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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED
THERAPIES PRODUCTS
LIABILITY LITIGATION

CASE NO. 13-md-2452 AJB (MDD)

**DEFENDANTS' OPPOSITION TO
MOTION TO COMPEL AGAINST ALL
DEFENDANTS FOR THEIR
COMMUNICATIONS WITH OR
RELATED TO CERTAIN FOREIGN
REGULATORY AGENCIES**

Date: September 29, 2014
Time: 10:00 a.m. (telephonic)
Judge: Hon. Anthony J. Battaglia
Magistrate: Hon. Mitchell D. Dembin

1 **I. INTRODUCTION**

2 The foreign regulatory material sought by Plaintiffs far exceeds the narrow
3 scope of current discovery, which is limited to issues of general causation and
4 preemption. The Court stated that “scientific documents and/or scientific evidence
5 frame the universe of contemplated discovery” as to general causation, and that
6 discovery is focused on “communications between the FDA and drug
7 manufacturers at issue and what the FDA had or did not have before it” as to
8 preemption. Doc. No. 567 at 2. Disregarding these limitations, Plaintiffs move to
9 compel “the written communications sent to or received from” all foreign
10 regulatory agencies “that have communicated with a Defendant about the
11 relationship between incretins and pancreatic cancer,” as well as all “internal
12 company communications regarding same.” (Pl. Mem. at 7.)

13 The requested discovery is irrelevant and, at best, duplicative of the
14 scientific evidence Defendants have produced. Plaintiffs claim that foreign
15 regulatory communications are of “obvious relevance” because they discuss
16 “scientific evidence” relating to pancreatic cancer. (Pl. Mem. at 1.) But Plaintiffs
17 overlook the fact that Defendants have *already produced* the scientific evidence
18 underlying their communications with regulators (domestic and foreign). In
19 particular, the data sources Defendants draw upon in responding to requests from
20 regulators—such as adverse event and clinical trial databases—*are global*, and
21 Defendants have produced information from these sources.

22 Moreover, the burden of complying with Plaintiffs’ demand far exceeds any
23 hypothetical benefit. As of February 28, 2014, each of the products at issue was
24 approved for use in scores of countries (Byetta (88); Januvia (127); and Victoza
25 (85)). Complying with Plaintiffs’ requests would require collection and review of
26 millions of pages of documents, in many different languages. In light of this
27 excessive burden, and the fact that the requested discovery is irrelevant and
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1 duplicative of information that has already been produced, Plaintiffs' motion
2 should be denied.

3 **II. ARGUMENT**

4 **A. Discovery Of Foreign Regulatory Communications Is Not** 5 **Reasonably Calculated To Lead To Admissible Evidence Of** 6 **General Causation**

7 Plaintiffs' primary argument in support of their motion to compel is that
8 foreign regulatory communications are of "obvious relevance" because "they
9 contain documents concerning whether the incretin drugs are capable of causing
10 pancreatic cancer." (Pl. Mem. at 1, 6.) But Plaintiffs' requests for foreign
11 regulatory materials are not "reasonably calculated to lead to the discovery of
12 admissible evidence" regarding general causation. Fed. R. Civ. P. 26(b)(1).

13 Communications with foreign regulators are irrelevant to general causation
14 and, at best, duplicative of scientific evidence Defendants have already produced.
15 The mere fact that a foreign agency has inquired about incretin-based therapies and
16 pancreatic cancer is irrelevant to general causation. For example, Plaintiffs attach
17 to their motion a handful of underwhelming communications with certain foreign
18 regulatory agencies, stating that these communications provide "probable cause"
19 for each agency. (Pl. Mem. at 3-5.) But these communications have no "tendency
20 in logic to prove or disprove whether Defendants' incretin mimetic drugs cause
21 pancreatic cancer," Order of Feb. 18, 2014 (Dkt. No. 325), because this
22 "anecdotal" evidence does not amount to scientific data and "is way beyond the
23 scope [of discovery] that the Court has narrowly crafted to date." Sept. 10, 2014
24 Hrg. Tr. at 26-27.

25 Courts have repeatedly recognized that communications with foreign
26 agencies reflect the differing requirements of individual countries, and have
27 excluded such evidence on that basis. "Each country has its own legitimate
28 concerns and its own unique needs which must be factored into its process of
weighing the drug's merits, and which will tip the balance for it one way or the

1 other.” *Harrison v. Wyeth Labs.*, 510 F. Supp. 1, 4-5 (E.D. Pa. 1980); *see also*,
2 *e.g.*, *In re Seroquel Prods. Liab. Litig.*, U.S. Dist. LEXIS 124798, at *289 (M.D.
3 Fla. Jan. 30, 2009) (“foreign regulatory actions have no relevance to Plaintiffs’
4 main case.”); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn.
5 2007) (excluding expert testimony on foreign regulatory matters for all purposes).
6 The handful of courts that have admitted limited evidence of foreign regulatory
7 materials in pharmaceutical cases have allowed it to show a defendant’s knowledge
8 of the alleged risk—liability questions which are not at issue here.¹

9 Plaintiffs nevertheless argue that foreign regulatory communications are
10 relevant because the communications discuss scientific data regarding incretin-
11 based therapies and pancreatic cancer. (*See* Pl. Mem. at 6.) However, Plaintiffs
12 have already received discovery of *the scientific data underlying Defendants’*
13 *communications with foreign regulators*. Defendants have produced, among other
14 materials, pre-clinical data, clinical data, epidemiological data, and post-marketing
15 adverse event data, as well as their complete regulatory files for the FDA and
16 EMA.² Defendants have produced their scientific data regardless of whether it was
17 submitted to FDA or any other regulatory agency. This body of scientific data is

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19 ¹ *See, e.g., Newman v. McNeil Consumer Healthcare*, 2013 U.S. Dist. LEXIS
20 113439, 39-40 (N.D. Ill. Mar. 29, 2013) (allowing evidence of foreign regulatory
21 materials as relevant to the “knowledge and willfulness of the manufacturer”).

22 ² Plaintiffs describe Defendants’ production of material from their EMA files
23 as “curious[,]” and claim that “the only logical difference between the EMA and
24 other Foreign Regulatory Files appears to be that Defendants believe that the EMA
25 may support some of their arguments . . . and that other Foreign Regulatory files
26 may counter some of their arguments.” (Pl. Mem. at 2 n.2.) But Defendants
27 agreed to produce material from their EMA files only because the FDA worked
28 jointly with EMA in assessing whether incretin-based therapies are linked to
pancreatic cancer, including the publication of a joint article by the FDA and EMA
in the *New England Journal of Medicine*. In such unique circumstances, there is
nothing “curious” about Defendants’ production of material from the EMA files.

1 not unique to any particular country. For example, Defendants’ adverse event and
2 clinical trial databases are global. Plaintiffs are also taking depositions of
3 personnel who worked in Defendants’ respective global safety organizations.

4 Plaintiffs make no showing that foreign regulatory files will provide new
5 scientific data not already available to them. On this critical point, Plaintiffs state
6 only that Defendants’ rejection of their proposal to “exclude documents already
7 submitted to the FDA” suggests that “the Foreign Regulatory Files contain
8 information *not* provided to FDA.” (Pl. Mem. at 2.) However, consistent with
9 Rule 26, counsel for Defendants have made reasonable inquiries and confirmed
10 that Defendants’ responses to foreign regulators would be based on the same
11 scientific data that Defendants relied upon in responding to FDA—and the same
12 scientific data which Defendants have already produced to Plaintiffs. Plaintiffs
13 accordingly have all the scientific data they need, and any additional document
14 production is therefore unwarranted. *See* Fed. R. Civ. P. 26(b)(2)(C)(i) (a court
15 “must limit” discovery that is “unreasonably cumulative or duplicative, or can be
16 obtained from some other source that is more convenient, less burdensome, or less
17 expensive”).³

18 Even if Defendants’ communications with foreign regulators were relevant
19 and not duplicative, the burden and expense of such discovery would far
20 “outweigh[] its likely benefit.” Fed. R. Civ. P. 26(b)(2)(C)(iii). Complying with
21 Plaintiffs’ request would require Defendants to collect and review their regulatory
22 files for each country in which their products are approved to determine whether

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25 ³ To be clear, Defendants did not actively exclude foreign regulatory materials
26 from their productions, as demonstrated by the exemplar documents that Plaintiffs
27 attach to their motion. Accordingly, Plaintiffs have already received information
28 concerning foreign regulatory communications to the extent they appear in the
custodial files that were produced.

1 any communications regarding pancreatic cancer exist in the file, and then prepare
2 for production the regulatory files of any country with which there were such
3 communications. A large volume of these documents are in foreign languages, and
4 Defendants would need to hire attorneys with the requisite foreign-language
5 abilities to review them. And many documents submitted to foreign regulatory
6 agencies contain information such as patient identifying information, which must
7 be carefully redacted prior to production. Moreover, many countries have their
8 own particularized laws or regulations regarding privacy that could require
9 additional scrutiny and redaction.

10 Such a production would be a very large and expensive undertaking. As of
11 February 2014, Byetta was approved in 88 countries, Januvia in 127 countries, and
12 Victoza in 85 countries. Not all countries require submission of as much data as
13 the FDA or EMA, but Defendants' productions of their FDA and EMA regulatory
14 files are a useful reference. For Byetta, the FDA regulatory file contained over 1.4
15 million pages, and the EMA file over 500,000 pages. For Januvia, the FDA file
16 contained over 400,000 pages plus 2.29 gigabytes of native data, and the EMA file
17 over 1.6 million pages. For Victoza, the FDA file had over 1.4 million pages, and
18 the EMA file over 49,000 pages. Thousands of hours of attorney time was
19 required to prepare these files for production. To accomplish what Plaintiffs now
20 demand would multiply that figure by the number of foreign regulatory files
21 requiring review and production, with the added burden of hiring foreign-language
22 attorneys to review some of these files.⁴

23 _____
24 ⁴ Plaintiffs suggested that the burden of production would be lessened if
25 Defendants cull documents already submitted to FDA from any foreign regulatory
26 production. (Pl. Mot. at 2-3.) But all of the files would still have to be collected
27 and reviewed. Plaintiffs' proposed limitation would therefore only add the
28 additional burden of comparing the documents in the foreign files to the documents
in the FDA files, a task that can only be done manually.

1 And Plaintiffs’ motion is not even limited Defendants to communications
2 between the Defendants and foreign regulatory agencies – Plaintiffs also seek
3 emails and any other “internal company communications related to the Foreign
4 Regulatory Files.” (Pl. Mem. at 1.) To locate such information would require
5 Defendants to interview regulatory employees from every country in which
6 Defendants’ products are marketed, and collect and review potentially hundreds of
7 custodial files. Such an undertaking far exceeds the scope of discovery that the
8 Court has permitted at this time. *See* Sept. 10, 2014 Hrg. Tr. at 26-27 (discovery is
9 to focus on the “scientific data,” production of every “anecdotal note or
10 communication is way beyond the scope” of permitted discovery.”)

11 The limited hypothetical utility of the requested discovery pales in
12 comparison to the burden it would impose. Plaintiffs have not cited a single case
13 where such broad foreign regulatory discovery—or indeed *any* foreign regulatory
14 discovery—was permitted, and their motion falls far short of establishing a need
15 for such materials as part of general causation discovery here.

16 **A. Discovery Of Foreign Regulatory Communications Is Not**
17 **Reasonably Calculated To Lead To Admissible Evidence**
18 **Regarding Preemption**

19 Plaintiffs’ alternative basis for discovery of foreign regulatory materials is
20 even less persuasive. As the Court has recognized, preemption discovery must
21 focus on “what *the FDA* would or would not have done with regards to a proposed
22 labeling change” for pancreatic cancer. Order of Aug. 14, 2014 (Dkt. No. 567)
23 (emphasis added). Foreign regulatory materials, which reflect how some other
24 agency may have evaluated safety and labeling issues under their own regulatory
25 standards and requirements, have no bearing on this inquiry. *See* pp. 2-3, *supra*.
26 Plaintiffs speculate that the production of foreign regulatory files might reveal
27 “instances of under-reporting or misreporting to the FDA,” and that this
28 hypothetical under-reporting or misreporting might have affected the FDA’s
determination. (Pl. Mem. at 6). This argument fails for at least two reasons.

1 *First*, Plaintiffs have no basis, other than rank speculation, to surmise that
2 Defendants did not provide FDA with all requisite information. Speculation,
3 however, does not justify the enormous burden of foreign regulatory discovery.
4 *See Dichter-Mad Family Partners, LLP v. United States*, 709 F.3d 749, 751 (9th
5 Cir. 2013) (“A plaintiff seeking discovery must allege enough fact to raise a
6 reasonable expectation that discovery will reveal the evidence he seeks”) (internal
7 citations omitted); *Rivera v. NIBCO, Inc.*, 364 F.3d 1057, 1072 (9th Cir. 2004)
8 (“District courts need not condone the use of discovery to engage in ‘fishing
9 expeditions.’”). In any event, Defendants have already produced the actual
10 scientific data on which their responses to the FDA (and foreign regulatory
11 agencies) were based, *see pp. 3-4, supra*, and Plaintiffs can investigate their
12 speculation concerning under-reporting and misreporting by analyzing that data
13 and comparing it to Defendants’ submissions to the FDA. In light of Plaintiffs’
14 access to that underlying data, Plaintiffs fail to demonstrate that discovery of
15 foreign regulatory communications is necessary.

16 *Second*, Plaintiffs are precluded from relying on a “fraud-on-the-FDA”
17 argument, because it would “conflict with the FDA’s responsibility to police fraud
18 consistently with the Administration’s judgment and objectives.” *Buckman Co. v.*
19 *Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347-48 (2001). Here, Plaintiffs’ stated goal
20 in seeking the discovery is to support their theory that Defendants’ hypothetical
21 “fraud-on-the-FDA” might have impacted the FDA’s assessment of incretin-based
22 therapies and pancreatic cancer. (*see Pl. Mem. at 6.*) As the MDL court
23 overseeing the Fosamax litigation explained, any such theory must fail:

24 Moreover, to the extent that Plaintiffs claim that Merck
25 withheld information from the FDA and clear evidence does
26 not exist as to whether the FDA, if fully informed, would
27 have rejected a stronger label, this does not defeat
28 Defendant’s showing that it is entitled to judgment as a
 matter of law on preemption grounds Plaintiffs’
 contention appears to be a fraud-on-the-FDA theory which

1 was rejected by the Supreme Court in *Buckman*, or
2 alternatively, is based largely on speculation and cannot
3 defeat summary judgment.

4 *In re Fosamax*, 2014 U.S. Dist. LEXIS 42253, 57-58 (D.N.J. Mar. 26, 2014)
5 (citations omitted).⁵ Here, as in *Fosamax*, Plaintiffs' allegations of misreporting
6 are entirely speculative and irrelevant.

7 **III. CONCLUSION**

8 For the foregoing reasons, the Court should deny Plaintiffs' Motion to
9 Compel Against All Defendants for Their Communications with or Related to
10 Certain Foreign Regulatory Agencies.

11
12 Dated: September 24, 2014

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24 ⁵ Plaintiffs cite *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013). (Pl.
25 Mem. at 6.) But Plaintiffs previously acknowledged that *Stengel* "has no
26 relationship to us whatsoever," because it was a case covered by the Medical
27 Device Act, which requires plaintiffs to make a separate state law claim alleging
28 violation of FDA regulations in order to avoid preemption. *Seufert v. Merck, et al.*,
July 31, 2014, Hrg. Tr. at 39-40.

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s/ Stephen P. Swinton

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2 I am employed in the County of San Diego, State of California. I am over
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5 On September 24, 2014, I served the following document described as:

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7 **AGAINST ALL DEFENDANTS FOR THEIR COMMUNICATIONS**
8 **WITH OR RELATED TO CERTAIN FOREIGN REGULATORY**
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20 I declare that I am employed in the office of a member of the Bar of
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22 was made and declare under penalty of perjury under the laws of the State of
23 California that the foregoing is true and correct.

24 Executed on September 24, 2014, at San Diego, California

25 _____
26 /s/ Stephen P. Swinton
27
28