UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY LITIGATION	MDL Case No.13md2452 AJB (MDD) As to all related and member cases ORDER DENYING PLAINTIFFS' MOTION TO COMPEL DISCOVERY OF ADVERSE EVENT SOURCE DOCUMENTS AND DATABASES (Doc. No. 554)

Presently before the Court is Plaintiffs' motion to compel production of adverse event source documents and databases. (Doc. No. 554.) Defendants filed an opposition to Plaintiffs' motion on August 26, 2014. (Doc. No. 579.) Plaintiffs' reply was filed September 9, 2014. (Doc. No. 613.) Pursuant to Civil Local Rule 7.1.d.1, the Court finds the motion suitable for determination on the papers and without oral argument. For the reasons set forth below, the Court **DENIES** Plaintiffs' motion to compel adverse event source documents and databases. Accordingly, the motion hearing set for October 9, 2014, is hereby vacated.[1]

[1] The status conference scheduled for October 9, 2014, at 3:00 p.m. will remain on calendar.

I. INTRODUCTION

Plaintiffs' motion to compel seeks production of the "underlying documents for each pre- and post- marketing adverse event known to each Defendant; and the adverse event databases[2] maintained by each Defendant." (Doc. No. 554-1 at 1.) Plaintiffs claim that without Defendants' source documents and databases, the adverse event reports produced by Defendants are insufficient. (*Id.*) Plaintiffs justify their requests for production as relevant to both preemption and causation. (*Id.*) With respect to preemption, Plaintiffs allege all of the source documents underlying the adverse event reports are necessary to determine whether Defendants misreported or under-reported information to the FDA in connection with their incretin drugs. Plaintiffs assert the source files are the "only way to tell if the MedWatch forms given to the FDA accurately characterize an adverse event . . . " and "whether pancreatic cancers were properly reported to the FDA." (*Id.* at 2:23-24, 3:1-2.) Plaintiffs make such arguments throughout their motion.[3] ("There are reasons to believe such cancers were not correctly reported, and were under-reported." (*Id.* at 3:2 -3); "The MedWatch summaries manufacturers prepare and submit to

---

[2] At the October 2, 2014, hearing on Plaintiffs' motions to compel production of foreign regulatory files, (Doc. No. 630), and further written responses (Doc. No. 643), counsel stated they are conferring on completing production of the "scientific data" and as the Court understands it, this may include information from the adverse event databases. The instant motion and the Court's ruling relate to the complete production of the underlying documents for each pre- and post- marketing adverse event known to each Defendant and the complete adverse event databases maintained by each Defendant. "Scientific data" is described differently by each party, but is generally referenced as the SAS files, clinical trials, animal trials, epidemiology and histology files. These terms are not mutually exclusive, and no doubt are redundant. The Court is not making a finding on the definition per se, but merely noting the potential components for context to this footnote.

[3] Plaintiffs previously asserted similar arguments related to misreporting and under-reporting in connection with their motion to compel foreign regulatory files. (Doc. No. 630.) In that motion, Plaintiff's argued the documents at issue were "relevant to impossibility preemption, because any scientific evidence provided to foreign regulatory officials but *not* to the FDA could show under-reporting or misreporting by Defendants to the FDA. . . ." (Doc. No. 630 at 1:22-24)(emphasis in original). Plaintiffs also plainly assert they are "entitled to challenge" Defendants' preemption argument "with instances of under-reporting or misreporting to the FDA." (Doc. No. 630 at 6:15-17.) The Court references these prior arguments as they are relevant to the discussion herein, and indicative of the allegations Plaintiffs assert against Defendants with respect to FDA reporting.

the FDA are known to be fraught with error." (*Id.* at 8:2-3); "Source files contain safety signals and causation information withheld by Defendants from the FDA." (*Id.* at 9:2-3).)

Defendants deny any misreporting or under-reporting and object to Plaintiffs' requests on the grounds that production of source documents and databases would be unreasonably burdensome. (*See* Doc. No. 579.) Further, Defendants argue Plaintiffs' motion should be denied because Defendants have offered to produce source files relevant to this litigation, adverse event reports cannot in and of themselves establish general causation and are irrelevant to preemption, and Defendants are precluded by law from producing "their entire databases." (*Id.* at 1:9-10; 2:4-5; 2:20-21.)

The scope of discovery in this case was previously limited to only issues of general causation. (*See* Doc. No. 325.) Following Defendants' motion for summary judgment based on preemption, the Court granted additional discovery and expanded the scope of inquiry to include facts relevant to preemption. (*See* Doc. No. 472.) Specifically, with respect to preemption, the Court framed relevant discovery as "what the [Food and Drug Administration] would or would not have done with respect to the proposed label change as expressed in *Wyeth v. Levine*." (Doc. No. 567 at 2:14-16.) On August 12, 2014, Plaintiffs filed the instant motion to compel. (Doc. No. 554.)

Given the procedural posture of this case, the currently set scope of discovery, and anticipated motions, the Court finds a careful consideration of Plaintiffs' preemption-based argument is warranted.

II. DISCUSSION

A. Fraud-on-the-FDA

Although the Court recognizes Plaintiffs in this matter have not pleaded fraud-on-the-FDA claims, Plaintiffs frequently invoke allegations of misreporting and under-reporting as a justification for additional discovery, and as pertinent to a preemption defense. It is important, however, to distinguish between an analysis of whether Plaintiffs' state law failure-to-warn causes of action are preempted and whether instances of

fraud-on-the-FDA can be asserted to rebut a defense of federal preemption. Whether Plaintiffs' state law failure-to-warn claims are preempted is not the issue before the Court. Instead, the Court considers whether the policy underlying the Supreme Court's holding in *Buckman Co., v. Plaintiffs Legal Community* precludes Plaintiffs from asserting fraud-on-the-FDA type claims as a defense to federal preemption or as otherwise relevant to a preemption analysis, and thereby precludes discovery thereon.

"Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The relationship between a federal agency and the entity it regulates is "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Buckman Co.*, 531 U.S. at 347. Accordingly, fraud-on-the-FDA claims "inevitably conflict" with the federal regulatory scheme, and would "dramatically increase the burdens facing potential [drug] applicants" by causing applicants "to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 350-51. Thus, the law is well established that claims amounting to fraud-on-the-FDA are preempted by the Food, Drug, and Cosmetic Act ("FDCA") because such claims conflict with the federal statutory scheme that empowers the FDA to punish and deter fraud against the Agency. *Id.*

Plaintiffs' assertions that there are "reasons to believe [pancreatic] cancers were not correctly reported and were under-reported" and that information was "withheld by Defendants from the FDA" are fraud-on-the-FDA claims expressly preempted by *Buckman*. *See Dusek v. Pfizer, Inc.*, CIV.A. H-02-3559, 2004 WL 2191804 at *7 (S.D. Tex. Feb. 20, 2004)(Plaintiffs' arguments that the FDA was not aware of the "full evidence" concerning the drug at issue amounted to allegations of fraud-on-the-agency); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003)(plaintiffs could not "bootstrap" arguments about defendants alleged failure to report and to investigate

adverse incidents to the FDA into a defective warning case.) The policy underlying *Buckman* also supports deferring consideration of those claims when raised not as an individual basis for relief, but as relevant to a preemption analysis. To allow otherwise and permit fraud-on-the-FDA type claims to alter a federal preemption analysis would put at issue allegations expressly removed from judicial consideration.

Accordingly, the Court finds the fraud-on-the-FDA type allegations asserted by Plaintiffs in support of their motion irrelevant to the determination of whether Plaintiffs state law failure-to-warn claims are preempted. *See in re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 05-1699 CRB, 2006 WL 2374742 at *10 (N.D. Cal. Aug. 16, 2006)(allegations that the defendant "withheld material cardiovascular risk data from the FDA does not change the preemption analysis."); *In re Trasylol Products Liab. Litig.*, 08-MD-01928, 2010 WL 4259332 at *9 (S.D. Fla. Oct. 21, 2010)(evidence that Defendant failed to adequately or timely provide information to the FDA would "only be relevant to a fraud-on-the-FDA claim that is preempted by Buckman"). Therefore, even if Plaintiffs could establish Defendants committed fraud-on-the-FDA by failing to report incidences of pancreatic cancer, the analysis of whether Plaintiffs' state law claims are preempted would not change. As such, discovery regarding speculated instances of misreporting or under-reporting is unnecessary.

Further, the absence of or mis-characterization of data due to alleged FDA reporting violations is not within the purview of the Court. It is not the role of courts to evaluate or enforce the degree to which manufacturers comply with FDA regulations. *See Wilson v. Wyeth*, 3:07-CV-00378-R, 2008 WL 4696995 at *6 (W.D. Ky.)("It is the proper role of the FDA, not the Court to determine whether Defendants have failed to comply with FDA reporting requirements."); *In Re: Medtronic Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010)(arguments that defendant failed to provide the FDA with sufficient information and did not timely file adverse event reports was an attempt by private parties to enforce the Medical Device Amendments to the

FDCA.); *In re Bextra*, 05-1699 CRB, 2006 WL 2374742 at *9 ("The Court cannot conclude that the FDA is wrong; the FDA is the agency charged with administering the FDCA and striking a somewhat delicate balance among its statutory objectives." (internal citations omitted).) The judiciary and its litigants are neither the appropriate people nor the appropriate forum for evaluations of compliance with FDA reporting requirements.

It must be noted, the Court is not addressing the merits of Defendants' preemption argument or the basis of Plaintiffs' state law failure-to-warn claims. Instead, the Court's conclusion is limited to whether Plaintiffs' allegations of misreporting and under-reporting to the FDA justify production of source documents and databases on the premise they are relevant to preemption. As such, both parties' arguments as to the merits of Defendants' preemption defense are premature.

Specifically, Plaintiffs cite *Stengel v. Medtronic, Inc*. 704 F.3d 1224 (9th Cir. 2013) to argue fraud-on-the-FDA preemption "has no application where Plaintiffs assert a state law claim that is independent of the FDA's premarket approval process at issue in *Buckman*." (Doc. No. 613 at 5.) Such citations are premature as application of *Stengel* would require the Court to consider the origin of Plaintiffs' state law failure-to-warn claims. Accordingly, while *Stengel* may be applicable to a determination of whether Plaintiffs' claims are preempted or arise from a separate "parallel"[4] state duty, it is not relevant to the issue presently before the Court.

Likewise, Plaintiffs' argument that *Buckman* "has no bearing on the discovery permitted when evaluating a preemption affirmative defense" is of little impact. (Doc. No. 613 at 6, n.5.)[5] While *Buckman* may not speak directly to whether fraud-on-the-

---

[4] The court in *Stengel v. Medtronic, Inc.* held that the plaintiffs' failure-to-warn claim was based on an independent state-law duty that paralleled the FDA's pre-market approval process and thus was distinguishable from *Buckman. Stengel*, 704 F. 3d 1224, 1233.

[5] Plaintiffs cite to *Glynn II (In re Fosamax)*, 2014 US Dist. LEXIS 42253 at *58 (D.N.J. Mar. 26, 2014) to argue the court in *Glynn II* permitted discovery and trial on the issue of "whether providing information to the FDA would have changed the FDA's conclusion that a Precaution was not warranted" and thus the Court should similarly

FDA claims are relevant to a preemption determination, *Buckman* definitively establishes that such claims are preempted for fear of "exert[ing] an extraneous pull on the scheme established by Congress." *Buckman Co.*, 531 U.S. at 353. The same rationale suggests fraud-on-the-FDA claims should not be allowed to rebut the defense of federal preemption.

The fact that the FDA's regulatory authority to evaluate and investigate instances of misreporting or under-reporting and the defense of federal preemption both arise within the federal regulatory construct does not negate that these two concerns emerge within the context of Plaintiffs' state law failure-to-warn claims. The power of the FDA to regulate reporting requirements compliments, rather than conflicts with, the affirmative defense of federal preemption. The conflict arises not within the context of federal preemption versus the FDA's power to regulate, but within the fraud-on-the-FDA type arguments and Plaintiffs' multi state law failure-to-warn claims. To allow discovery, and by extension judicial consideration, of compliance with federal reporting requirements would erode the FDA's role in pharmaceutical regulation and neglect the policy underlying *Buckman*. Thus, the tension is not, as Plaintiffs suggest, the result of two regulatory provisions, but with the plaintiffs state law claims and the regulatory scheme promulgated by Congress.

Finally, when similar fraud-on-the-FDA claims were previously raised in the context of Defendants' motion for summary judgment, the Court anticipated such claims could be relevant to whether Plaintiffs' state law failure-to-warn causes of action are preempted.[6] However, upon further review and consideration, following various briefing

---

permit discovery of misreporting or under-reporting in this case. The court in *Glynn II* however, continued to note that "Plaintiffs' contention appear[ed] to be a fraud-on-the-FDA theory which was rejected by the Supreme Court in *Buckman*." Accordingly, the Court is not persuaded that *Glynn II* supports Plaintiffs' request for discovery in the instant case.

[6] In the Court's June 5, 2014, order denying Defendants' motion for summary judgment and granting Plaintiffs' motion for additional discovery the court stated, "Plaintiffs have also alleged instances of under-reporting or misreporting by Defendants

and allusion to this issue in various proceedings, the Court finds the policy underlying federal preemption of fraud-on-the-FDA claims equally applicable in this case. Granting the discovery sought on the basis such claims are relevant to preemption would require courts to overstep the bounds placed in effect by the FDA's federal regulatory scheme and Supreme Court precedent. This would result in a frustration of the statutory scheme for regulation in this field. Thus, the Court does not consider Plaintiffs' allegations of misreporting or under-reporting relevant to a preemption analysis.

B. Causation

Plaintiffs also argue that production of source documents and databases is relevant to general causation. (Doc. No. 554-1 at 5.) As the Court previously stated, the scope of discovery with respect to causation is "a matter of science, and therefore, scientific documents and/or scientific evidence frame the universe of contemplated discovery." (Doc. Nos. 377, 567.) Defendants have produced adverse event reports and provided Plaintiffs with scientific evidence relevant to establishing whether a causal relationships exists between the drugs at issue and pancreatic cancer. Whether an indeterminate number of adverse event reports were classified differently than Plaintiffs allege they should have been does not overcome the weight of scientific data Defendants have produced. Given the narrowed scope of discovery and the emphasis on scientific data within that scope, the Court is not persuaded the source documents and databases Plaintiffs seek are relevant to general causation as defined by the Court.

As Defendants submit, Courts have recognized that adverse event reports are collected "without any medical controls or scientific assessment," and as a result are "one

---

to the FDA. Such serious allegations require substantial evidence to support, and Plaintiffs must have the full opportunity to discover it, if indeed it exists." (Doc. No. 472 at 5:22-24.)

of the least reliable sources to justify opinions about both general and individual causation." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005).[7]

C. Undue Burden

Plaintiffs also assert production of adverse event source documents and databases will not unduly burden Defendants because manufacturers are required to maintain source files and thus "the only 'extra' expense is that of redacting patient and provider identifying information." (Doc. No. 554-1 at 9:13-14.) However, the Rules permit a court to limit discovery when the "burden or expense of the proposed discovery outweighs its likely benefit . . . ." The Court recognizes the significant burden imposed on Defendants if forced to identify, redact, and produce the source files Plaintiffs request. Defendants contend the estimated cost of production would be between $280,000 and $400,000. (Doc. No. 579 at 12, n. 7.) Although initially estimated as the cost for production of source files including pancreatitis as well as pancreatic cancer, Defendants argue the estimate may be even greater if required to produce source files located outside Defendants' centralized databases.[8] 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. Accordingly, the Court finds production of source documents and databases would be unduly burdensome.

///

///

///

---

[7] *See also Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989–90 (8th Cir. 2001); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995).

[8] The estimate for producing adverse event source documents and databases was originally prepared in March 2014, by Merck and included costs for production of source files related pancreatic cancer as well as pancreatitis. (*See* Doc. No. 554-1 at n. 25.) However, as Plaintiffs' current motion seeks to compel production of source documents and databases from all Defendants, the Court finds Merck's estimate instructive in considering the total time and cost associated with the production sought by Plaintiffs.

III. CONCLUSION

For the reasons set forth above, the Court **DENIES** Plaintiffs' motion to compel production of adverse event source documents and databases.

DATED: October 6, 2014

Hon. Anthony J. Battaglia
U.S. District Judge