 and 2010. In 2014 Spellman “underwent revision of her right hip due to right hip pain.”<sup>1</sup> Her doctor informed her that the BHR system implanted in her right hip was defective and was causing her to suffer pain and “an adverse metal reaction.”<sup>2</sup> Spellman alleges that the BHR system installed in her left hip failed as well, causing her to undergo a second revision surgery.

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<sup>1</sup>Doc. 1 at 9 ¶ 10.

<sup>2</sup>*Id.* at 3-4 ¶ 11.

1 Spellman brings two Arizona-common-law causes-of-action against S&N: strict  
2 liability and negligence. She alleges that S&N is liable for “designing and/or  
3 manufacturing” the BHR systems in violation of the Federal Food, Drug, and Cosmetic  
4 Act” (“FDCA”)<sup>3</sup> and related federal regulations.<sup>4</sup> Specifically, Spellman alleges the  
5 following ten regulatory violations:

- 6 (1) failure to accurately establish the in vivo life expectancy of the BHR;
- 7 (2) failure to validate the anticipated wear of the acetabular cup prior to its  
8 release into commercial distribution;
- 9 (3) failure to establish and maintain appropriate reliability assurance  
10 testing to validate the BHR design both before and after its entry into the  
11 marketplace;
- 12 (4) failure to conduct adequate bio-compatibility studies to determine the  
13 BHR’s latent propensity to effuse metallic contaminants into the human  
14 blood and tissue;
- 15 (5) failure to identify the component discrepancy;
- 16 (6) failure to capture the component discrepancy or defect during their  
17 “Final Acceptance Activities;”
- 18 (7) failure to establish and maintain procedures for implementing  
19 corrective and preventative action in response to, inter alia, complaints  
20 regarding the BHR, returned BHR, and other quality problems associated  
21 with the BHR;
- 22 (8) failure to appropriately respond to adverse incident reports that  
23 strongly indicated the acetabular component was “Malfunctioning [as  
24 defined in 21 C.F.R. 803.3],” or otherwise not responding to its “Design  
25 Objection Intent;”
- 26 (9) failure to complete device investigations on returned BHR and  
27 components, including the acetabular component; and
- 28 (10) continuing to inject BHR into the stream of interstate commerce when  
it knew, or should have known, that the acetabular component was  
“Malfunctioning [as defined in 21 C.F.R. 803.3]” or otherwise not  
responding to its “Design Objective Intent.”

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<sup>3</sup>21 U.S.C. § 301 *et seq.*

<sup>4</sup>Doc. 1 at 4 ¶ 12; 8 ¶ 21.

1 S&N moves for dismissal under Rule 12(b)(6), arguing that Spellman has not pleaded  
2 specific, plausible facts showing that her state law claims are not preempted by federal  
3 law.

### 4 III. STANDARD OF REVIEW

5 Rule 12(b)(6) tests the legal sufficiency of a plaintiff's claims. In reviewing such  
6 a motion, "[a]ll allegations of material fact in the complaint are taken as true and  
7 construed in the light most favorable to the nonmoving party."<sup>5</sup> To be assumed true,  
8 the allegations, "may not simply recite the elements of a cause of action, but must  
9 contain sufficient allegations of underlying facts to give fair notice and to enable the  
10 opposing party to defend itself effectively."<sup>6</sup> Dismissal for failure to state a claim can be  
11 based on either "the lack of a cognizable legal theory or the absence of sufficient facts  
12 alleged under a cognizable legal theory."<sup>7</sup> "Conclusory allegations of law . . . are  
13 insufficient to defeat a motion to dismiss."<sup>8</sup>

14 To avoid dismissal, a plaintiff must plead facts sufficient to "state a claim to relief  
15 that is plausible on its face."<sup>9</sup> "A claim has facial plausibility when the plaintiff pleads  
16 factual content that allows the court to draw the reasonable inference that the  
17 defendant is liable for the misconduct alleged."<sup>10</sup> "The plausibility standard is not akin  
18 to a 'probability requirement,' but it asks for more than a sheer possibility that a  
19 defendant has acted unlawfully."<sup>11</sup> "Where a complaint pleads facts that are 'merely  
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21 <sup>5</sup>*Vignolo v. Miller*, 120 F.3d 1075, 1077 (9th Cir. 1997).

22 <sup>6</sup>*Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011).

23 <sup>7</sup>*Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990).

24 <sup>8</sup>*Lee v. City of Los Angeles*, 250 F.3d 668, 679 (9th Cir. 2001).

25 <sup>9</sup>*Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550  
26 U.S. 544, 570 (2007)).

27 <sup>10</sup>*Id.*

28 <sup>11</sup>*Id.* (citing *Twombly*, 550 U.S. at 556).

1 consistent with' a defendant's liability, it 'stops short of the line between possibility and  
2 plausibility of entitlement to relief.'"<sup>12</sup> "In sum, for a complaint to survive a motion to  
3 dismiss, the non-conclusory 'factual content,' and reasonable inferences from that  
4 content, must be plausibly suggestive of a claim entitling the plaintiff to relief."<sup>13</sup>

#### 5 IV. DISCUSSION

##### 6 **A. Federal Preemption**

##### 7 **1. Express preemption**

8 When Congress passed the Medical Device Amendments ("MDA")<sup>14</sup> to the  
9 FDCA, it "imposed a regime of detailed federal oversight" from the Food and Drug  
10 Administration ("FDA") over the introduction of new medical devices into the market.<sup>15</sup>  
11 The MDA contains the following clause that generally preempts states from imposing  
12 their own requirements on medical device manufacturers:

13 Except as provided in subsection (b) of this section, no State or political  
14 subdivision of a State may establish or continue in effect with respect to a  
device intended for human use any requirement—

15 (1) which is different from, or in addition to, any requirement  
16 applicable under this chapter to the device, and

17 (2) which relates to the safety or effectiveness of the device or to  
18 any other matter included in a requirement applicable to the device  
19 under this chapter.<sup>16</sup>

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23 <sup>12</sup>*Id.* (quoting *Twombly*, 550 U.S. at 557).

24 <sup>13</sup>*Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009); *see also Starr*, 652 F.3d  
25 at 1216.

26 <sup>14</sup>21 U.S.C. § 360c *et seq.*

27 <sup>15</sup>*Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

28 <sup>16</sup>21 U.S.C. § 360k(a).

1 Because the MDA preempts only requirements that are “different from, or in addition to”  
2 the federal requirements,<sup>17</sup> it does not bar “a state-law claim for violating a state-law  
3 duty that parallels a federal-law duty under the MDA.”<sup>18</sup>

## 4 **2. Implied preemption**

5 The Supreme Court in *Buckman Co. v. Plaintiffs’ Legal Comm.*, held that, in  
6 addition to express preemption, the MDA also impliedly preempts “state-law fraud-on-  
7 the-FDA” claims—claims that the manufacturer made fraudulent representations to the  
8 FDA in the course of obtaining pre-market approval of a device.<sup>19</sup> If plaintiffs were  
9 allowed to maintain fraud-on-the-agency claims, the Court reasoned, such claims would  
10 conflict with, and would therefore be impliedly preempted by, the FDA’s statutory  
11 responsibility to “police fraud consistently with the Administration’s judgment and  
12 objectives.”<sup>20</sup> The Court ruled that such claims are federal in nature because they do  
13 not rely on “traditional state tort law which had predated the federal enactments in  
14 question[].”<sup>21</sup>

## 15 **B. Whether Spellman’s Complaint Satisfies Rule 8(a)**

16 S&N argues that the complaint is insufficient under Rule 8(a) because it lacks  
17 well-pleaded facts that show that S&N violated the FDA’s regulations. S&N contends  
18 that the complaint “merely recites a laundry list of federal regulations S&N supposedly  
19 violated” without connecting any of the violations to specific facts.<sup>22</sup> Without well-  
20 pleaded regulatory violations, S&N argues, the complaint cannot overcome S&N’s  
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22 <sup>17</sup>*Id.*

23 <sup>18</sup>*Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc).

24 <sup>19</sup>531 U.S. 341, 348 (2001).

25 <sup>20</sup>*Id.* at 350.

26 <sup>21</sup>*Id.* at 353.

27 <sup>22</sup>Doc. 16 at 2.

1 express preemption defense.<sup>23</sup> In response, Spellman does not point to any specific  
2 facts that support her allegations that S&N violated the FDA’s regulations. As she does  
3 in her complaint, she merely concludes without explanation that S&N violated the  
4 regulations.<sup>24</sup>

5 As an initial matter, it should be noted that federal preemption is an affirmative  
6 defense upon which the defendant bears the burden of proof.<sup>25</sup> Rule 8(a), which states  
7 that the complaint must include “a short and plain statement of the claim showing that  
8 the pleader is entitled to relief,” does not apply to affirmative defenses. Affirmative  
9 defenses are addressed in Rule 8(c), which states that affirmative defenses may be  
10 pleaded in response to a complaint.<sup>26</sup> Because a complaint “need not anticipate or  
11 attempt to circumvent affirmative defenses,”<sup>27</sup> Rule 8(a) does not inherently require  
12 Spellman to plead any regulatory violations in order to sufficiently state her two Arizona-  
13 law claims.<sup>28</sup>

14 This does not end the discussion, however, because S&N’s alleged regulatory  
15 violations play a critical role in Spellman’s state-law claims. In order to establish a  
16 prima facie case of strict liability under Arizona law, Spellman must show that the BHR  
17 system is (1) “defective and unreasonably dangerous;” (2) “the defective condition  
18 existed at the time it left [S&N’s] control;” and (3) “the defective condition is the  
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20 <sup>23</sup>*Id.* at 1.

21 <sup>24</sup>Doc. 21 at 3.

22 <sup>25</sup>See *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011); *Dilts v. Penske Logistics*,  
23 LLC, 769 F.3d 637, 649 (9th Cir. 2014); *Hunter v. Philip Morris USA*, 582 F.3d 1039, 1044 (9th  
24 Cir. 2009); *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1342 n.2 (10th Cir. 2015); *Bausch v.*  
*Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010).

25 <sup>26</sup>Fed. R. Civ. P. 8.

26 <sup>27</sup>*Bausch*, 630 F.3d at 561. See also *Jones v. Bock*, 549 U.S. 199, 216 (2007).

27 <sup>28</sup>See *Bausch*, 630 F.3d at 561–62; *Caplinger*, 784 F.3d at 1342 n.2. See also *cf. Albino*  
28 *v. Baca*, 747 F.3d 1162, 1169 (9th Cir. 2014) (en banc).

1 proximate cause of [her] injuries and property loss.”<sup>29</sup> To establish negligence,  
2 Spellman must show “(1) a duty owed to [her], (2) a breach thereof and (3) an injury  
3 proximately caused by the breach.”<sup>30</sup> For each of these torts, Spellman has  
4 incorporated S&N’s regulatory violations into the statement of her claims: her strict  
5 liability cause of action alleges that the BHR system was unreasonably dangerous due  
6 to S&N’s regulatory violations,<sup>31</sup> and her negligence cause of action alleges that S&N  
7 breached a duty to her by violating the FDA’s regulations.<sup>32</sup> Thus, S&N’s alleged  
8 regulatory violations are essential to Spellman’s statement of her two claims. Although  
9 no heightened pleading standards apply, Rule 8(a) requires Spellman to plead sufficient  
10 factual matter to render plausible the alleged regulatory violations.

11 When analyzing whether a complaint’s allegations satisfy Rule 8(a), courts  
12 employ a two-step process.<sup>33</sup> Courts “begin by identifying pleadings that, because they  
13 are no more than conclusions, are not entitled to the assumption of truth.”<sup>34</sup> If the court  
14 identifies well-pleaded factual allegations, it proceeds to the next step, under which it  
15 assumes the veracity of the allegations and determines “whether they plausibly give rise  
16 to an entitlement to relief.”<sup>35</sup> Spellman’s complaint fails at the first step. The complaint  
17 merely concludes, without any factual context, that S&N violated the various listed  
18 regulations. On the face of Spellman’s complaint it is possible that S&N violated the  
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21 <sup>29</sup>*Dietz v. Waller*, 685 P.2d 744, 747 (Ariz. 1984).

22 <sup>30</sup>*Boyle v. City of Phoenix*, 563 P.2d 905, 906 (Ariz. 1977).

23 <sup>31</sup>Doc. 1 at 4 ¶ 13.

24 <sup>32</sup>*Id.* at 8 ¶ 22.

25 <sup>33</sup>*Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 995–96 (9th Cir.  
26 2014).

27 <sup>34</sup>*Iqbal*, 556 U.S. at 679.

28 <sup>35</sup>*Id.*

1 FDA's regulations, but the complaint does not include any "factual enhancement" to  
2 cross "the line between possibility and plausibility."<sup>36</sup> Dismissal is appropriate.

3 Spellman's opposition relies primarily on *Stengel* and *Bausch*, but to no avail.  
4 *Stengel* is inapposite because there the Ninth Circuit's decision rested on the merits of  
5 whether the state-law claims were preempted, not whether the complaint satisfied the  
6 *Twombly* standard.<sup>37</sup> With regard to *Bausch*, Spellman correctly notes that the Seventh  
7 Circuit held that Rule 8(a) does not require the complaint to identify specific federal  
8 regulations that were allegedly violated.<sup>38</sup> Even so, *Bausch* does not stand for the  
9 proposition that the complaint need not plausibly allege regulatory violations at all. The  
10 *Bausch* plaintiff alleged that the FDA had informed the defendant that its manufacturing  
11 methods did not conform to "industry and regulatory standards."<sup>39</sup> According to the  
12 Seventh Circuit, this allegation satisfied Rule 8(a) because it plausibly alleged  
13 "regulatory violations."<sup>40</sup> Spellman's complaint lacks analogous factual enhancement.

#### 14 **V. CONCLUSION**

15 Based on the preceding discussion, Defendant's motion to dismiss at docket 16  
16 is GRANTED without prejudice to Plaintiff's ability to attempt to file an amended  
17 complaint that complies with the standards set out in *Twombly*. Plaintiff may file a  
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22 <sup>36</sup>*Twombly*, 550 U.S. at 557.

23 <sup>37</sup>See *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013), rev'd on other  
24 grounds by *Stengel*, 704 F.3d at 1228 (The district court "did not dismiss the Stengels'  
25 complaint on the ground that it did not conform to the *Twombly* standard, but instead on the  
ground that the Stengels' claims were preempted.").

26 <sup>38</sup>630 F.3d at 560.

27 <sup>39</sup>*Id.* at 559.

28 <sup>40</sup>*Id.*

1 motion to amend her complaint within 21 days. If she does not do so, this case will be  
2 dismissed without further notice.

3 DATED this 24<sup>th</sup> day of September 2016.

4 /s/ JOHN W. SEDWICK  
5 SENIOR JUDGE, UNITED STATES DISTRICT COURT  
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