

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS**

<b>CHARLES R. LUTTRELL,</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Case No. 17-2137-HLT-GEB</b>
	)	
<b>JAMES K. BRANNON, M.D., et. al.,</b>	)	
	)	
	)	
<b>Defendants.</b>	)	
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**MEMORANDUM AND ORDER**

This matter is before the Court on Plaintiff’s First Motion to Remove Confidentiality Designation of Documents Produced by Defendant Orthopedic Sciences, Inc. in Response to Plaintiff’s First Requests for Production (Motion) (**ECF No. 139**) and Defendant Orthopedic Sciences, Inc.’s Response to the Motion (ECF No. 148). Plaintiff did not file a reply brief. After careful consideration of the parties’ briefs and attached exhibits, the Court **GRANTS IN PART AND DENIES IN PART** Plaintiff’s Motion.

**I. Background**

**A. Nature of the Case<sup>1</sup>**

Plaintiff’s claims are set forth in the Second Amended Complaint (ECF No. 151) and arise from medical treatment he received from Defendants James K. Brannon, M.D. (Dr. Brannon) and Mauricio Garcia, M.D. (Dr. Garcia). Plaintiff alleges the two doctors

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<sup>1</sup> The information recited in this section is taken from the Second Amended Complaint (ECF No. 151) and should not be construed as judicial findings or factual determinations unless specifically stated.

unnecessarily prescribed him pain medications, to which he became addicted and suffered permanent physical damage. Plaintiff further alleges Dr. Brannon convinced him to undergo an unnecessary “joint preservation” surgery to alleviate pain in his right hip. As relevant to the instant Motion, this surgery involved the use and implantation of a device called the Titanium Hip Tool Locking Plate Bone Graft Stabilization System (BGSS). Plaintiff claims the surgery and BGSS device failed, causing him additional injury and pain. Plaintiff also alleges he and Missouri Medicaid, his insurer, paid for this unnecessary medical treatment.

In addition to the claims against Dr. Brannon and Dr. Garcia, Plaintiff also brings claims against the following entities: Orthopedic Sciences, Inc. (OSI); Joint Preservation Institute of Kansas, L.L.C. (JPI); Doctors Hospital, L.L.C (Doctors Hospital); The Headache & Pain Center, P.A. (HPC); and PatientFirst Healthcare Alliance, P.A. (PatientFirst). According to Plaintiff, the actions described above exemplify a broader scheme perpetrated by Dr. Brannon, Dr. Garcia, and these other Defendants to swindle Missouri Medicaid recipients, such as himself, by overprescribing them pain medications and then convincing them to undergo medically unnecessary joint preservation surgeries. Plaintiff further claims the two physicians profit from this alleged scheme because the supplies and devices used in the joint preservation surgeries are manufactured and provided by, and the surgeries themselves are performed by, the various Defendant entities, which in turn, are related to each other and owned in whole or in part by the two physicians.

Based on the above, Plaintiff asserts the following causes of action against the Defendants: professional negligence, lack of informed consent, RICO violations, civil

conspiracy, Kansas Consumer Protection Act violations, breach of implied warranty of fitness, strict liability for failure to warn, vicarious liability, alter ego liability, and punitive damages.

**B. Procedural Posture**

Plaintiff filed his original Complaint against Dr. Brannon, OSI, JPI, and Doctors Hospital on March 3, 2017. (ECF No. 1.) As relevant here, the Court entered an agreed upon Protective Order on August 15, 2017 (ECF No. 44), and the parties engaged in some discovery before Plaintiff filed his First Amended Complaint on December 21, 2017. (ECF Nos. 43, 45, 48, 51, 64, and 84.) The instant Motion deals with documents produced by OSI to Plaintiff during this time period.

Plaintiff added Dr. Garcia, HPC and PatientFirst as Defendants when he filed his First Amended Complaint. (ECF No. 84.) All Defendants then filed various motions to dismiss. (ECF Nos. 85, 87, 106, 108, and 131.) On June 19, 2018, the Court granted in part and denied in part the motions to dismiss and allowed Plaintiff until July 3, 2018 to file a second amended complaint, which Plaintiff timely filed. (ECF Nos. 149 and 151.) The Defendants filed a second round of motions to dismiss on August 15, 2018, which are currently pending before the District Judge. (ECF Nos. 156, 158, 160 and 162.)

**C. Plaintiff's First Motion to Remove Confidentiality Designation of Documents Produced by Defendant Orthopedic Sciences, Inc. in Response to Plaintiff's First Requests for Production (ECF No. 139)**

Plaintiff's Motion<sup>2</sup> deals with nearly 1,000 pages of records OSI produced on September 11, 2017 in response to Plaintiff's first set of document requests (ECF No. 51). These documents consist of Plaintiff's medical records (found at OSIRFP100000001–11) and OSI's 510(k) submissions to the Food and Drug Administration (FDA) regarding marketing of the Hip Tool™ (Hip Tool), the BGSS, and other Hip Tool related medical devices (found at OSIRFP100000012–999). Pursuant to the Protective Order (ECF No. 44), OSI marked all 999 pages as confidential. Plaintiff now challenges a majority of those confidential designations.

As explained in more detail below, the parties, through the conferral process, agreed OSI would remove the confidentiality designations from Plaintiff's eleven pages of medical records (OSIRFP100000001–11) and from six pages (OSIRFP100000045–50) of OSI's 510(k) submissions. Through the instant Motion, Plaintiff is challenging the confidentiality designations on the remaining 982 documents in OSI's 510(k) submissions to the FDA (OSIRFP100000012–44 and 51-999).

The term "510(k)" is a reference to a section of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act of 1938 (Act), which is currently codified at 21 U.S.C. § 360(k). This section provides manufacturers a limited, or expedited, FDA review process when seeking to market certain medical devices. It

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<sup>2</sup> Although the parties' briefs and exhibits are filed under seal, this Memorandum and Order will not be filed under seal due to the public interest in judicial opinions.

requires manufactures to submit a “premarket notification” to the FDA (the process is commonly called the “510(k) process,” after the section number in original Act and will be referred to as such herein). If the FDA concludes on the basis of the 510(k) notification that the device is “substantially equivalent” to a pre-existing device, it can be marketed without further regulatory analysis.<sup>3</sup>

Plaintiff’s main argument for de-designation of the remaining 510(k) documents is they are publicly available. In support, Plaintiff states he located 60 of the 982 documents independently via public sources. OSI argues it did not know which specific documents Plaintiff was challenging as public documents until this Motion was filed. After review, OSI does not dispute those documents are publicly available and agrees to remove those confidentiality designations. Regarding the remaining documents at issue, however, OSI argues the confidentiality designations should stand because those documents contain detailed trade secrets and proprietary information, which if disclosed, would be extremely harmful to OSI’s business.

## **II. Legal Standard: Designation of Confidential Information under the Protective Order**

The Protective Order<sup>4</sup> entered in this case allows a party producing records to designate them as “Confidential Information.” (ECF No. 44.) Documents so designated are afforded certain protections, including a prohibition on being used outside of this

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<sup>3</sup> See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-480 (1996) (describing the 510(k) process).

<sup>4</sup> Fed. R. Civ. P. 26(c)(1)(G) provides that “[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specific way.”

litigation, a limitation on who may view the documents, and the ability to seek permission to file such documents under seal. (ECF No. 44, ¶¶ 6(a)-(b) and 7.)

“Confidential Information” is defined in the Protective Order as “information that the producing party designates in good faith has been previously maintained in a confidential manner and should be protected from disclosure and use outside the litigation because its disclosure and use is restricted by statute or could potentially cause harm to the interests of the disclosing party or nonparties.” (ECF No. 44, ¶ 2.)

And, as relevant here, the Protective Order further provides the parties will limit their designation of “Confidential Information” to the following categories of information or documents: (1) plans for development of new products; (2) internal company operations; (3) trade secrets; (4) inventions; (5) patent applications; (6) trade names; (7) trademarks; (8) service marks; (9) copyrights; (10) proprietary business records; (11) nonpublic financial records; and (12) records whose disclosure is restricted or prohibited by statute. Additionally, information or documents available publicly may not be designated as Confidential Information. (ECF No. 44, ¶ 2.)

The Protective Order also allows a party to challenge another party’s confidential designations. Before filing any motion or objection to a confidential designation, the objecting party must meet and confer in good faith to resolve the objection informally without judicial intervention. If the meet and confer is unsuccessful, a party electing to challenge a confidentiality designation may file and serve a motion identifying the challenged material and setting forth in detail the basis for the challenge. The burden of

proving the necessity of a confidentiality designation, however, remains with the party asserting confidentiality. (ECF No. 44, ¶ 8.)

Thus, to maintain the confidentiality designations on the documents at issue, OSI must prove (1) the information has previously been maintained in a confidential manner and (2) the disclosure of the information is either restricted by statute or could potentially cause harm to OSI's interests.<sup>5</sup>

### **III. Duty to Confer**

As a threshold matter, the Court first considers whether the parties have sufficiently conferred as required by the Protective Order and D. Kan. Rule 37.2.<sup>6</sup> Sufficient conferral requires more than an exchange of letters or emails, it requires the parties to “in good faith converse, confer, compare views, consult, and deliberate, or in good faith attempt to do so.”<sup>7</sup>

The parties' briefs reveal when Plaintiff filed his First Amended Complaint, which occurred on December 21, 2017, the parties successfully conferred beforehand regarding removing OSI's confidentiality designations on OSIRFP100000045-50.<sup>8</sup> This allowed

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<sup>5</sup> See ¶ 2 of the Protective Order (ECF No. 44) for definition of “Confidential Information.”; see also *Fish v. Kobach*, 320 F.R.D. 566, 574 (D. Kan.), reconsideration denied, No. 16-2105-JAR, 2017 WL 2861668 (D. Kan. July 5, 2017), and review denied, 267 F. Supp. 3d 1297 (D. Kan. 2017), appeal dismissed, No. 17-3161, 2017 WL 7065741 (10th Cir. Aug. 30, 2017) (describing burden to support confidentiality designations as meeting the definition of confidential information used in the protective order).

<sup>6</sup> See ¶ 8 of the Protective Order (ECF No. 44); D. Kan. Rule 37.2 states the “court will not entertain any motion to resolve a discovery dispute . . . unless the attorney for the moving party has conferred or has made reasonable effort to confer with opposing counsel concerning the matter in dispute prior to the filing of the motion.”

<sup>7</sup> D. Kan. Rule 37.2.

<sup>8</sup> Plaintiff's Motion, p. 2 at ¶ 4 (ECF No. 139); OSI's Response, p. 3 (ECF No. 148).

Plaintiff to attach those documents as an exhibit to the First Amended Complaint without first moving to file those documents under seal.<sup>9</sup>

However, the parties were not as successful regarding the conferral process for the 900-plus documents at issue in this Motion. Per the parties' briefs, it appears counsel participated in at least one telephone call and a brief exchange of emails.<sup>10</sup> While the Court appreciates counsel could agree on removing the confidentiality designations from Plaintiff's medical records contained at OSIRFP100000001–11 during this conferral process,<sup>11</sup> it is unclear to the Court whether counsel fully and in good faith conferred as required by D. Kan. Rule 37.2 and the Protective Order regarding the approximately 982 remaining documents.

OSI states it re-reviewed the confidentiality designations on the documents as requested by Plaintiff.<sup>12</sup> After again finding the confidentiality designations to be appropriate, OSI's counsel contends he asked Plaintiff's counsel to specifically identify which documents they assert are non-confidential, but Plaintiff's counsel refused to do so.<sup>13</sup> OSI states it first learned of Plaintiff's specific arguments when reading the instant Motion.<sup>14</sup>

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<sup>9</sup> *Id.*; *see also* ECF No. 84.

<sup>10</sup> *See* Exhibits B-D attached to Plaintiff's Motion (ECF No. 139-1); OSI's Response, pp. 17-18 (ECF No. 148).

<sup>11</sup> *Id.*; *Id.* at p. 3.

<sup>12</sup> *See* OSI's Response, pp. 17-18 (ECF No. 148); *see also* Exhibit D attached to Plaintiff's Motion (ECF No. 139-1).

<sup>13</sup> *Id.*

<sup>14</sup> *See* OSI's Response, pp. 17-18 (ECF No. 148).

Given the volume of documents at issue here, the Court would have expected counsel to engage in more meaningful and detailed discussions regarding specific documents, or at least specific types of documents, and the reasons for why the confidentiality designations should or should not be removed. However, to avoid further delay of resolution of the matter, the Court will address the merits of the Motion instead of returning the matter to the parties for additional conferral.<sup>15</sup> As this case moves forward, however, the Court instructs and expects counsel to fully and in good faith meet and confer regarding disputes over confidentially designations.<sup>16</sup>

#### **IV. Discussion**

##### **A. Agreed-Upon Publicly Available Documents**

Plaintiff's main argument for asking the Court to de-designate OSI's documents is because they are publicly available. Citing 21 C.F.R § 807.95(e), Plaintiff argues once the FDA has cleared a new device for marketing through the 510(k) process, the submission from the medical device manufacturer is subject to public disclosure. Because the documents at issue are contained in OSI's successful 510(k) submissions to the FDA, Plaintiff reasons all documents are publicly available. In support of his argument, Plaintiff

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<sup>15</sup> See, e.g., *CCPS Transp., LLC v. Sloan*, No. 12-2602, 2013 WL 2405545, at \*1 (D. Kan. May 31, 2013) (stating that although the court can deny a motion on procedural grounds for failing to meet and confer, the court is within its discretion to address the merits of the argument); *White v. Graceland Coll. Ctr. for Profl Dev. & Lifelong Learning, Inc.*, No. 07-2319, 2009 WL 722056, at \*2 (D. Kan. March 18, 2009) (waiving non-compliance with duty to confer to avoid further delay of resolution of the matter); *Strasburg-Jarvis, Inc. v. Radiant Sys., Inc.*, No. 06-2552, 2009 WL 129361, at \*2 (D. Kan. Jan. 20, 2009) (electing to address the merits of discovery dispute despite failure to confer).

<sup>16</sup> See *CCPS Transp., LLC*, 2013 WL 2405545, at \*1 (describing the efforts that should go into the meet and confer process).

states he found the following 60 documents via public sources: OSIRFP100000012–25, 96–98, 142–152, 154–155, 158–162, 164–173, 177, 615–617, 622–624, 636–638 and 991–995.

While OSI disputes Plaintiff’s legal conclusion that all documents in a 510(k) submission become public documents after FDA clearance, it does agree, after review, the above-cited documents are publicly available and the confidentiality designations can be removed from those documents.

Therefore, pursuant to the Protective Order<sup>17</sup> and agreement of the parties, the Court **GRANTS** Plaintiff’s Motion regarding documents OSIRFP100000012–25, 96–98, 142–152, 154–155, 158–162, 164–173, 177, 615–617, 622–624, 636–638 and 991–995<sup>18</sup> and **ORDERS** OSI to remove the confidentiality designations from the same within **10 days** of the date of this Order.

#### **B. Remaining Documents**

The remaining documents at issue are the documents in OSI’s 510(k) submissions found at OSIRFP100000012-999, except for the 60 agreed-upon publicly available documents listed in the section above and OSIRFP100000045-50, for which the parties previously agreed to remove the confidentiality designations.<sup>19</sup>

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<sup>17</sup> See ECF No. 44, p. 3 (“Information or documents that are available to the public may not be designated as Confidential Information.”).

<sup>18</sup> These documents are attached to Plaintiff’s Motion as Exhibits E1, F1, G1, H1, I1, J1, K1, L1, M1, N1, O1, P1, Q1, R1, S1, T1, U1, V1, W1, X1, Y1 and Z1 (ECF No. 139-1).

<sup>19</sup> See *supra* Section III.

As stated earlier, to maintain the confidentiality designations for these remaining documents, OSI must prove (1) the information has previously been maintained in a confidential manner and (2) disclosure of the information is either restricted by statute or could potentially cause harm to OSI's interests.

### **1. Information Maintained in a Confidential Manner**

OSI states it has implemented various security measures to protect the remaining information at issue from being publicly disclosed. Internally, information pertaining to the Hip Tool, BGSS, and other medical devices is stored on a secured database and is not shared with the general public or unauthorized personnel.<sup>20</sup> In addition, OSI employees and contractors are subjected to confidentiality obligations and are prohibited from disclosing OSI's proprietary information to third parties.<sup>21</sup>

More specifically, OSI has entered into various confidentiality agreements with its staff members and contractors to protect their confidential information.<sup>22</sup> Contractors with OSI can only disclose confidential information to employees or associates who have a need to know and agree to be bound by a confidentiality agreement.<sup>23</sup> OSI staff members and contractors cannot use or disclose confidential information for any purpose other than in furtherance of OSI's interests.<sup>24</sup> Additionally, both contractors and staff members have an obligation to either protect or return OSI's confidential information at the end of their

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<sup>20</sup> OSI' Response, pp. 10-11 (ECF No. 148); Dr. Brannon's Declaration, ¶¶ 22-24, attached thereto as Exhibit A (ECF No. 148-1).

<sup>21</sup> *Id.*; *Id.* at ¶ 24.

<sup>22</sup> *Id.*; *Id.* at ¶¶ 24-26.

<sup>23</sup> *Id.*; *Id.* at ¶ 27.

<sup>24</sup> *Id.*; *Id.* at ¶ 28.

contractual relationships.<sup>25</sup> Finally, when making its 510(k) submissions, OSI requested that the FDA treat all material submitted to it regarding the Hip Tool and BGSS as confidential information under the FDA's regulations.<sup>26</sup>

To support these statements, OSI has submitted the signed Declaration of Dr. Brannon, the founder and majority owner of OSI.<sup>27</sup> Plaintiff has not disputed that OSI maintains its confidential information in the manner described above or otherwise rebutted Dr. Brannon's Declaration.<sup>28</sup> The Court, therefore, finds OSI has met its burden to show it maintains the information at issue in a confidential manner.

## **2. Disclosure of Information Restricted by Statute**

Plaintiff argues the remaining information at issue is available for public disclosure pursuant to 21 C.F.R. § 807.95(e). However, as relevant here, that federal regulation exempts information from public disclosure in accordance 21 C.F.R. § 20.61.<sup>29</sup> Specifically, 21 C.F.R. § 20.61(c) provides “[d]ata and information submitted or divulged

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<sup>25</sup> *Id.*; *Id.* at ¶¶ 29-30.

<sup>26</sup> *Id.* at p. 15; *Id.* at ¶ 20 and attached exhibit; *see also* 21 CFR § 20.61(d) (stating a person who submits records to the Government may designate part or all of the information in such records as confidential and exempt from disclosure).

<sup>27</sup> Dr. Brannon's Declaration is attached to OSI's Response as Exhibit A (ECF No. 148-1).

<sup>28</sup> Plaintiff did not file a reply brief.

<sup>29</sup> 21 C.F.R. § 807.95(e) states “[d]ata or information submitted with, or incorporated by reference in, a premarket notification submission . . . shall be available for disclosure by the Food and Drug Administration when the intent to market the device is no longer confidential in accordance with this section, unless exempt from public disclosure in accordance with part 20 of this chapter.” Part 20 at 21 C.F.R. § 20.100(a) states that a record “ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in subpart D of this part. . . .” Subpart D consists of the regulations found at 21 C.F.R. §§ 20.60 through 20.67.

to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.”

Trade secrets, as defined by 21 C.F.R. § 20.61(a), are “any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.” Confidential commercial or financial information, as explained in 21 C.F.R. § 20.61(b), means “valuable data or information which is used in one’s business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.”

OSI argues the remaining information at issue here is confidential because it meets the above definitions of trade secrets and confidential commercial or financial information. After reviewing the documents attached to Defendant’s Response and to the extent such documents are not public documents,<sup>30</sup> the Court agrees.

The documents at OSIRFP100000028–32, 42–44, 51–76, 77–81, 100–134, 135–139, 182–242, 259–271, 279–293, 311–398, 547–560, 563–573, 579–604, 642–655, 658–667, 671–673, 677–898, 904–929, 946–980 and 981–985<sup>31</sup> consists of draft package inserts, draft technique manuals, engineer drawings and design plans with specific design notes and changes made to the Hip Tool and other product variants, and other internal

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<sup>30</sup> Dr. Brannon declares he does not believe these documents are available to the public. *See* Dr. Brannon’s Declaration at ¶¶ 22–23, attached as Exhibit A to OSI’s Response (ECF No. 148-1).

<sup>31</sup> These documents are attached to OSI’s Response as Exhibits B, C-1, C-2, C-3, C-4 and C-5 (ECF Nos. 148-2 through 148-7).

information describing the design and functionality of OSI's medical devices and procedures. OSI describes these documents as the "monuments to the culmination of diligent effort, resources, and design innovation throughout OSI's history as a company."<sup>32</sup> The documents at OSIRFP100000243-254, 574-578, 605-611, 614, 668-670, 674, 899-903 and 930-936<sup>33</sup> contain safety-related information regarding failure modes, effects, and critical product analysis of OSI's medical devices, which describes potential weaknesses and failures and their effects pertaining to the Hip Tool and BGSS.

In the Court's view, the information contained in these documents meet the definitions of trade secrets and confidential commercial or financial information as defined in, and exempted from public disclosure by, 21 C.F.R. § 20.61.<sup>34</sup> Additionally, the Court notes Plaintiff has not disputed the above information meets these definitions.<sup>35</sup>

### **3. Harmful to OSI**

OSI further argues disclosure of the remaining information at issue would be harmful to its interests. OSI states it has spent millions of dollars and a considerable amount of time, effort, and resources in developing, manufacturing, and marketing its products and procedures to give it a competitive advantage over its many competitors.<sup>36</sup> If its trade secrets or commercially confidential information were disclosed, OSI contends its

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<sup>32</sup> OSI's Response, p. 15 (ECF No. 148).

<sup>33</sup> These documents are attached to OSI's Response as Exhibit D (ECF No. 148-8).

<sup>34</sup> The information therefore also fits into the categories of allowed Confidential Information listed in ¶ 2 of the Protective Order (ECF No. 44). The information also likely meets the definition of trade secrets found in the Defend Trade Secrets Act at 18 U.S.C. § 1839(3) and at K.S.A. § 60-3320(4) of the Kansas Uniform Trade Secrets Act.

<sup>35</sup> Plaintiff did not file a reply brief.

<sup>36</sup> OSI' Response, pp. 15-17 (ECF No. 148); Dr. Brannon's Declaration, ¶¶ 16-19, attached thereto as Exhibit A (ECF No. 148-1).

competitors could duplicate its technology, leading to a potentially substantial and significant loss of business.<sup>37</sup> Additionally, if such information were released to the public, OSI states it would need to expend at least the same amount or more than its original expenditure of time and resources in the development of its products to remain competitive.<sup>38</sup>

To support these statements, OSI submitted the signed Declaration of Dr. Brannon, the founder and majority owner of OSI.<sup>39</sup> And, Plaintiff has not disputed Dr. Brannon's Declaration or OSI's contentions it would be harmed by the disclosure of this information.<sup>40</sup> The Court, therefore, finds OSI has met its burden to show that disclosure of the remaining information at issue could be substantially adverse to its interests.<sup>41</sup>

### **C. Filing Confidential Documents**

Plaintiff complains of the burden placed upon the parties and the Court when having to prepare and decide, respectively, motions to file confidential documents under seal.<sup>42</sup> However, just because a document is marked confidential pursuant to a protective order does not mean it will automatically be filed under seal. The Court reminds the parties of the following:

[D]ocuments designated confidential under the protective order are not necessarily . . . subject to filing under seal when a party relies upon them in

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<sup>37</sup> *Id.*; *Id.* at ¶¶ 16-19, 22-23.

<sup>38</sup> *Id.*; *Id.* at ¶ 19.

<sup>39</sup> Dr. Brannon's Declaration is attached to OSI's Response as Exhibit A (ECF No. 148-1).

<sup>40</sup> Plaintiff did not file a reply brief.

<sup>41</sup> *See also* 21 C.F.R. § 20.61(f)(4) (FDA has discretion to deny public disclosure of documents when it "has substantial reason to believe that disclosure of the information would result in competitive harm.").

<sup>42</sup> Plaintiff's Motion, pp. 8-9.

support of a motion . . . . “The fact that the exhibits are ‘confidential’ within the meaning of the parties’ protective order has no bearing on whether those exhibits should be sealed in the record.” The disclosure analysis applicable to protective orders “generally balances the need for discovery against the need for confidentiality. But once such discovery material is filed with the court, it becomes a judicial record and the standard that applies when a party wants to keep such material under seal is much higher.” “Courts have long recognized a common-law right of access to judicial records.” “This right derives from the public’s interest in understanding disputes that are presented to a public forum for resolution and is intended to assure that the courts are fairly run and judges are honest.” Thus, a “strong presumption” exists that judicial records will not be sealed. A party seeking to overcome this presumption “must articulate a real and substantial interest that justifies depriving the public of access to the records that inform our decision-making process.” In weighing the interests, the court “works from the premise that the public’s interests ‘are presumptively paramount against those advanced by the parties.’”<sup>43</sup>

The parties are urged to keep these standards in mind should they seek to file confidential documents under seal as this case moves forward. Further, the Court expects the parties to fully meet and confer regarding filing confidentially-designated documents under seal before a party moves to file it as such.<sup>44</sup> Doing so will lessen the burden on the parties and the Court.

## **V. Conclusion**

Because the parties agree that OSIRFP100000012–25, 96–98, 142–152, 154–155, 158–162, 164–173, 177, 615–617, 622–624, 636–638 and 991–995<sup>45</sup> are publicly available

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<sup>43</sup> *Fish*, 320 F.R.D. at 576–77 (internal citations omitted).

<sup>44</sup> *See, e.g., Heartland Surgical Specialty Hosp., LLC v. Midwest Div., Inc.*, No. 05-2164-MLB-DWB, 2007 WL 101858, at \*5 (D. Kan. Jan. 10, 2007) (ordering the parties to meet and confer regarding whether a document should be filed under seal).

<sup>45</sup> These documents are attached to Plaintiff’s Motion as Exhibits E1, F1, G1, H1, I1, J1, K1, L1, M1, N1, O1, P1, Q1, R1, S1, T1, U1, V1, W1, X1, Y1 and Z1 (ECF No. 139-1).

documents, OSI shall remove the confidentiality designations from those documents within **10 days** from the date of this Order.

Regarding the documents at OSIRFP100000028–32, 42-44, 51–76, 77–81, 100–134, 135–139, 182–242, 243-254, 259–271, 279–293, 311–398, 547–560, 563–573, 574-578, 579–604, 605-611, 614, 642–655, 658–667, 668-670, 671–673, 674, 677–898, 899-903, 904–929, 930-936, 946-980 and 981–985,<sup>46</sup> the Court finds OSI has met its burden in proving the information found therein is confidential. Therefore, the confidential designations on those documents shall remain.

The Court notes neither party attached as an exhibit or specifically discussed by bates number the information in OSIRFP100000026-27, 33-41, 82-95, 99, 140-141, 153, 156-157, 163, 174-176, 178-181, 255-258, 272-278, 294-310, 399-546, 561-562, 612-613, 618-621, 625-635, 639-641, 656-657, 675-676, 937-945, 986-990 and 996-999.<sup>47</sup> Because Plaintiff has not identified these documents as being publicly available or otherwise specifically stated why these confidentiality designations should be removed,<sup>48</sup> and because the Court, for the reasons explained in Section IV.B. above, finds OSI has met its burden to show the non-public information at issue here is confidential, the Court orders that the confidential designations on these documents shall remain.

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<sup>46</sup> These documents are attached to OSI's Response as Exhibits B-D (ECF Nos. 148-2 through 148-8).

<sup>47</sup> OSIRFP100000996-999 are attached to Plaintiff's Motion at Exhibit Z1, but those pages appear to have been attached in error. Additionally, the information contained on those pages appear to contain OSI's confidential information as discussed in Section IV.B. of this Order.

<sup>48</sup> The Protective Order provides that a party electing to challenge a confidentiality designation should identify the challenged material and set forth in detail the basis for the challenge. (ECF No. 44, ¶ 8.)

**IT IS THEREFORE ORDERED** that Plaintiff's First Motion to Remove Confidentiality Designation of Documents Produced by Defendant Orthopedic Sciences, Inc. in Response to Plaintiff's First Requests for Production (ECF No. 139) is **GRANTED IN PART AND DENIED IN PART.**

**IT IS SO ORDERED.**

Dated at Wichita, Kansas this 18th day of September, 2018.

s/ Gwynne E. Birzer  
GWYNNE E. BIRZER  
United States Magistrate Judge