2016 WL 266353
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United States District Court,
D. New Jersey,
Camden Vicinage.

In re: Benicar (Olmesarten)
Products Liability Litigation.

Master Docket No. 15-2606 (RBK/JS)
|
Signed 01/21/2016

ORDER

JOEL SCHNEIDER, United States Magistrate Judge

***1** This matter is before the Court on the Motion to Seal [Doc. No. 150] ("Motion") filed by defendants Daiichi Sankyo U.S. Holdings, Inc. and Daiichi Sankyo, Inc. The Court received plaintiffs' memorandum in opposition [Doc. No. 166] ("Memorandum") and defendants' letter brief ("LB") reply [Doc. No. 177]. Defendants seek to seal seven exhibits attached to plaintiffs' Motion to Compel Discovery. [Doc. No. 107]. That motion has already been decided. Specifically, defendants seek to seal exhibits 6, 11, 13, 16, 17, 21, and 22. The Court exercises its discretion to decide defendants' motion without oral argument. See Fed. R. Civ. P. 78; L. Civ. R. 78.1. For the reasons to be discussed, defendants' motion is DENIED as to exhibit 6 and DENIED without prejudice as to exhibits 11, 13 16, 17, 21 and 22. [1]

BACKGROUND

This case is a multi-district products liability litigation wherein approximately 1200 plaintiffs brought suit against Daiichi Sankyo Inc., Daiichi Sankyo U.S. Holdings, Inc., and Forest Laboratories, Inc. alleging adverse drug reactions to the olmesarten family of pharmaceutical drugs, developed and marketed by defendants. See [Doc. Nos. 1, 2]. The specific drugs at issue are Benicar, Benicar HCT, Azor, and Tribenzor.

In anticipation of voluminous and confidential discovery the parties agreed to a stipulated Discovery Confidentiality Order ("DCO") in the early stages of the proceedings, which was approved by the Court on June 5, 2015. [Doc. No. 46]. The DCO permits a party producing "proprietary, trade secret and/or highly sensitive commercial information" to designate the material as "protected" so long as the producing party has a good faith belief that disclosure of the discovery materials being produced could cause "competitive harm" to the producing party. Id. at ¶ 10. This particular dispute concerns exhibits attached to plaintiffs' Motion to Compel, which has already been decided [Doc. No. 152]. Defendants claim plaintiffs' exhibits are "protected" and should be sealed. Mot. at 1 [Doc. No. 150-1]. Thus, defendants move to seal the documents pursuant to the DCO and L. Civ. R. 5.3. Id. In opposition plaintiffs argue the documents do not contain any personal patient information, trade secrets, proprietary information or sensitive commercial information. Plaintiffs also argue defendants have not established that there is "legitimate private or public interest which would warrant sealing" and that plaintiffs would suffer "a clearly defined and serious injury if their requested relief is not granted." Memo. at 1 [Doc. No. 166].

DISCUSSION

1. Local Civil Rule 5.3.

It is well established that there is "a common law public right of access to judicial proceedings and records." In re Cendant Corp., 260 F.3d 183, 192 (3d Cir. 2001) (citation omitted). Nonetheless, litigants may move to seal information associated with a judicial proceeding by demonstrating "good cause." Securimetrics, Inc. v. Iridian Techs., Inc., C.A. No. 03-4394 (RBK), 2006 WL 827889, at *2 (D.N.J. Mar. 30, 2006). Good cause requires "a particularized showing that disclosure will cause a 'clearly defined and serious injury to the party seeking closure.' " Id. (citing Pansy v. Borough of Stroudsburg, 23 F.3d 772, 786 (3d Cir. 1994)). The good cause standard is also applied where, as here, the disputed materials are discovery materials attached to a discovery motion. See Pansy, 23 F.3d at 786; Allied Corp. v. Jim Walter Corp., C.A. No. 86-3086, 1996 WL 346980, at *4 (E.D. Pa. June 17, 1996); Lite, New Jersey Federal Practice Rules Comment 3 to L. Civ. R. 5.3 (Gann).

***2** In this District motions to seal are governed by L. Civ. R. 5.3(c)(2) which requires the moving party to describe: (a) the nature of the materials or proceedings at issue; (b) the legitimate private or public interest which warrants the relief sought; (c) the clearly defined and serious injury that would result if the relief sought is not granted; and (d) why a less restrictive alternative to the relief sought is not available. After evaluating each factor, a court's ultimate decision must derive from a balancing test placing the specific need for privacy opposite the general presumption of public access. Pansy, 23 F.3d at 787. Where the specific need for privacy is related to a trade secret, privacy concerns may (but not always) outweigh the public's right of access. Id.

Defendants argue the materials in question should be sealed because disclosure would cause them harm. More specifically, defendants argue disclosure of the materials would reveal sensitive personal information of patients and defendants' business practices to competitors, as well as cause harm to defendants' reputation in the marketplace. Mot. at 3-4, 8-9 [Doc. No. 150-1]. Defendants assert that the identified harm to its legitimate private interests, in addition to the remainder of its submission, satisfy L. Civ. R. 5.3. Id. at 1. In addition, defendants argue exhibits 6 and 13 should be sealed pursuant to federal regulations. Mot. at 2; LB at 2-3. Specifically, defendants argue exhibit 6 should be sealed pursuant to 21 C.F.R. § 20.63, which forbids the disclosure of "[p]ersonnel, medical, and similar files" which would "identify patients or research subjects." 21 C.F.R. § 20.63(a); Mot. at 2 [Doc. No. 150-1]. Defendants also argue exhibit 13 should be sealed pursuant to 21 C.F.R. 20.111(d) which prevents the disclosure of data contained in a new drug application. LB at 2-3.

Plaintiffs counter by arguing defendants have not satisfied L. Civ. R. 5.3(c)(2), which does not credit conclusory statements of potential harm. Plaintiffs further argue defendants have not identified a legitimate private interest with respect to plaintiffs' exhibits, or satisfied the exacting standard for a clearly defined and serious injury set forth in the Local Rules. Memo. at 9. [Doc. No. 166]. As to 21 C.F.R. § 20.63, plaintiffs argue exhibit 6 does not implicate the regulation. Id. at 4-5.

2. Exhibits at Issue

Defendants seek to seal exhibits 6, 11, 13, 16, 17, 21, and 22 of plaintiffs' Motion to Compel [Doc. No. 107]. The Court has reviewed the exhibits in detail to decide this motion. A brief summary of the exhibits follows: [2]

- Exhibit 6 contains three "MedWatch" forms. These forms are used by the FDA and pharmaceutical companies to document potential adverse drug interactions. These particular forms discuss alleged gastrointestinal injuries suffered by patients taking defendants' drugs.

- Exhibit 11 contains November 24th and 25th, 2009 emails between defendants' employees about an internal review [3] of an alleged connection between olmesarten and celiac disease.

- Exhibit 13 contains an executive summary of a study conducted by defendants. The study was conducted at the behest of the FDA, which, on July 11, 2012, asked defendants to review their MedWatch forms and other safety data regarding olmesarten products in light of publications linking olmesarten to sprue-like enteropathy.

- Exhibit 16 contains information relating to defendants' internal studies of adverse drug reactions.

- Exhibit 17 contains slides from a presentation, dated March 27, 2014, discussing foreign regulatory requirements and defendants' organizational structure.

- Exhibit 21 contains defendants' employees' email correspondence with licensing partners between April 17, 2007 and April 24, 2007 regarding written materials associated with olmesarten.

***3** • Exhibit 22 contains emails between defendants' employees regarding foreign regulatory review beginning on May 21, 2014 and ending May 29, 2014.

3. Defendants' Arguments

Defendants are under a misconception regarding their burden to seal documents filed of record. Defendants argue that since the materials they seek to seal were designated as "protected" pursuant to the Court's June 10, 2015 Stipulated Discovery Confidentiality Order [Doc. No. 46], the documents should be sealed. See Mot. at 1-2; LB at 1 ("The Stipulated Discovery [Confidentiality] Order ... controls here[.]"). This argument is a non-starter because it is well-settled that a party's classification

of material as protected or confidential does not automatically satisfy the criteria for sealing pursuant to Local Civil Rule 5.3. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 786-90 (3d Cir. 1994); MEI, Inc. v. JCM Am. Corp, C.A. No. 09-351 (RBK/JS), 2010 WL 4810649, at *2 (D.N.J. Nov. 1, 2010).

Several of defendants' other arguments are rejected out of hand. Defendants argue their documents should be sealed because they may be read out of context. Mot. at 9. If the Court accepted this argument then it would justify sealing almost any document. Further, defendants ask the Court to take into account that there has been "massive" discovery in the case. LB at 3. This factor is not relevant as to whether a particular document should be sealed. In addition, defendants argue release of their documents may damage their reputation. Again, if this argument is accepted defendants could bar public access to any document that may be detrimental to their interests. The fact that a party may not want the public to view its potentially damaging documents is not determinative as to whether a document should be sealed.

Defendants ultimately recognize they must satisfy the criteria in L. Civ. 5.3(b)(2) to seal a document. Defendants make various arguments as to why they satisfy this criteria. First, the materials in question are derived from defendants' internal drug development and business processes, and they were never intended for public dissemination. Mot. at 6-7 [Doc. No. 150-1]. Second, defendants have a legitimate private interest in preventing competitors from viewing their internal processes. Id. at 7. Third, defendants would suffer substantial commercial harm if competitors in their highly competitive industry learned of their internal operations, and substantial reputational harm if their documents are disclosed out of context. Id. at 2-3, 8-9. Four, defendants' requested relief represents the least restrictive alternative for sealing. Id. at 10. And last, exhibits 6 and 13 should be sealed because disclosure of the exhibits is barred by relevant federal regulations, namely 21 C.F.R. §§ 20.63 and 21 20.111(d). Id. at 2; LB at 2-3.

4. Analysis

The Court's analysis will focus on the application of the balancing test it must apply. The analysis will start by summarizing the general principles the Court will apply and then the specific documents at issue will be examined. The first factor under L. Civ. R. 5.3 evaluates the nature of the materials at issue. The key to evaluating this factor rests on whether the materials "involve[ ] matters of legitimate public concern." Pansy, 23 F.3d at 788. Where the materials in a confidentiality dispute are of particular interest to the public this factor weighs in favor of public access; where the materials are truly of a private nature this factor weighs in favor of sealing the materials. Id. Where the materials in question relate to "information important to public health and safety" confidentiality is disfavored. Id. at 787.

***4** The second factor considers whether there is a legitimate private or public interest which merits sealing the documents. In operation, this factor is often utilized to weigh legitimate private interests against the public's general interest in disclosure, as well as the public's specific interest in information involving "matters of legitimate public concern." Castellani v. City of Atl. City, C.A. No. 13-5848 (RMB/AMD), 2015 WL 1578990, at *7 (D.N.J. Apr. 9, 2015).

In practice, Courts are more likely to grant motions to seal where a party's private interest outweighs the public interest. For instance, courts have granted motions to seal where a person or business has a legitimate private interest in preventing public disclosure of "business agreements, trade secrets, or commercial information." Bock v. Pressler & Pressler, LLP, C.A. No. 11-7593 (KM/MCA), 2014 WL 1233039, at *3 (D.N.J. Mar. 25, 2014). Internal email communications between different members of a company or organization may qualify as protected business information if the emails relate to private financial information. Goldenberg v. Indel, Inc., C.A. No. 09-5202 (JBS/AMD), 2012 WL 15909, at *3 (D.N.J. Jan. 3, 2012). A litigant's interest in preventing reputational harm may also qualify as a legitimate private interest. However, it is more difficult for a business to show a legitimate interest in avoiding reputational harm than for an individual. See Glenmede Trust Co. v. Thompson, 56 F.3d 476, 484 (3d Cir. 1995). Furthermore, a reputational interest can only satisfy the second prong of L. Civ. R. 5.3 where the reputation damage is "particularly serious." Pansy, 23 F.3d at 787. In addition, the reputational harm must be specifically identified. Vague assertions of reputational damage are insufficient. Sec'y of Labor v. Koresko, 378 F. App'x 152, 154 (3d Cir. 2010).

The third factor identified by L. Civ. Rule 5.3 directs courts to determine whether the moving party demonstrated that a "clearly defined and serious injury" would occur if the documents are publicly available. This factor is not satisfied where the moving party provides only "broad allegations of harm, unsubstantiated by specific examples or articulated reasoning." Pansy, 23 F.3d at 786; Younes v. 7-Eleven, Inc., C.A. No. 13-3500 (RMB/JS), 2014 WL 1959246, at *3 (D.N.J. May 15, 2014); Supernus Pharm., Inc. v. Actavis, Inc., C.A. No. 13-4740 (RMB/JS), 2014 WL 6474039, at *3 (D.N.J. Nov. 18, 2014). The burden to show such injury falls upon the moving party. Supernus, 2014 WL 6474039, at *1. Where the moving party has demonstrated disclosure would result in a clearly defined and serious loss of a competitive business advantage, this factor weighs in favor of protecting the disputed document. Bock, 2014 WL 1233039, at *3; Goldenberg, 2012 WL 15909, at *4.

The fourth factor examines whether the moving party has selected the least restrictive means available to protect its sensitive information. This factor need not be considered where the moving party failed to meet its burden under the first three factors. Securimetrics, 2006 WL 827889, at *n.4. However, where the burden has been met, this factor evaluates whether the moving party's requests to protect documents are overbroad. Bock, 2014 WL 1233039, at *3. A motion to seal is overbroad where the moving party's interests "can be adequately served by filing a more narrowly tailored" motion to seal. Id.

***5** The Court will now proceed to examine the exhibits at issue.

a. Exhibit 6

Exhibit 6 contains three MedWatch forms which discuss alleged adverse reactions to olmesarten. The nature of these materials favors disclosure, as they implicate the public's concern in matters of public health. Pansy, 23 F.3d at 787. As to the second factor, defendants' asserted interest in protecting their sensitive business information and reputation is not persuasive. The forms at issue do not contain defendants' confidential business or trade secret information. The documents merely address an alleged "adverse event" reported by an unknown third-party. Further, the reputational harm asserted by defendants is too broad and speculative to merit consideration. Reputational harm must be specifically identified and particularly serious to merit consideration as a legitimate private interest. Koresko, 378 F. App'x at 154; Glenmede Trust Co., 56 F.3d at 484. Defendants merely argue that dissemination of the protected materials could be "unfavorable or damaging" and "it may lead to unnecessary alarm in the patient community." Mot. at 9 [Doc. No. 150-1]. The Court rejects defendants' conclusory arguments. [4]

L. Civ. R. 5.3 requires a court evaluating a motion to seal to balance the legitimate private interests against the legitimate public interests under the "good cause" standard of Pansy. 23 F.3d at 787; Lite, New Jersey Federal Practice Rules Comment 2 to L. Cir. R. 5.3 (Gann). After evaluating defendants' interest in sealing exhibit 6, the public's interest in public health information predominates. The Court recognizes that even where a company is generally involved in the healthcare sector, it should still examine if the documents at issue contain information pertinent to public health. See Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm., Inc., C.A. No. 14-4727 (NLH/KMW), 2015 WL 4715307, at *2 (D.N.J. Aug. 7, 2015). In other words, the public health factor of Pansy does not justify disseminating the confidential financial or business information of a healthcare provider simply because the company provides health services to the public. Id. The Court took this into account in reaching its decision.

Courts employing the Pansy standard have elevated the importance of the public's interest in public health information where the disputed materials weighed directly on the health effects of a medical product upon patients. In re Orthopedic Bone Screw Products Liab. Litig., C.A. No. MDL 1014, 1995 WL 764580, at *3 (E.D. Pa. Dec. 14, 1995). In Orthopedic Bone Screw, the court permitted a party to disclose information previously protected by a confidentiality order because the information concerned the relative danger of a medical device which "directly relate[d] to public health and safety." In addition, the public health rationale of Pansy has also been applied to permit disclosure of information related to asbestos risks, Allied Corp, 1996 WL 346980, at *7, and water contamination. Ohio Valley Envtl. Coal. v. Elk Run Coal Co., 291 F.R.D. 114, 123-124 (S.D.W. Va. 2013). The Pansy analysis has also recognized an elevated public interest in the operation of a public agency and its employees. Shingara v. Skiles, 420 F.3d 301, 307 (3d Cir.

2005). This case is analogous to the foregoing authorities. The MedWatch forms at issue concern potential injuries caused by widely distributed prescription drugs. Thus, the public's interest in disclosure outweighs defendants' countervailing arguments.

***6** The third factor of the Pansy test also weighs against defendants, as defendants have failed to identify a particular harm that would result from disclosure of Exhibit 6. The MedWatch forms simply document symptoms allegedly suffered by olmesarten patients. Since the forms do not discuss the development of olmesarten products, their disclosure has no anti-competitive effect. The nature of the MedWatch forms also factors into the Court's decision to distinguish exhibit 6 from exhibits 11, 12, 16, 17, 21, and 22. The MedWatch forms, which are required across the pharmaceutical industry and merely document alleged adverse reactions to a pharmaceutical drug, do not contain commercial information beneficial to defendants' competitors.

Defendants' argument pursuant to 21 C.F.R. § 20.63 is unpersuasive. All personal identifying information in exhibit 6 has been redacted. While 21 C.F.R. § 20.63 bars disclosure of "personnel, medical, and similar files," the regulation is targeted towards information which identifies patients or research subjects. Because patient identifying information has already been removed from exhibit 6 by redaction, 21 C.F.R. § 20.63 does not apply. Thus, exhibit 6 will not be sealed.

b. Exhibits 11, 13, 16, 17, 21, and 22

The Court's decision to deny defendants' motion without prejudice as to exhibits 11, 13, 16, 17, 21, and 22 is prompted by defendants' failure to include a competent affidavit or certification to support the elements in L. Civ. R. 5.3(c)(2). More specifically, defendants' submission is insufficient to support their contention that the above exhibits contain trade secrets or highly sensitive commercial information, and that defendants will suffer a clearly defined and serious injury if the exhibits are not sealed. Defendants' motion relies on the affidavit of Kimberly Stranick, Ph.D. Stranick Affidavit [Doc. No. 32-5]. The Stranick affidavit was submitted to support the entry of the Discovery Confidentiality Order and generally avers defendants: will produce sensitive business information over the course of this litigation, Id. at ¶ 4; that discovery will include information about defendants' internal product testing and the result of those tests, Id. at ¶ 5-7; and that the disclosed materials have commercial value, Id. at ¶ 6. Stranick's averments do not provide the information defendants are required to submit to seal a document.

Stranick's affidavit is insufficient because it is too generalized. The affidavit, which was not drafted for the purposes of this motion but rather in support of a proposed discovery confidentiality order, establishes that the market for hypertension drugs is competitive, that defendants will be harmed by disclosure of some information sought by plaintiffs, and that defendants go to great lengths to maintain security. However, the affidavit fails to demonstrate Stranick's personal knowledge as to how disclosure of the exhibits in question will create a "clearly defined and serious injury." Courts are free to disregard affidavits which do not contain relevant personal knowledge. See Fowler v. Borough of Westville, 97 F. Supp. 2d 602, 607 (D.N.J. 2000); L. Civ. R. 7.2. Stranick's affidavit is plainly inadequate to support defendants' motion because it does not even address the documents at issue.

By way of example, the Court directs the defendants' attention to exhibit 17. Defendants argue generally that all exhibits should be sealed because they "contain material terms governing Defendants' business which," if disclosed to the public, would harm defendants by informing competitors of their business practices. Mot. At 9. [Doc. No. 150-1]. As to exhibit 17 specifically, defendants argue competitive harm would result from disclosure of the exhibit's "internal analysis concerning foreign regulatory compliance and safety." Id. at 4. The Stranick affidavit fails to support this assertion because it does not address how a competitor viewing defendants' internal analysis of foreign regulatory compliance would harm defendants. Where regulatory documents are addressed, the affidavit states in conclusory fashion "[r]egulatory documents and submissions *may* contain trade secret" information. Stranick Affidavit at ¶ 10 [Doc. No. 32-5] (emphasis added). This assertion is insufficient to satisfy the standard of L. Civ. R. 5.3 because it is speculative and conclusory.

***7** Despite the lack of an appropriate supporting affadavit, the Court hesitates to deny defendants' motion to seal exhibits 11, 13, 16, 17, 21, and 22 with prejudice because defendants may be able to identify trade secrets

or other commercially sensitive information. If properly documented, commercially sensitive information may be sealed. See Mars, Inc. v. JCM Am. Corp., C.A. No. 05-3165 (RBK/JS), 2007 WL 496816, at *2 (D.N.J. Feb. 13, 2007)("Courts generally protect materials containing trade secret[s] or other confidential research, development, or commercial information to prevent harm to a litigant's standing with the marketplace.")(alteration in original). Therefore, the Court will deny defendants' motion as to exhibits 11, 13, 16, 17, 21, and 22 without prejudice, and provide defendants with an opportunity to submit competent evidence. The Court will not legitimize pro forma, conclusory or generalized affidavits.

To be clear, the decision to allow defendants to refile their motion is not prompted by meritorious arguments, but rather the Court's abundance of caution in the face of insufficient information. The Court's ultimate determination on this matter will rest primarily on the second and third factors of L. Civ. R. 5.3(c). These are the balancing of public versus private interests and any clearly defined and serious harm to defendants that will result from disclosure. As discussed above, defendants' precise private interests are difficult to gauge based on defendants' current submission.

Stranick's affidavit is not the only problem with defendants' motion. Exhibits 11 and 13 relate to studies conducted by defendants at the request of the FDA. The exhibits explicitly mention patients' alleged adverse reactions to defendants' drugs, and interactions with regulatory bodies. Exhibits 16 and 17 appear to be slides used in a presentation, presumably for the internal use of defendants, regarding defendants' reaction to the alleged adverse effects suffered by olmesarten users. Exhibit 21 and 22 comprise a series of emails between various employees of defendants discussing potential labelling changes. Several emails within the exhibits explicitly identify the alleged adverse side effects of defendants' olmesarten drugs. The public has a paramount interest in this information. Furthermore, exhibits 11 and 13, which memorialize interactions between defendants and the FDA, also implicate the public's interest in the operation of public agencies.

Defendants assert a private interest in the protection of trade secrets. Trade secrets include "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Rohm & Haas Co. v. Adco Chem. Co., 689 F.2d 424, 431 (3d Cir. 1982) (quoting Restatement of Torts § 757 cmt. B (1939)). In this district, a trade secret must "derive independent economic value from not being known to others who can obtain economic value from its disclosure or use." Diversified Indus., Inc. v. Vinyl Trends, Inc., C.A. No. 13-6194 (JBS/JS), 2014 WL 1767471, at *7 (D.N.J. May 1, 2014). Having reviewed the exhibits, the Court questions whether defendants derive an independent economic value from the secrecy of their content. Nonetheless, in the interest of justice the Court believes it is appropriate to give defendants another opportunity to support their arguments.

Further, as to the third factor, as yet defendants' assertions of injury merely consist of "broad allegations of harm unsubstantiated by specific example or articulated reasoning." Pansy, 23 F.3d at 786. Such allegations do not demonstrate the "good cause" required to seal a document. Id. It cannot be gainsaid that broad and conclusory allegations of harm, unsupported by specific examples or articulated reasoning, do not support a request to seal. Supernus Pharmaceuticals, Inc., 2014 WL 6474039, at *3. Defendants' submissions generally argue the exhibits contain "material terms governing Defendants' business" without explaining how the exhibits could be used to actually harm defendants. Memo. at 9 [Doc. No. 150-1].

***8** In addition, the Court finds that defendants' argument claiming disclosure of exhibit 13 is barred by 21 C.F.R. § 20.111(d) is insufficient to satisfy their burden. To summarize, defendants contend exhibit 13 should be sealed because it was submitted as part of Benicar's new drug application file and such files are not subject to disclosure under 21 C.F.R. 20.111(d). Mot. at 3; LB at 2. In this instance, the applicability of 21 C.F.R. 20.111(d) depends on whether or not the material in question constitutes a trade secret. As discussed above, the insufficient affidavit provided by defendants makes it impossible to determine whether the contents of exhibit 13 rise to the level of a trade secret. Thus, to date defendants have not shown that sealing exhibit 13 pursuant to the cited regulation is appropriate.

Accordingly, for the foregoing reasons,

IT IS hereby ORDERED this 21st day of January, 2016, that defendants' "Motion to Seal" [Doc. No. 150] is DENIED as to exhibit 6 to plaintiffs' Motion to Compel [Doc. No. 107]. This exhibit shall be unsealed by the Clerk of the Court at the appropriate time; and it is further

ORDERED that defendants' "Motion to Seal" [Doc. No. 150] is DENIED without prejudice as to exhibits 11, 13 16, 17, 21, and 22; and it is further

ORDERED that defendants are granted leave to refile a Motion to Seal as to exhibits 11, 13, 16, 17, 21, and 22 by February 15, 2016. The motion must be supported by a competent certification or affidavit. If the motion is not timely filed, the Clerk of the Court is directed to unseal exhibits 11, 13, 16, 17, 21, and 22 to plaintiffs' brief in support of their Motion to Compel [Doc. No. 107]. [5]

All Citations

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Footnotes

1 Since this is the first filed of what is expected to be a number of motions to seal in the case, the Court will address in detail the standard to be applied when the motions are decided.

2 Plaintiffs also describe the exhibits on pp. 3-4 of their Memorandum.

3 Although this review was conducted by defendants, the review was done at the request of the FDA.

4 Similar arguments are rejected when made as to the other exhibits addressed in defendants' motion.

5 As to plaintiffs' Motion to Compel Discovery, the Court is satisfied that plaintiffs attached relevant documents to their moving papers. To be sure, however, the Court will not permit plaintiffs to attach irrelevant documents so the documents become part of the public record. Although the Court has no reason to believe this will occur, the Court expects defense counsel to raise the issue with the Court if a problem arises.