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United States District Court, D. Minnesota.

Lamar HODGES, Jr., Plaintiff,
v.
PFIZER, INC., doing business as Pfizer Consumer Healthcare, LLC, Wyeth, LLC, and Wyeth Consumer Healthcare, Inc., Defendants.

Case No. 14-cv-4855 (ADM/TNL)
|
Signed 12/17/2015

Attorneys and Law Firms

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Andrew Croner and Richard M. Barnes, Goodell, DeVries, Leech & Dann, LLP, 1 South Street, 20th Floor, Baltimore, MD 21202; and Anna M. Petosky, Catherine H. Ahlin-Halverson, and Cooper S. Ashley, Maslon LLP, 90 South Seventh Street, Suite 3300, Minneapolis, MN 55402 (for Defendants).

ORDER

Tony N. Leung, United States Magistrate Judge

I. INTRODUCTION

***1** This matter comes before the Court, United States Magistrate Judge Tony N. Leung, on three motions: Plaintiff's Motion to Compel (ECF No. 72), Defendants' Motion for Clarification and Modification of Order (ECF No. 82), and Defendants' Motion to Compel Responsive Answers to Defendants' First Set of Interrogatories and Request for Production of Documents (ECF No. 89).

A hearing was held on October 7, 2015. (Court Minutes, Oct. 7, 2015, ECF No. 110.) Connor G. Sheehan and William Dunn appeared on behalf of Plaintiff Lamar Hodges, Jr. (Court Minutes.) Richard M. Barnes appeared on behalf of Defendants Pfizer, Inc., doing business as Pfizer Consumer Healthcare, LLC; Wyeth, LLC; and Wyeth Consumer Healthcare, Inc. (Court Minutes.)

At the hearing, a number of discovery requests were reported as resolved or withdrawn by the parties. With respect to the discovery requests that remained at issue in the motions to compel, the Court ordered the parties to meet and confer again in an effort to resolve their disputes and address whether supplementation that had been provided following the briefing of these motions had further resolved any outstanding discovery. (Court Minutes.) The Court ordered the parties to provide an update concerning any outstanding discovery on or before October 19. These updates were provided to the Court via e-mail.

With respect to the motion for clarification, the Court ordered additional briefing on certain categories of information in dispute. (*See* Court Minutes.) Relatedly, the parties agreed to amend the existing Protective Order (ECF No. 63). (Court Minutes.)

II. BACKGROUND

As stated by the district court judge,

> [t]he medical condition giving rise to this lawsuit is undeniably horrific. Plaintiff ... ingested Advil when he was 16 years old and suffered a severe adverse drug reaction known as Stevens-Johnson Syndrome ("SJS") / Toxic Epider[m]al Necrolysis ("TEN"). Severe blistering affected 35% of his body, leaving essentially no skin on his face, neck, scalp, trunk, back, buttocks, arms, and legs. [Plaintiff] spent over one month in

> the hospital and underwent numerous surgeries. As a result of SJS/TEN, [Plaintiff] is permanently disfigured, blind in one eye, and will likely lose all sight in the future.

Hodges v. Pfizer, Inc., No. 14-cv-4855 (ADM/TNL), 2015 U.S. Dist. LEXIS 39229, at, *1-2 (D. Minn. Mar. 27, 2015) (citations omitted). Plaintiff brings claims for failure to warn, defective design, fraud and fraudulent inducement, breach of express warranty, negligence, unjust enrichment, and violations of Minn. Stat. §§ 325D.13, 325F.67, and 325F.69. (Am. Compl. ¶¶ 98-176, ECF No. 51.)

III. DISCOVERY MOTIONS

At issue are dozens of discovery requests. The Federal Rules of Civil Procedure allow a party to "obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). "Relevance is construed broadly at the discovery stage." *Heilman v. Waldron*, No. 11-cv-1930 (JRT/SER), 287 F.RD. 467, 473 (D. Minn. 2012); *see also Mead Corp. v. Riverwood Natural Res. Corp.*, Civ. No. 5-91-21, 145 F.R.D. 512, 522 (D. Minn. 1992) (McNulty, M.J.) (noting "[r]elevancy, in the discovery context, is extremely broad"). "Information sought in discovery need not be admissible at trial, so long as it appears reasonably calculated to lead to the discovery of admissible evidence." *Heilman*, 287 F.R.D. at 473.

***2** Nonetheless, some threshold showing is necessary "before parties are required to open wide the doors of discovery and to produce a variety of information which does not reasonably bear upon the issues in the case." *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 380 (8th Cir. 1992); *see Bredemus v. Int'l Paper Co.*, No. 06-cv-1274 (PJS/RLE), 252 F.R.D. 529, 533 (D. Minn. 2008) (stating "relevancy under Rule 26 is not without bounds"). Similarly,

> [o]n motion or on its own, the court must limit the frequency or extent of discovery ... if it determines that ... the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

Fed. R. Civ. P. 26(b)(2)(C)(iii); *accord Roberts v. Shawnee Mission Ford, Inc.*, 352 F.3d 358, 361 (8th Cir. 2003) ("[Rule 26] vests the district court with discretion to limit discovery if it determines, inter alia, the burden or expense of the proposed discovery outweighs its likely benefit."); *see Webb v. Ethicon Endo-Surgery, Inc.*, No. 13-cv-1947 (JRT/JJK), 2015 WL 317215, at *5-7 (D. Minn. Jan. 26, 2015) (discussing balancing of expense, burden, and likely benefit performed by magistrate judge when considering discovery requests).

As of December 1, 2015, Rule 26(b)(1) was amended to emphasize the proportionality language formerly contained in subdivision (b)(2)(C)(iii). In relevant part, Rule 26(b)(1) now states:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense *and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.*

Fed. R. Civ. P. 26(b)(1) (emphasis added). "The recent amendment to Rule 26 restores the 'proportionality factors to their original place in defining the scope of discovery.' " *Meeker v. Life Care Ctrs. of Am., Inc.*, No. 14-cv-02101-WYD-NYW, 2015 WL 7882695, at *3 (D. Colo. Dec. 4, 2015) (quoting Fed. R. Civ. P. 26 2015 advisory committee's note); *see Uppal v. Rosalind Franklin Univ. of Med. & Sci.*, No. 15 C 3806, 124 F.Supp.3d 811, 2015 WL 5026228, at *3 (N.D. Ill. Aug. 26, 2015) (noting "Rule 26(b)(2)(C)(iii)'s implicit

requirement of proportionality").

"The amendments to Rule 26 govern in all proceedings in civil cases thereafter commenced and, insofar as just and practicable, in all proceedings then pending." *Carr v. State Farm Mut. Auto. Ins., Co.*, No. 3:15-cv-1026-M, 312 F.R.D. 459, 2015 WL 8010920, at *6 (N.D. Tex. Dec. 7, 2015); *see* Fed. R. Civ. P. 86 (effective dates of amendments); *Meeker*, 2015 WL 7882695, at *3 n.4. "[A]pplying the standards of Rule 26(b)(1), as amended, to [the instant] motion[s] to compel is both just and practicable," *Nguyen v. Versacom, LLC*, No. 3:13-cv-4689-D, 2015 WL 8316436, at *5 (N.D. Tex. Dec. 9, 2015) and, in any event, the result would be the same. *See Bendure v. Star Targets*, No. CV 14-89-BLG-SPW-CSO, 2015 WL 8375137, at *2 n.6 (D. Mont. Dec. 9, 2015) (concluding that "it is neither infeasible nor unjust" to apply amended Rule 26(b)(1) to motion to compel that was fully briefed nearly one week before amendment became effective and "application of either version of Rule 26(b)(1) ... would yield the same result").

> ***3** To be sure, just as was the case before the December 1, 2015 amendments, under Rules 26(b)(1) and 26(b)(2)(C)(iii), a court can—and must—limit proposed discovery that it determines is not proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit—and the court must do so even in the absence of a motion.

Carr, 2015 WL 8010920, at *9, 312 F.R.D. 459.

Under Rule 37, "[a] party seeking discovery may move for an order compelling an answer, designation, production, or inspection." Fed. R. Civ. P. 37(a)(3)(B).[1] This Court "has considerable discretion in granting or denying discovery requests." *Bredemus*, 252 F.R.D. at 534.

A. Plaintiff's Motion to Compel

The discovery sought in Plaintiff's motion can be divided into the following categories: (1) product; (2) timeframe; (3) injury; (4) foreign materials; (5) database searches; (6) document custodians and search of custodial files; (7) marketing and financial information; (8) subpopulation data; (9) specific safety materials regarding Advil; (10) the *Madden* documents; and (11) the deposition of Manfred Hauben, M.D. To the extent that Defendants have previously agreed to produce responsive materials in excess of the parameters set forth below, this Order does not in any way curtail Defendants' proffered production. The rulings below are intended to serve as guideposts for the parties in addressing aspects of Plaintiff's requests that still remain in dispute.

1. Product

The product at issue in this case is adult Advil, a single-ingredient ibuprofen product in its 200 mg form. (*See* Am. Compl. ¶¶ 7, 10, 11, 12, 13, 14.) Plaintiff seeks discovery regarding both adult and children's single-ingredient ibuprofen products. (Pl.'s Mem. in Supp. at 12-15, ECF No. 74.) Defendants have agreed to produce discovery regarding adult, single-ingredient ibuprofen products. Defendants assert that the burden of producing materials related to children's single-ingredient ibuprofen products outweighs the "possible relevance" such materials may have in this case, noting the different regulatory schemes applicable to pediatric medications. (Defs.' Opp'n at 36, ECF No. 98.) Plaintiff alleges that he was harmed by adult Advil and the Court concludes that, when considering the proportionality principles embodied in Fed. R. Civ. P. 26(b), the burden and cost of producing materials related to children's single-ingredient ibuprofen products outweigh both their likely benefit to this litigation and their importance to resolving issues regarding adult Advil. That being said, to the extent Defendants have already offered to produce materials which include information concerning children's single-ingredient ibuprofen products, such materials shall still be produced.

2. Timeframe

The parties' biggest dispute concerns the relevant timeframe of discoverable information. Plaintiff contends that the "relevant time frame for information bearing on Advil's safety profile and known propensity to cause SJS/TEN dates back to at least 1984, when Defendants first began collecting post-marketing safety information and continues to the present." (Pl.'s Mem. in Supp. at 9.) Defendants contend that "the relevant time period for discovery is January 1, 2005 to July 1, 2010." (Defs.' Opp'n at 10.) Defendants' proposed timeframe covers approximately the period between a 2005 relabeling and the onset of Plaintiff's adverse reaction.

***4** The year 2005 is a pivotal point. In early 2005, a Citizen Petition was filed with the Food and Drug Administration ("FDA") concerning ibuprofen and the risks of SJS and TEN. (Am. Compl. ¶ 47.) *See Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 7217197, at *2 (N.D. Ill. Mar. 29, 2013) [hereinafter *Newman III*] ("On February 15, 2005, a Citizen Petition was submitted to the FDA. In it, petitioners requested that a full risk assessment of SJS and TEN associated with ibuprofen be conducted by the FDA; that the FDA require the manufactures of ibuprofen to amplify their prescription and OTC labeling to adequately warn prescribers, health care professionals and consumers of the increased risk of SJS and TEN associated with ibuprofen; and that the FDA require the manufacturers to provide to physicians and consumers instructions to discontinue all ibuprofen products at the first sign of a rash, mucosal blisters, or sores in the mouth, eyes, throat, or genitalia, and any unexplained or persistent fever." (citation omitted)).

Ultimately, the FDA required ibuprofen labels to contain warnings about the symptoms of SJS and TEN, including "rash," "blisters," and "skin reddening" among the signs of an allergic reaction. (Am. Compl. ¶¶ 48, 52.) *See Newman III*, 2013 WL 7217197, at *2 ("The FDA refused to require the petitioners' proposed warning, and specifically declined to require that manufacturers include references to SJS and TEN in OTC ibuprofen labels. The FDA noted that adding easily identifiable references to the symptoms associated with SJS and TEN (*e.g.*, skin reddening, rash and blisters) under the 'allergy alert' subheading and including a warning that instructed consumers to stop use and seek medical help right away if an allergic reaction occurs would alert and educate consumers about the nature of the reaction associated with SJS and TEN." (citation omitted)). Defendants were notified in 2005 about the required label change and Defendants' revised warning was approved by the FDA in January 2006. (*See* Am. Compl. ¶¶ 48-50, 52.)

The Court concludes that some pre-2005 discovery is relevant in order for Plaintiff to properly contextualize the events and findings leading to the label change and Defendants' knowledge of the risk of SJS and TEN, but not back to 1984.[2] Plaintiff alleges that, in 2001, a Periodic Safety Update Report ("PSUR") was generated and discussed at a meeting held by Defendants in November 2001. (Am. Compl. ¶ 33.) Plaintiff alleges that "[t]he discussion at the meeting specifically included case reports of SJS associated with ibuprofen." (Am. Compl. ¶ 33.) Therefore, unless otherwise already agreed to by Defendants, Defendants shall produce responsive information dating back to January 1, 2001.

While Plaintiff seeks responsive information dating up to the present time, the Court agrees with Defendants that the appropriate cut-off period is the onset of Plaintiff's adverse reaction, namely, July 1, 2010. (*See* Am. Compl. ¶¶ 11-18.) *See Neman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 4460011, at *15 (N.D. Ill. Mar. 29, 2013) [hereinafter *Newman II*] (finding irrelevant adverse event reports after date of injury as well as defendants' knowledge or mental state after injury occurred). Therefore, unless otherwise already agreed to by Defendants, Defendants shall produce responsive information dating up to July 1, 2010.

3. Injury

Plaintiff contends that Defendants have unreasonably restricted the relevant injury in this case to only SJS and TEN. (Pl.'s Mem. in Supp. at 7.) "Plaintiff seeks information relating to 'serious skin reactions'—which is defined in Plaintiff's discovery requests to include SJS/TEN and related serious skin adverse drug reactions that are collectively analyzed by the FDA and medical community." (Pl.'s Mem. in Supp. at 8.) The Court will narrow Plaintiff's definition of "serious skin reactions" to include those adverse-event terms agreed to as set forth in Exhibit 22 to Plaintiff's Appendix, (*see* Ex. 22 at 1 to Pl.'s App., ECF No. 75-4), and those terms encompassing Plaintiff's symptomology as described in his medical records.[3] There are a number of terms included in Plaintiff's definition of "serious skin reactions" which are not present in his medical records and which Plaintiff has withdrawn from the relevant adverse events. (Ex. 22 at 3, 5.) As such, the Court will strike the following terms from the definition of "serious skin reactions": Sweet's syndrome, toxiderma, Reiter's syndrome, medicomentosa

dermatitis, toxic pustuloderma, vasculitis, and Kawasaki's disease.

4. Foreign Materials

***5** The parties also dispute the geographic scope of production. Initially, Plaintiff sought foreign labeling and pharmacovigilance data worldwide. (Pl.'s Mem. in Supp. at 22-27.) The disputed requests include, for example, foreign pharmacovigilance assessments and studies; foreign package inserts and labels; foreign annual safety reports; documents reflecting warnings, objections, or criticisms by foreign regulatory authorities of marketing activities; foreign patient leaflets and consumer information; communications with foreign regulatory authorities concerning safety issues and label changes; foreign PSURs; foreign periodic benefit-risk evaluation report ("PBRERs"); and restriction or withdrawal of Advil or ibuprofen products from foreign markets. Plaintiff also requests that Defendants include English translations of the materials in Defendants' possession. Following the hearing, Plaintiff has generally limited his request for foreign materials to France, the United Kingdom, the Netherlands, Germany, Japan, Australia, and Taiwan. Plaintiff asserts that

> Defendants have provided different information and different warnings about SJS/TEN to regulators, doctors and consumers depending on the country in which the product was marketed. If Defendants (or their affiliates) told consumers, doctors or regulators in Europe, Canada, or Japan about dangers associated with Advil, but concealed those dangers from American consumers or the FDA, that fact—and the precise content of the warnings that were provided overseas—is highly relevant to this case.

(Pl.'s Mem. in Supp. at 25.) Plaintiff also asserts that Defendants are required to submit foreign material to the FDA.

Defendants "have agreed to produce documents that are global in nature and accessible to Defendants in the United States." (Defs.' Resp. to Pl.'s First Request for Prod. of Docs. at 10, ECF No. 99-2; *accord* Defs.' Opp'n at 20-21.) Defendants have also agreed to "produc[e] documents that are foreign in nature from the files of U.S.-based custodians." (Defs.' Opp'n at 21.) Following the hearing, Defendants have also agreed to provide PSURs submitted to the European Medicines Agency[4] for all single-ingredient ibuprofen products from 1996 to the present, "global" adverse-event reports for single-ingredient ibuprofen products without a date restriction, and labels in use in June 2010 for 200 mg single-ingredient adult Advil or its equivalent product in the United Kingdom, France, the Netherlands, German, Japan, Australia, and Taiwan. Defendants contend that their "submission of 'foreign data' to the FDA does not make every Advil document in the world relevant to this case"; they have "already produced [investigational-new-drug and new-drug application] materials, which contain their FDA submissions"; and they "have agreed to produce documentation for relevant adverse events on a global scale." (Defs.' Opp'n at 22.) Defendants contend that "Plaintiff fails to show how any other foreign documents are relevant." (Defs.' Opp'n at 22.)

Further, Defendants contend that requiring them to produce material from their foreign affiliates is unduly burdensome. (Defs.' Opp'n at 24-27.) Defendants state that they do not have "ready access" to such materials and the breadth of the requests further increases the burden, noting that "[m]any [r]equests are not limited to any particular country, custodian, or issue, nor are they limited to Defendants' interactions with foreign regulators about Advil." (Defs.' Opp'n at 25.) Defendants also state that responsive materials "encompass documents with personal information that is protected by foreign data privacy laws." (Defs.' Opp'n at 26.) Defendants contend that Plaintiff has not explained how "interactions with a regulator in some other country with its own set of laws and regulations has any bearing on his claim that Advil's U.S. label was inadequate when he ingested the product." (Defs.' Opp'n at 22.)

***6** Defendants are correct that the foreign regulatory authorities may have different priorities. *Newman II*, 2013 WL 4460011, at *13. But, communications with foreign regulators is relevant to Defendants' knowledge of the risks of SJS and TEN. *Id.* Therefore, in addition to the "global" materials proffered by Defendants, the Court will grant Plaintiff's motion with respect to foreign documents concerning single-ingredient, adult ibuprofen products between 2001 and 2010 (a) from France, the United

Kingdom, the Netherlands, Germany, Japan, Australia, or Taiwan (b) pertaining to (i) labeling and package inserts, (ii) adverse events and pharmacovigilance, (iii) regulatory actions and correspondence with regulatory authorities, or (iv) restrictions or withdrawals from the market.[5] Plaintiff's motion is otherwise denied.

5. Database Searches

The next area of dispute concerns adverse-event information maintained on Defendants' pharmacovigilance databases. The parties dispute the terms to be used in searching the databases.

Based on supporting declarations submitted by the parties, the parties agree that adverse events are coded using a standardized dictionary, the Medical Dictionary for Regulatory Activities ("MedDRA"). (Decl. of Randall Tackett, Ph.D. ¶ 17, Ex. 21 to Pl.'s App., ECF No. 75-4; Decl. of Sheila Weiss, Ph.D. ¶ 5, Ex. 17 to Decl. of Andrew W. Croner, ECF No. 99-17.) MedDRA uses a hierarchical system. (*See* Tackett Decl. ¶¶ 22-24; Weiss Decl. ¶ 6; *see also MedDRA Hierarchy*, Medical Dictionary for Regulatory Activities, http://www.meddra.org/how-to-use/basics/hierarchy (last accessed December 4, 2015).) In part, MedDRA uses "preferred terms," each of which "is a distinct descriptor (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic." *MedDRA Hierarchy*, Medical Dictionary for Regulatory Activities, http://www.meddra.org/how-to-use/basics/hierarchy. (*See* Tackett Decl. ¶ 22; Weiss Decl. ¶ 6.) A preferred term is linked to one or more "lowest level terms," which "reflect[s] how an observation might be reported in practice." *MedDRA Hierarchy*, Medical Dictionary for Regulatory Activities, http://www.meddra.org/how-to-use/basics/hierarchy. (*See* Tackett Decl. ¶ 22; Weiss Decl. ¶ 6.) For example, the preferred term "nausea" is linked to the lowest level term "feeling queasy." *MedDRA Hierarchy*, Medical Dictionary for Regulatory Activities, http://www.meddra.org/how-to-use/basics/hierarchy. (*See* Weiss Decl. ¶ 6.) Each lowest level term is linked to only one preferred term. *MedDRA Hierarchy*, Medical Dictionary for Regulatory Activities, http://www.meddra.org/how-to-use/basics/hierarchy.

A standardized medical query ("SMQ") is a "group[ ] of MedDRA terms that relate to a medical condition or a particular area of interest in pharmacovigilance." (Weiss Decl. ¶ 7; *see Standardised MedDRA Queries*, Medical Dictionary for Regulatory Activities, http://www meddra.org/standardised-meddra-queries (last visited December 4, 2015); *see also* Tackett Decl. ¶¶ 19, 37, 38.) SMQs "are intended to address the important pharmacovigilance topics needed by regulatory and industry users." *Standardised MedDRA Queries*, Medical Dictionary for Regulatory Activities, http://www meddra.org/standardised-meddra-queries. (*See* Weiss Decl. ¶ 7.) Of relevance to this case, SMQs have been developed for "severe cutaneous adverse reactions," or "SCAR." *Standardised MedDRA Queries*, Medical Dictionary for Regulatory Activities, http://www meddra.org/standardised-meddra-queries. (*See* Tackett Decl. ¶ 37; Weiss Decl. ¶¶ 11-12.)

***7** Defendants contend that Plaintiff's proposed terms are beyond SCAR SMQs and the associated MedDRA terms. (*See* Defs.' Opp'n at 28-30.) The Tackett Declaration, however, has identified a SCAR SMQ utilizing MedDRA terms that encompass many of the disputed terms. (Attach. F to Tackett Decl., ECF No. 75-4.) Plaintiff has also provided an exhibit showing how these disputed terms are tied to his medical records. (*See* Ex. 22 at 2-3.) An SMQ that includes MedDRA terms reflecting the symptomology contained in Plaintiff's medical records is reasonably calculated to lead to the discovery of admissible evidence. Accordingly, the Court will grant Plaintiff's motion with respect to the SCAR SMQ identified in Paragraph 37 and Attachment F of the Tackett Declaration. To the extent the disputed search terms are not included in that SCAR SMQ, Defendants need only search those additional terms that are contained in Plaintiff's medical records as shown in Exhibit 22 of Plaintiff's Appendix.[6]

In addition to the adverse-event data,

> Plaintiff also seeks the clinical trial case reports and the underlying sources documents for the Advil clinical trials for all dosage forms in order to examine whether there were any instances of serious skin reactions in the clinical trials that Defendants did not disclose or properly report to the FDA (*i.e.*, whether information was withheld from the FDA as part of the approval process).

(Pl.'s Mem. in Supp. at 19.) Plaintiff seeks this information so that his experts can determine whether "Defendants miscoded or misclassified serious skin reactions; failed to report them to the FDA; and opine that the frequency or increased risks to subpopulations were higher than Defendants reported." (Pl.'s Mem. in Supp. at 19.) Defendants contend that (1) Plaintiff's request for source documents "goes towards an impermissible fraud-on-the-FDA theory of liability," (Defs.' Opp'n at 31); (2) the source documents are "largely duplicative" of the adverse-event data, (Defs.' Opp'n at 32); and (3) the production of the source documents would be particularly burdensome given the volume of data, the "large amounts of protected personal information" contained within such documents, and the time ("months") and expense ("hundreds of thousands of dollars") involved in collection and redaction, (Decl. of Edward O. Gramling ¶¶ 16-22, Ex. 14 to Croner Decl., ECF No. 99-14.) Considering that "[i]t is not the role of the courts to evaluate or enforce the degree to which manufacturers comply with FDA regulations," *In re Incretin Mimetics Prods. Liability Litig.*, No. 13md2452 AJB (MDD), 2014 WL 4987877, at *3 (S.D. Cal. Oct. 6, 2014), and the proportionality principles of Rule 26(b), the Court concludes that the burden and expense of producing the source documents outweighs their benefit to this matter. *See In re Incretin Mimetics Prods. Liability Litig.*, 2014 WL 4987877, at *5 ("The Court finds the additional time as well as expense of identifying, redacting, and producing the source files outweighs the likely benefit that will result from evaluating source files for instances of mis-classification."). Therefore, Plaintiff's motion is denied with respect to the source documents.

Plaintiff also seeks the SMQs that Defendants have drafted and used to search serious skin reactions. The relevance of Plaintiff's request is unclear and limited. Defendants have since agreed to produce their manuals and standard operating procedures describing how Defendants report, assess, submit, and analyze adverse events. Plaintiff contends that "Defendants ... refuse to produce their own internal SMQs—likely because they will show that Defendants' standard internal searches use a search protocol which is much broader than what they contend is permissible in this case." (Pl.'s Mem. in Supp. at 19.) But, as stated above, the Court is granting Plaintiff's motion with respect to the SCAR SMQ identified in Paragraph 37 and Attachment F of the Tackett Declaration as well as those additional terms that are contained in Plaintiff's medical records as shown in Exhibit 22 of Plaintiff's Appendix. And, as Defendants point out, Plaintiff's request is "overbroad in seeking the terms used for 'data searches' for 'Serious Skin Reactions' for *any product* at *any* time." (Defs.' Opp'n at 33.) The Court concludes that this request is not reasonably calculated to lead to the discovery of admissible evidence and therefore denies Plaintiff's motion with respect to Request for Production No. 78.

6. Document Custodians & Search of Custodial Files

***8** The parties also dispute how Defendants' custodial documents should be searched. On June 24, 2015, the Court entered an Order Governing Production of Documents and Electronically Stored Information ("Order Governing Production") (ECF No. 62). The Order Governing Production required the parties to meet and confer to discuss a number of measures "in an effort to reduce the number of documents to be reviewed during the discovery process," including the use of search terms and "file-type culling." (Order Governing Produc. at 2.) The Order Governing Production also stated that "[t]he [p]arties may identify hard-copy documents or [electronically stored information]: (a) by identifying and selecting custodians that most likely possess relevant documents; and (b) by applying the agreed upon search terms to identifiable data repositories and custodian data sources." (Order Governing Produc. at 3.)

Defendants identified a number of document custodians and proposed a "tiered" search approach, in which a responsive document was required to include a product-identifier term, e.g., Advil or ibuprofen, and a "relevant" search term. Following the hearing, Defendants have agreed to increase the number of document custodians.

Plaintiff objected to the custodians identified by Defendants because Plaintiff had not received organizational charts "enabl[ing] Plaintiff to review the committees on which Defendants' custodians sit." (Pl.'s Mem. in Supp. at 36.) Plaintiff also objected to Defendants' tiered approach, arguing it "would effectively cull out the vast majority of the relevant records in the custodial files." (Pl.'s Mem. in Supp. at 37.) Plaintiff asserts that "[a]lthough Defendants will likely claim they do not 'always' segregate Advil documents and communications from those related to other drugs, Defendants maintain separate files for Advil records and communications" and should be required to "search the entire Advil custodial file of each document custodian." (Pl.'s Mem. in Supp. at 37 n. 44.) Plaintiff asserts that Defendants should "search their custodial files as a whole for the categories of records sought by Plaintiff through

this Motion (i.e. through the traditional review course) and without the application of a tiered search term approach." (Pl.'s Mem. in Supp. at 38.)

Plaintiff initially proposed 330 search terms to Defendants. Following the hearing, Defendants' last offer in compromise consisted of 6 product-identifier terms (all of which were terms proposed by Plaintiff) and approximately 50 search terms (nearly 40 of which were terms proposed by Plaintiff).

a. Document Custodians

Of the now 21 document custodians proposed by Defendants, approximately half of them were individuals Plaintiff included in his proposed search terms, indicating that, at least with respect to these custodians, the parties agree. At the hearing, Plaintiff withdrew those document requests regarding organizational charts and Plaintiff has not identified any individuals not included in Defendants' list whose files he believes should be searched. Therefore, the relevant document custodians are as follows: Patricia Williams, M.D.; Margaret Carr; Paul Desjardins, D.M.D.; Donald Frye; Elizabeth Savage; David Kellstein; Carl Strotz; Gabriela Gonzalez; Paul Bryers; Christopher Kocun; Alfredo Paredes Diaz; Barbara Wolfe; Manfred Hauben, M.D., MPH; Jennifer Su, M.D.; Nicola Romano; Stephen Cooper; Anthony Ewell; Sharon Heddish; Margarita Gardiner; Roger Berlin; and Eleanor Barbo.

b. Search Terms

The Court agrees that Defendants' tiered approach is most consistent with the Court's directive to the parties to work together in an effort to increase the efficiency of discovery in this matter—with one exception. To the extent any of the identified document custodians maintain files for Advil, such custodial files should be searched in their entirety using the search terms identified herein without a product-identifier term.

***9** Following the hearing, Plaintiff provided a revised list of search terms, reducing the total number of search terms to 265 (which included both the product-identifier and search terms agreed to by Defendants).[7] The Court has reviewed the revised list. Many of the proposed terms can be found in Plaintiff's medical records as identified in Exhibit 22 to Plaintiff's Appendix. But, again using Exhibit 22 as guide, there are several terms describing medical conditions that Plaintiff himself has admitted are not in his records. Therefore, the Court will strike these terms: 239, 254, 255, 259, 260, 261, 262.[8] There are also a number of duplicative terms as a document responsive to these terms would have already been identified through another more general term. Accordingly, the Court will also strike these terms: 62 (duplicative of "ibuprofen"); 92, 218 (duplicative of "safety signal"); 115-122 (duplicative of "Advil"); 237, 247, 248-50 (duplicative of "rash"); and 245 (duplicative of "blister"). The Court will also strike those terms encompassing the document custodians identified above: 25, 46, 87, 89, 90, and 196-201. Finally, the Court will strike two terms not relevant to Plaintiff's claims in this matter: 34 and 181. The search terms approved by the Court are attached as Exhibit A to this Order.

c. Search of Custodial Files to Be Repeated

In their First Supplemental Response to Plaintiff's First Request for Production of Documents, Defendants state that they have searched for and produced responsive documents from a subset of document custodians identified above using a narrower time frame and a significantly more narrow set of search terms. Because the Court has ruled that the appropriate timeframe is January 1, 2001 through July 1, 2010, and approved a broader set of search terms, Defendants will likely have to again search the files of those document custodians previously searched under the new criteria.

7. Marketing and Financial Information

Plaintiff seeks information regarding Defendants' marketing, advertising, profits (gross and net), sales forecasts, advertising budgets, and business plans (including marketing and financial plans) for Advil and ibuprofen products as well as the amount Defendants spent on safety initiatives and risk evaluation with regard to Advil and serious skin reactions. Following the hearing, Plaintiff narrowed his requests concerning Advil marketing and advertising documents to those distributed in 2010 and profits (gross and net) from 2010 to the

present in the United States. Plaintiff still seeks funds spent on pharmacovigilance and safety initiatives for Advil and serious skin reactions in the United States from 1995 through 2010 as well as sales forecasting, advertising budgets, and business plans (including marketing and financial plans) from 1995 to the present. Plaintiff contends that "Defendants' advertising materials are directly relevant to Plaintiff's claims" and "[t]he more significant Defendants' efforts and expenditures to promote and sell Advil without adequate warnings, the more culpable their behavior in exposing users such as Plaintiff to life-threatening injuries." (Pl.'s Mem. in Supp. at 35.)

Defendants have agreed to produce "available story boards, creative briefs, and associated approval documents used in connection with the marketing of OTC single-ingredient adult Advil (200 mg) in the United States in 2010" and "information on the unit and dollar sales for OTC single-ingredient adult Advil products in the United States in 2010." Defendants contend that the requested information is irrelevant and overbroad. (Defs.' Opp'n at 37-40.) Similarly, recognizing that financial information can be relevant to a claim for punitive damages, Defendants argue that "Plaintiff has not made the prima facie showing necessary for him to assert a punitive damages claim pursuant to Minnesota Statutes §§ 549.191 and 549.20." (Defs.' Opp'n at 38-39, 40.)

***10** A party's financial position is relevant to assessing punitive damages. *See, e.g.*, *In re Heparin Prods. Liability Litig.*, 273 F.R.D. 399, 406-09 (N.D. Ohio 2011) (finding information relating to defendant's overall financial condition relevant to punitive-damages claims); *accord Cunningham v. Smithkline Beecham*, 255 F.R.D. 474, 479 (N.D. Ind. 2009) ("Revenue and profits from the sale of Paxil in Indiana may be relevant to a jury determination of punitive damages if the jury finds that Smithkline knew of an increased risk of suicide and failed to warn physicians or the public about these risks.") But information about sales goals, projections, and trends "is certainly relevant particularly when it may impact decision making regarding labeling. There is an inherent tension between the desire for profit and scientific decisions that suggest warnings that may well shrink the customer base because of cautionary tone str[u]ck[ ] by the warnings." *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices & PMF Prods. Liability Litig.*, No. 3:09-md-2100-DRH, 2011 WL 6740391, at *10 (S.D. Ill. Dec. 22, 2011); *accord In re Depakote*, 87 F.Supp.3d 916, 928 (S.D. Ill. 2015) (promotional activities, distribution of promotional materials, sales and marketing practices related to drug "may also be relevant to the content of the 1999 label if, as Plaintiffs suggest, they can show that Abbott's marketing strategy influenced its label"). As the Third Circuit observed,

> [e]vidence tending simply to show that [the manufacturer] wanted to successfully market [certain] drugs and make a profit selling them would not be relevant to show, for example, that [the manufacturer] acted negligently. But, excessive concern with the image and marketing of [those] drugs at the expense of making efforts towards determining whether they were safe could be probative as to whether [the manufacturer] breached a duty of care towards the plaintiffs.

In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liability Litig., 369 F.3d 293, 314 (3rd Cir. 2004). Further, promotional activities, distribution of promotional materials, sales and marketing practices concerning a particular drug have been deemed relevant to what and when the manufacturer knew about certain risks. *In re Depakote*, 87 F.Supp.3d at 928.

Accordingly, Plaintiff's motion is granted for marketing and advertising documents distributed for Advil in the United States in 2010; the amount spent by Defendants on Advil and serious skin reactions between 2001 and 2010; profits (gross and net) for sales of Advil in the United States between 2001 and 2010; and sales forecasts, advertising budgets, business plans, marketing plans, and financial plans for Advil in the United States between 2001 and 2010. Plaintiff's motion is otherwise denied with respect to marketing and financial information.

8. Subpopulation Data

Plaintiff also seeks discovery regarding risk assessment information relating to certain subpopulations, including young adults and the pediatric population, adults, African Americans, and females. Plaintiff asserts that this information is relevant to his allegations "that Defendants knew or should have known that certain subpopulations, including the pediatric population (defined as 17 years or

younger), females, and African Americans like Plaintiff, are at a greater risk of SJS/TEN from Advil." (Pl.'s Mem. in Supp. at 28.) Defendants contend that Plaintiff's requests are overbroad in that they "are not limited to the injuries relevant to this case" and are not limited "to 'subpopulations' to which [Plaintiff] belongs." (Defs.' Opp'n at 42.)

As the district court observed, Plaintiff's "specific allegations relating to his position of peril include his African-American race and his age of 16 years old[, and Plaintiff] ... includes a detailed history of incidents and circumstances that he alleges put Defendants on notice that certain populations, including young people and African Americans were more likely to suffer a SJS/TEN reaction from Advil." *Hodges*, 2015 U.S. Dist. LEXIS 39229, at *5. To the extent Plaintiff's requests seek subpopulation data relating to females or injuries beyond the serious skin reactions at issue in this case, these aspects of Plaintiff's requests are not reasonably calculated to lead to the discovery of admissible evidence in this case and, therefore, Plaintiff's motion is denied in part. Moreover, given that Defendants do not separately maintain such subpopulation data, (Defs.' Opp'n at 42), the burden of producing subpopulation data relating to females or injuries beyond the serious skin reactions at issue in this case outweighs any benefits such data might yield regarding relevant evidence bearing on the issues in this case. *See* Fed. R. Civ. P. 26(b)(1). Plaintiff's motion is otherwise granted with respect to the subpopulation data.

9. Specific Safety Materials Regarding Advil

***11** The information Plaintiff seeks in these requests can be loosely categorized as safety materials regarding Advil. The disputed breadth of a majority of these requests can be resolved by applying the Court's prior rulings with respect to the relevant timeframe (January 1, 2001 through July 1, 2010); foreign materials; product (single-ingredient, adult ibuprofen products); injury (serious skin reactions); and search terms.

A handful of requests merit further discussion. With respect to Request for Production No. 39, Plaintiff's motion is granted to the extent of Defendants' most recent compromise proposal in Defendants' First Supplemental Response to Plaintiff's First Request for Production of Documents as modified by the relevant timeframe and document custodians ordered herein. Request for Production No. 39 is otherwise denied.

As for Requests for Production Nos. 56 and 80, these requests address the 2005 Citizen Petition. Given the potential significance of the 2005 Citizenship Petition to the labeling claims at issue here, these requests are reasonably calculated to lead to the discovery of admissible evidence and are therefore granted.

10. *Madden* Documents

Plaintiff also seeks the production of documents and electronic data ordered produced in response to a discovery order issued in *Madden v. Wyeth*, a case out of the Northern District of Texas, to the extent such documents have not been previously produced in response to another request. (*See Madden* Pretrial Discovery Order, Dec. 8, 2003, Ex. 11 to Pl.'s App., ECF No. 75-3.) *Madden* involved Children's Advil and the development of SJS in a seven-year-old child. *Madden v. Wyeth*, No. 3-03-CV-0167-BD, 2005 WL 2278081, at *1 (N.D. Tex. Sept. 14, 2005). The Court has already ruled that the relevant product(s) in this case are *adult*, single-ingredient ibuprofen products. Moreover, as Defendants point out, "the label[ ] at issue [in *Madden*] *preceded* the 2005 class label that Plaintiff attacks" and turned on whether there should have been "a warning for SJS and TEN *before* the FDA reviewed the 2005 Citizen Petition and required the SJS warning that Plaintiff saw." (Defs.' Opp'n at 12.) While there may indeed be a significant amount of overlap between documents responsive to Plaintiff's requests in this case and the *Madden* documents, requiring wholesale production of any other *Madden* documents is likely to result in the production of documents not bearing on the products at issue here and which go well beyond the relevant time period for this case as well as increase litigation costs. *See* Fed. R. Civ. P. 1, 26(b)(1). Accordingly, Plaintiff's motion is denied with respect to Request for Production No. 91.

11. Deposition of Manfred Hauben, M.D.

The parties disputed the timing of the deposition of Defendants' employee Manfred Hauben, M.D. In a letter to the Court dated November 10, 2015, Plaintiff states that, "[o]n November 5, 2015, Defendants provided one deposition date (December 17, 2015) for [Dr. Hauben],

which Plaintiff accepted." Therefore, Plaintiff's motion is denied as moot concerning the deposition of Dr. Hauben.

B. Defendants' Motion to Compel

As for Defendants' motion, one interrogatory and several document requests remain in dispute.

1. Interrogatory No. 16

Interrogatory No. 16 requests Plaintiff to "identify all documents where Defendants expressly warranted that Advil was 'safe and well accepted by consumers and was safe for long-term use,' as alleged in Count V of [the] Amended Complaint." (Pl.'s Supplemental Resp. to Defs.' Interrog. Nos. 2-5, 7-17, 19-24, 26 and 27 at 17 ("Pl.'s Supplemental Resp. to Interrogs."));[9] *see* Defs.' Mem. in Supp. at 13, ECF No. 91.) Plaintiff first responded by generally referring to, among other things, allegations in the Amended Complaint, forthcoming expert reports, the Citizen's Petition, new drug applications for any Advil product whether prescription or over the counter "where statements regarding safety and effectiveness" were made, and "all prior and current versions of published marketing statements or television, or Internet marketing materials on www.advil.com." (Pl.'s Supplemental Resp. to Interrogs. at 18.) Following the hearing, Plaintiff supplemented his response to Interrogatory No. 16, identifying specific paragraphs of the Amended Complaint and referencing documents by bates numbers. (Pl.'s Supplemental Resp. to Interrogs. at 18.)

***12** Defendants seek "a declarative statement that identifies the documents containing the statement Plaintiff claims constituted an express warranty between him and Defendants in this case." Defendants contend that that this information is uniquely within Plaintiff's knowledge and they are "entitled to fair notice of the specific statements Plaintiff claims were an express warranty." Plaintiff contends that this is a contention interrogatory and he "is not required to marshal all evidence at this stage of the case." Plaintiff has, however, offered to "further supplement his response to identify the representations in Defendants' website Advil.com, pages of which were previously produced to Defendants." Plaintiff also indicates that he "is not relying on verbal warranties from Defendants"[10] and "Defendants are in possession of an affidavit from Plaintiff's father stating that he reviewed the label before he purchased the product." (Pl.'s Opp'n at 15, ECF No. 105.)

Plaintiff's argument that Interrogatory No. 16 is a contention interrogatory is without merit. Contention interrogatories " 'may ask another party to indicate what it contends, to state all the facts on which it bases its contentions, to state all the evidence on which it bases its contentions, or to explain how the law applies to the facts.' " *In re Grand Casinos, Inc.*, No. 4-96-890 (JRT/RLE), 181 F.R.D. 615, 618 (D. Minn. 1998) (quoting *McCarthy v. Paine Webber Grp., Inc.*, 168 F.R.D. 448, 450 (D. Conn. 1996)). Contention interrogatories " '*are distinct from interrogatories that request identification of witnesses or documents that bear on the allegations*.' " *Id.* (alteration in original) (quoting *McCarthy*, 168 F.R.D. at 450). Interrogatory No. 16 requests the identification of documents bearing on Plaintiff's express-warranty claim. "[T]he 'non-contentious' nature of the Interrogatory is confirmed by the fact that it is largely duplicative of [Plaintiff's initial-]disclosure obligations." *Id.*; *see* Fed. R. Civ. P. 26(a)(1)(A)(ii) (requiring a party to provide without waiting for a discovery request "a copy—or a description by category or location—of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control, and may use to *support its claims* or defenses, unless the use would be solely for impeachment" (emphasis added)).

Defendants' motion is granted in part with respect to Interrogatory No. 16. Plaintiff is ordered to supplement his response to Interrogatory No. 16 to: (1) identify the representations on Defendants' website that were relied upon, (*see* Am. Compl. ¶ 129 (Plaintiff's father "visited internet websites that advertised for Advil (both sites operated and maintained by Defendants and sites maintained by third parties) and which contained information relating to the purported safe and effective nature of the drug"); (2) specifically state that Plaintiff is not relying on any oral warranties; and (3) include a reference to the affidavit of Plaintiff's father. Defendants' motion is otherwise denied with respect to Interrogatory No. 16.

2. Document Requests

In response to document requests addressing such diverse

topics as meeting minutes, alleged failures to report safety data and identification of such data, specific PSURs, interactions with the French government, a particular study, the emergence of new safety information allegedly ignored by Defendants, a particular subpopulation, and the rate of occurrence of SJS and TEN with ibuprofen compared to other nonsteroidal anti-inflammatory drugs, Plaintiff's supplemental responses refer to broad categories of documents such as new drug applications for any Advil product whether prescription or over the counter, Defendants' litigation files from previous actions, lists of medical literature references, and forthcoming expert disclosures. The following is a representative response:

> ***13** Plaintiff objects that the request improperly asks him to marshal all of his evidence at this early stage in the case. Subject to and without waiving the foregoing objection, see any and all [new drug application]s, [investigational new drug application]s, and [supplemental new drug application]s for any Advil products, whether it be for prescription, or switch to OTC, or for OTC regarding any Advil product that will be produced by Defendants in this matter. Given Defendants are refusing to produce any information pre-dating 2005 (and in fact have not produced one single document in this case as of the date of this response), Plaintiff directs Defendants to the documents in their files and will supplement this response as discovery continues. With respect to any deposition testimony or transcripts that involve previous Advil SJS/TEN litigation that may be responsive to this request, Plaintiff directs Defendants to their own litigation files for the two cases, *Madden, et al. v. Wyeth, et al.*, U.S. District Court Northern District of Texas (Dallas), CIVIL DOCKET FOR CASE #: 3:03cv00167BD, and *Julie and Keith Steies* v. *Wyeth, et al.*, U.S. District Court of Minnesota, Civil Action No.: 10-1986 PAM-JJG, or alternatively, Plaintiff directs Defendants to the equally and publicly available responsive documents that are posted and accessible through PACER, which are incorporated herein fully by reference. Plaintiff will produce additional responsive documents to this request subject to the Scheduling order when it is required to produce his Rule 26 expert disclosures, reports, and attachments thereto.
>
> See scientific literature table, attached as Exhibit 1, and PACER documents produced from the *Madden* and *Kiss* lawsuits. Additionally, since investigation and discovery are ongoing, Plaintiff will supplement with any responsive documents, if any new documents or information should become available.

(Pl.'s Supplemental Resp. to Defs.' First Request for Production Nos. 29-58 & 61-66 at 5 ("Pl.'s Supplemental Resp. to Requests for Prod.").[11]) While Plaintiff, at times, provides more specific information, (*see, e.g.*, responses to Request for Production Nos. 47, 52, 53, 55, and 58 at pages 20-21, 25-27, 29-30, and 32-33 of Pl.'s Supplemental Resp. to Requests for Prod.), each of his supplemental responses contain the same vague references exemplified above.

Defendants assert that "[t]hese broad 'en masse' references ... fail completely to identify documents with the specificity required by Fed. R. Civ. P. 34." (Defs.' Mem. in Supp. at 28 (quotation omitted).) Further, Defendants complain that Plaintiff has identified non-responsive documents, impermissibly "refer[s] to documents that 'will be produced' in the future as support for the allegations made in a complaint that has already been filed," and "has an obligation under Rule 26 to provide the information and documents that bear on Plaintiff's claims, whether or not those documents are also in Defendants' possession or otherwise available." (Defs.' Mem. in Supp. at 29-30.)

Plaintiff responds that he "is not required to specifically identify documents in response to requests for production," (Pl.'s Opp'n at 18), and is not required to further categorize his production because the documents have been produced in the matter in which they are maintained by him or counsel. Plaintiff asserts that his responses "not only identify responsive records, but identify the relevant bates ranges for many of the records," and the breadth of his responses is driven by the breadth of Defendants' requests. Plaintiff additionally asserts that he "is not required to marshal all evidence at this stage of the case in response to a contention discovery request."

Under Rule 34, "[a] party must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the request." Fed. R. Civ. P. 34(b)(2)(E)(i).[12] Plaintiff asserts that he is "producing records in the manner in which they are maintained by him or his counsel." To the extent that Plaintiff is attempting to rely on the option to produce documents maintained in the ordinary course of business, Plaintiff has not met his burden. "If a party claims that the documents were kept in the ordinary course of business, ... it bears the burden of demonstrating that fact." *Mizner Grand Condo. Ass'n, Inc. v. Travelers Prop. Cas. Co. of Am.*, 270 F.R.D. 698, 700 (S.D. Fla. 2010) [hereinafter *Mizner*] (citing *Synventive Molding Solutions, Inc. v. Husky Injection Molding Sys.*, 262 F.R.D. 365, 370 (D. Vt. 2009)); *see Johnson v. Kraft*

Foods N. Am., Inc., 236 F.R.D. 535, 540-41 (D. Kan. 2006). "[A] mere assertion that [the documents] were so produced is not sufficient to carry that burden." *Johnson*, 236 F.R.D. at 540-41; *accord In re Mentor Corp. Obtape Transobturator Sling Prods. Liability Litig.*, No. 4:08-MD-2004, 2009 WL 152495, at *2 (M.D. Ga. Jan. 22, 2009) [hereinafter *In re Mentor Corp.*] ("It is clear, however, that simply producing a mass of documents with the assurance that they are produced in the same manner as they are kept in the ordinary course of business does not automatically satisfy a party's obligation under Rule 34(b)(2)(E)(i)."). "Moreover, even when a party produces documents as they are kept in the ordinary course of business, if the business record-keeping system used by the producing party is so deficient as to undermine the usefulness of production, that party may not have met its obligations under Rule 34." *Mizner*, 270 F.R.D. at 700 (quotation omitted).

***14** Plaintiff has done nothing more than to say that the documents were maintained either by himself or counsel. "Plaintiff fails to provide the Court with any information, let alone evidentiary proof to establish that the documents were produced as kept in the ordinary course of business." *Johnson*, 236 F.R.D. at 540; *see Mizner*, 270 F.R.D. at 701 ("Mizner has made no meaningful attempt to show that its production satisfies the business records option in Rule 34(b)(2)(E)(i)."). Moreover, "[u]nless [Plaintiff] habitually keeps all documents [he] receives in storage with [his] attorneys, the documents [he] acquired ... were simply not maintained in the 'usual course of business.' " *Mizner*, 270 F.R.D. at 701; *see Wagner v. Dryvit Sys., Inc.*, 208 F.R.D. 606, 611 (D. Neb. 2001) (maintaining document repository was not plaintiff's business). Because Plaintiff has not met his burden to show that the documents were produced in the usual course of business "he should have organized and labeled them to correspond with the categories in each request, as required by Rule 34(b)." *Johnson*, 236 F.R.D. at 541.

As to Plaintiff's reliance on Defendants' own possession of the responsive documents, "a party is required to produce documents in its possession, custody, or control, regardless of whether it believes the requesting party already has those documents." *Gomez v. Tyson Foods, Inc.*, No. 8:08CV21, 2012 WL 3111897, at *4 (D. Neb. July 31, 2012). Thus, it is not sufficient for Plaintiff to generally direct Defendants to their own litigation files in two prior matters.

Plaintiff's objection that Defendants' documents requests constitute contention discovery is similarly misplaced. Discovery requests that ask a party to identify documents bearing on a particular allegation are not contention requests. *See In re Grand Casinos*, 181 F.R.D. at 618; *B. Braun Med. Inc. v. Abbott Labs.*, 155 F.R.D. 525, 528 (E.D. Penn. 1994).

Lastly, Plaintiff cannot rest on an assertion that documents will be provided in the future. While Plaintiff may, and indeed has an obligation to, supplement his responses "in a timely manner if [he] learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to [Defendants]," Fed. R. Civ. P. 26(e)(1)(A), Plaintiff is required to identify those responsive documents currently in his possession. "A plaintiff must adequately plead a claim before obtaining discovery, not the other way around. Discovery is not to be used to find a cause of action. Plaintiffs are not permitted to assert first, without basis, and discover later." *Brown v. Ameriprise Fin. Servs., Inc.*, No. 09-cv-2413 (RHK/FLN), 276 F.R.D. 599, 605 (D. Minn. 2011) (quotation and citations omitted). "Neither is it sufficient to say the information will be forthcoming in [an] expert's report which normally falls due at the end of the period of discovery, since, besides being selective, that simply deprives defendant of an opportunity to adequately investigate and analyze for itself information the plaintiff is relying upon." *Equal Emp't Opportunity Comm'n*, No. 1:08-cv-907, 2010 WL 748250, at *7 (W.D. Mich. Feb. 26, 2010).

"The parties have a duty to provide true, explicit, responsive, complete and candid answers to discovery ...." *Wagner*, 208 F.R.D. at 609. At the same time, "[t]he Court will not condone ... any attempt by the requesting party that overburdens the producing party simply to make th[e] ascertainment [of which documents are responsive to which requests] more convenient for the requesting party." *In re Mentor Corp.*, 2009 WL 152495, at *2. Rule 34 requires that documents be produced as they are kept in the usual course of business or organized and labeled "to correspond to the categories in the request." Fed. R. Civ. P. 34(b)(2)(E)(i). Because Plaintiff has not met his burden to show than the documents were produced as they are kept in the usual course of business, Defendants' motion is granted with respect to Request for Production Nos. 31, 32, 34, 38, 39-45, 47, 49, 50, 52, 53, 55, and 58, and Plaintiff shall serve more detailed responses to these document requests, identifying by bates number which documents are responsive to the request. *See Johnson*, 236 F.R.D. at 541; *see also Mancini v. Ins. Corp. of N.Y.*, No. 07cv1750-L(NLS), 2009 WL 1765295, at *5 (S.D. Cal. June 18, 2009).

IV. MODIFICATION TO ORDER GOVERNING PRODUCTION OF DOCUMENTS AND ELECTRONICALLY STORED INFORMATION & AMENDMENT OF PROTECTIVE ORDER

***15** Defendants also moved for modification of the Order Governing Production. Defendants sought clarification of Section I.F., which allowed any producing party to "use redactions to protect attorney-client or attorney work product privileges or *protected patient health information or other personal information*." (Order Governing Produc. at 4 (emphasis added).) The Order Governing Production further required that, "[f]or all redactions, the redacting party will produce a redaction log in a form sufficient to enable the receiving party to analyze the validity of the redaction." (Order Governing Produc. at 4.) Given "the magnitude of Defendants' anticipated document productions and the likely number of redactions [for protected patient health information and other personal information]," (Defs.' Mem. in Supp. of Clarification at 2, ECF No. 84), Defendants sought relief from the logging requirement for six specific categories of information, which Defendants asserted they were not permitted to disclose under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, and related regulations as well as regulations governing information about adverse-event reporters. At the hearing, the Court requested additional briefing from the parties on certain categories of information. (*See* Court Minutes.)

Following the hearing, the parties were able to reach an agreement on the redaction of all of the categories of information at issue as well as under what circumstances such information needed to be logged, and filed a stipulation reflecting their agreement. (*See* Stip. for Modification of Order Governing Produc. of Docs. & Electronically Stored Information, ECF No. 116.) Based on the parties' stipulation, the Court will deny Defendants' motion as moot and enter a separate order on the parties' stipulation.

Similarly, Defendants raised concerns about the existing Protective Order's (ECF No. 63) compliance with HIPAA at the hearing. The parties agreed to amend the existing Protective Order and have filed a stipulation addressing the Protective Order as well. (*See* Stip. for Am. HIPAA-Qualified Protective Order, ECF No. 113.) Based on the parties' stipulation, the Court will enter a separate order amending the Protective Order.

V. ORDER

Based on the foregoing, and on all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Plaintiff's Motion to Compel (ECF No. 72) is **GRANTED IN PART** and **DENIED IN PART** as set forth herein.

2. Defendants' Motion to Compel Responsive Answers to Defendants' First Set of Interrogatories and Request for Production of Documents (ECF No. 89) is **GRANTED IN PART** and **DENIED IN PART** as set forth herein.

3. Defendants' Motion for Clarification and Modification of Order (ECF No. 82) is **DENIED AS MOOT**.

4. Separate orders modifying the Order Governing Production of Documents and Electronically Stored Information and amending the Protective Order as stated herein shall issue shortly.

5. Each party shall bear its own costs and attorneys' fees. *See* Fed. R. Civ. P. 37(a)(5)(C).

6. All prior consistent orders remain in full force and effect.

7. Failure to comply with any provision of this Order or any other prior consistent Order shall subject the non-complying party, non-complying counsel and/or the party such counsel represents to any and all appropriate remedies, sanctions and the like, including without limitation: assessment of costs, fines and attorneys' fees and disbursements; waiver of rights to object; exclusion or limitation of witnesses, testimony, exhibits, and other evidence; striking of pleadings; complete or partial dismissal with prejudice; entry of whole or partial default judgment; and/or any other relief that this Court may from time to time deem appropriate.

EXHIBIT A

1	Periodic Safety Update Report
2	Periodic Benefit Risk Evaluation Report
3	Safety signal
4	Periodic Adverse Experience Report
5	Citizen Petition
6	Labeling Committee
7	Labeling Executive Committee
8	Safety Committee
9	Executive Committee
10	Safety or regulator queries
11	Skin reaction
12	Cutaneous
13	Stevens-Johnson syndrome and/or SJS
14	Toxic epidermal necrolysis and/or TEN
15	Labeling changes
16	Life threatening
17	Serious reactions
18	Data mining
19	Pharmacovigilance
20	Withdrawal from market
21	Deaths
22	FDA
23	EMEA
24	French Query
~~25~~	~~Roger Berlin~~
26	Jean-Claude Roujeau
27	Maja Mockenhaupt
28	Robert Stern
29	Labrea Williams
30	Madden
31	Heather Kiss
32	Pharmacogenetic
33	African-American
~~34~~	~~Females~~
35	Increased incidence or frequency
36	Reporting rate
37	Relative risks or odds ratio
38	Blister or mucosal lesions
39	Rash
40	Pustular
41	Peeling
42	Erosions
43	Blindness
44	Hospitalization
45	Life-threatening
~~46~~	~~Manfred Hauben~~
47	William Gregory
48	SCAR
49	EuroSCAR
50	RegiSCAR
51	Slone epidemiology
52	Bruce Weintraub
53	Pharmacia and Upjohn
54	McNeil
55	Multi-poisson
56	Proportional reporting ratios or PRR
57	483 notice
58	Recall
59	Advil
60	Spalt
61	Ibuprofen
~~62~~	~~Ibuprofen sodium~~
63	Erythema multiforme
64	MedDRA
65	Standardized MedDRA Query or SMQ for SJS and TEN
66	S^3
67	ARISg
68	ARGUS
69	DOCUMENTUM
70	GSSE
71	CRPV or French National PV centers
72	German Registry
73	Vigibase
74	EB05
75	Class labeling
76	NSAIDs
77	Children's Analgesic Medicine Project or CAMP Study
78	Summary of Medical Product Characteristics or SPMC or SPC
79	Patient Information Leaflets (PILs)
80	Risk management
81	Core labeling and/or Core data sheet
82	International
83	Advisory Committee
84	Foreign affiliates
85	Consumer leaflet
86	Global labeling
~~87~~	~~A. Parades-Diaz~~
88	Wendy Stephenson

~~89~~	~~Anthony Ewell~~
~~90~~	~~Margarita Gardiner~~
91	Safety review
~~92~~	~~Safety signal meeting~~
93	Physician reviewer
94	Medical Affairs
95	Safety surveillance
96	Healthcare inquiry
97	Consumer complaint
98	Allen Perelson
99	Ramiro Jervis
100	EMEA
101	EU
102	CIOMS
103	Bullous
104	iSAEC
105	Judith Jones
106	ISPE
107	Stomatitis
108	Toxicity
109	Steies
110	Lamar Hodges
111	Hodges
112	Connor Sheehan
113	Regions Hospital
114	ACT-3
~~115~~	~~Advil Liquid Gel~~
~~116~~	~~Advil Soft Gel Caplets~~
~~117~~	~~Advil tablets~~
~~118~~	~~Advil caplets~~
~~119~~	~~Advil Chewable~~
~~120~~	~~Advil suspension~~
~~121~~	~~Advil Drops~~
~~122~~	~~Advil Liquid~~
123	Multi organ failure
124	Corneal
125	Reference Safety Information or RSI
126	French Health Authority or AFFSAPS
127	UK regulatory agency (MCA) or (MHRA)
128	Japanese regulatory authority or PMDA
129	German regulatory authority or Federal Institute for Drugs and Medical Devices or BfArm
130	Exfoliative
131	Positive rechallenge
132	Lyell syndrome
133	Drug Reaction with Eosiphinolia Systemic Symptoms or DRESS
134	acute generalized exanthematous pustolosis (AGEP)
135	Advil File/National Commission on Monitoring Side Effects of Drugs
136	Advil DMI-Request for Modification of Information or Demande de Modification de Information
137	Florence Rideau
138	Alban Dhanani
139	Doctor Marie-Josephe Jean Pastor
140	Doctor Daniel Julien
141	Maryse Rouxel
142	Bubbly toxidermias
143	Neal Shear
144	affiliate labeling
145	SMART/Ex Comm
146	International Regulatory Affairs
147	International Medical Affairs
148	P. Chapman
149	Motrin
150	Anadin
151	M. Coehlo
152	David Kessler
153	Expert consultant
154	Expert report
155	Draft response
156	Draft labeling
157	Expert appraisement
158	Upper management
159	Global Medical Research
160	Global Medical Affairs and/or GMA
161	Consultant physician opinion
162	Dossier
163	Dossier NL 18301
164	Dossier NL 27068
165	Dossier NL 14713
166	Dossier NL 14714
167	Roger Salisbury
168	Burn center
169	Analgesic Therapeutic Team
170	William Soller
171	Mouth sores
172	Life-threatening skin reactions
173	Netherlands Pharmacovigilance Centre Lareb
174	WHO database of the Uppsala Monitoring Centre
175	EudraVigilance
176	Mortality rate

177	Health Canada
178	Causal relationship
179	Increased risks
180	Causal Plausibility
~~181~~	~~Vaginal scarring~~
182	American Burn Association
183	Subpopulations
184	Prodromal
185	Time to onset
186	ALDEN
187	Medication Guide
188	Dexibuprofen
189	Duration of therapy
190	Risk communication
191	WATSIN
192	Budgets for PV
193	Budgets for marketing/advertising
194	Restrict use of Advil
195	Contraindicate use of Advil
~~196~~	~~Paul Desjardins, D.M.D~~
~~197~~	~~Donald Frye~~
~~198~~	~~Elizabeth Savage~~
~~199~~	~~Stephen Allen Cooper~~
~~200~~	~~Barbara Wolfe~~
~~201~~	~~Margaret Carr~~
202	Elizabeth Ashraf
203	Suspected Unexpected Serious Adverse Reactions (SUSARs)
204	ICH E2D
205	ICH E2A
206	ICH E2E
207	ICH E6
208	ICH E2B (R2)
209	GPRD
210	DSRU
211	FAERS
212	AERS
213	ADROIT
214	EEA countries
215	Non-EEA countries
216	Designated medical events or targeted medical events (DME) and (TME)
217	J-PSURs
~~218~~	~~Safety signal detection methods~~
219	Dear healthcare professional letter/communication
220	CIOMS Working Group VI
221	MAH or Marketing Authorization Holder
222	Company Core Safety Information (CSI)
223	CIOMS VIII Report
224	Bradford Hill criteria
225	Causality assessment
226	Reporting odds ratio
227	Michael Blum
228	Michael Cook
229	Canada Vigilance
230	epidermal necrolysis
231	epidermal necrosis
232	fixed drug eruption (FDE)
233	vesiculobullous
234	vesicular
235	blister
236	exfoliative dermatitis
~~237~~	~~pustular rash~~
238	toxic drug eruption
~~239~~	~~toxic pustuloderma~~
240	purpura
241	vesicles
242	pustules
243	exfoliation
244	skin peeling
~~245~~	~~skin blister~~
246	mucosal erosions/ulcers
~~247~~	~~maculopapular rash~~
~~248~~	~~morbilliform rash~~
~~249~~	~~rash vesicular~~
~~250~~	~~rash bullous~~
251	apthous sores/ulcers
252	erythema nodusum
253	erythoderma
~~254~~	~~medicamentosa dermatitis~~
~~255~~	~~toxiderma~~
256	bullae
257	skin ulcer
258	photosensitivity
~~259~~	~~Reiter' syndrome~~
~~260~~	~~Sweet's syndrome~~
~~261~~	~~vasculitis~~
~~262~~	~~kawasaki's disease~~
263	toxic shock syndrome
264	epidermal bullosa
265	scalded skin syndrome

All Citations

Slip Copy, 2015 WL 13804602

Footnotes

1 Portions of Rule 37 were also amended.

2 The Court declines to address Defendants' preemption/"fraud-on-the-FDA" argument. Whether a claim is preempted is a dispositive question.

3 For purposes of clarification, this Order does not permit Plaintiff to add terms to the definition of "serious skin reactions" as put forth by Plaintiff in his First Request for Production of Documents to Defendants. Plaintiff's definition is narrowed by this Court's ruling.

4 "The European Medicines Agency is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union." *About us*, European Medicines Agency, http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000235.jsp&mid= (last visited November 17, 2015).

5 The parties shall use all reasonable efforts to comply with any implicated foreign data privacy laws and shall take guidance from the Court's forthcoming Amended HIPAA-Qualified Protective Order and Order on Stipulation to Modify Order Governing Production of Documents and Electronically Stored Information when responsive foreign materials involve similar types of protected health information, adverse-event-reporter information, and sensitive personal information. *See infra* Section IV.

6 For example, the term "skin unspecified" is neither contained in the SCAR SMQ identified in the Tackett Declaration nor in Plaintiff's medical records. (Ex. 22 at 2.) Therefore, Defendants would not need to search this term.

7 The terms are numbered 1 through 265 and the Court adopts Plaintiff's numbering schematic for purposes of this Order.

8 To the extent terms describing medical conditions, symptoms, and the like are included on Exhibit A and not reasonably identified by the references to Plaintiff's medical records in Exhibit 22 of Plaintiff's Appendix, Defendants may request that Plaintiff provide medical-record support for the term before including it in their custodial search.

9 The Court received this document via e-mail following the hearing.

10 The Court presumes Plaintiff means "oral" not "verbal" warranties. *Compare Black's Law Dictionary* 1205 (9th ed. 2009) (defining "oral" as "[s]poken or uttered; not expressed in writing") *with* 1696 (defining "verbal" as "[o]f, relating to, or expressed in words").

11 This document was also received by the Court via e-mail.

12 Portions of Rule 34 were also amended.