UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

IN RE PRADAXA	)	**MDL No. 2385**
(DABIGATRAN ETEXILATE)	)	**3:12-md-02385-DRH-SCW**
PRODUCTS LIABILITY	)	
LITIGATION	)	

This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER No. 19
Regarding BIPI's Motion for a Protective Order

HERNDON, Chief Judge:

I. INTRODUCTION

This matter is before the Court on the defendant's, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), motion for a protective order regarding the plaintiffs' second set of interrogatories and second request for production of documents (Doc. 75). BIPI bases its request for a protective order on the following: (1) the plaintiffs' discovery requests seek information not relevant to any claim or defense in this Multidistrict Litigation ("MDL") or reasonably calculated to lead to any relevant, admissible evidence; (2) the plaintiffs discovery requests improperly seek information about products not related to this MDL; (3) the plaintiffs' discovery requests would subject BIPI to undue burden and

expense; and (4) the plaintiffs' discovery requests will thwart the Court's efforts to expeditiously advance this litigation.

After review and consideration of the parties written[1] and oral arguments,[2] and for the reasons discussed herein, the Court **DENIES** BIPI's motion for a protective order.

II. BACKGROUND[3]

A. The "Whistleblower" Action

Approximately 8 years ago, a former BIPI employee, Robert Heiden, filed a "whistleblower" (or "*qui tam*") action regarding four drugs: (1) Aggrenox, a prescription medication to lower the risk of stroke in people who have had either a transient ischemic attack or "mini-stroke" or stroke due to a blood clot; (2) Atrovent, an aerosol prescription medication approved for treatment of bronchospasms associated with chronic obstructive pulmonary disease; (3) Combivent, an aerosol prescription medication for patients with chronic obstructive pulmonary disease; and (4) Micardis, a prescription medicine used to

[1] The plaintiffs' filed a response to BIPI's motion on January 7, 2013 (Doc. 80) and BIPI filed a reply on January 11, 2013 (Doc. 83).
[2] The Court heard the parties' oral arguments on January 14, 2013.
[3] The background is taken from the parties' pleadings and the exhibits attached thereto. As well as the information provided after oral argument regarding BIPI's voluntary Compliance Program.

treat high blood pressure.[4] All of these drugs were approved by the FDA in the mid – to late – 1990s. Pradaxa was approved by the FDA in October 2010.

The *qui tam* action, filed under the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), and the FCA's state-law counterparts, alleged that BIPI "illegally promoted [Micardis, Atrovent, Combivent, and Aggrenox] through the use of a pervasive scheme to induce physicians to prescribe these drugs through kickbacks, unsubstantiated representations about drug efficacy, and other illegal conduct." (Doc. 80-2 ¶ 2). Amongst the allegations at issue were claims that BIPI (1) improperly promoted and marketed their products by making unsubstantiated, unwarranted, and/or off-label claims; (2) overstated the efficacy of their products in comparison to competitor's products; and (3) engaged in illegal remuneration and kickbacks to medical providers.

The *qui tam* action culminated with a settlement agreement on October 22, 2012. As part of the settlement, BIPI entered into a Corporate Integrity Agreement ("CIA"), which governs BIPI's conduct as it relates to all of BIPI's drugs, including Pradaxa. The CIA acknowledged that prior to the effective date of the CIA, "BIPI established a voluntary compliance program applicable to all BIPI officers, managers, and employees" ("Compliance Program") (Doc. 80-3 p. 1). According to the CIA, the Compliance Program included (and would continue to

[4] BIPI states that only three drugs, Aggrenox, Combivent, and Micardis, were involved in the *qui tam* action. The plaintiffs response and attached exhibits indicate that a fourth drug, Atrovent (which appears to be similar to Combivent) was also involved in the *qui tam* action.

include) "a Code of Conduct, written policies and procedures, educational and training initiatives, a disclosure program, investigation of potential compliance violations, disciplinary procedures, and regular internal auditing procedures." *Id*.[5] The CIA also stated as follows:

> The Code of Conduct includes, or within 90 days after the Effective Date, shall be revised to address or include the following:
>
> a. BIPI's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions; [6]
>
> b. BIPI's requirement that all of its Covered Persons[7] shall be expected to comply with all applicable Federal health care program requirements, FDA Requirements, and with BIPI's own Policies and Procedures;

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[5] *See also* (Doc. 80-3 p. 7) ("Prior to the [CIA] Effective Date, BIPI developed, implemented, and distributed a written code of conduct to all Covered Persons who are BIPI employees. This code is known as BIPI's Code of Conduct and Corporate Integrity (Code of Conduct). BIPI makes, and shall continue to make, adherence to the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons.").

[6] According to the CIA, the term "Covered Functions" refers to "Promotional Functions" and "Product Related Functions'" (Doc. 80-3 p. 3). The term "Promotional Functions" includes: "(a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees." *Id*. The term "Product Related Functions" includes, among other things, "the preparation or external dissemination of non-promotional materials that are governed by Federal health care program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products…" *Id*.

[7] According to the CIA, the term "Covered Persons" includes all owners of BIPI, all employees of BIPI, and all contractors, subcontractors, agents, and other persons who perform any "Covered Functions" as that term is defined by the CIA (Doc. 80-3 p. 2).

> c. BIPI's requirement that all Covered Persons shall be expected to report to the CECO, or other appropriate individual designated by BIPI, suspected violations of any Federal health care program requirements, FDA requirements, or of BIPI's own Policies and Procedures;
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> d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and BIPI's Policies and Procedures; and
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> e. the right of all individuals to use the Disclosure Program described in Section III.E. and BIPI's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures

(Doc. 80-3 p. 8).

The CIA does not indicate the effective date of the Compliance Program. At the Court's request, BIPI reviewed the issue and reports the Compliance Program was implemented in 2001. According to BIPI, since the Compliance Program was implemented in 2001, it has evolved including modifications in 2010 (the year Pradaxa was approved by the FDA). As noted above, the CIA, adopted in 2012, was a continuation of the Compliance Program that placed additional obligations on BIPI.

B. Overview of the Plaintiffs' Discovery Requests

The plaintiffs' discovery requests ask BIPI to respond to interrogatories and produce documents regarding "any lawsuit alleging that BIPI (a) engaged in off-label promotion of any medicine, (b) marketed or promoted any medicine for use that was not approved by the FDA or (c) paid "kick-backs" or other benefits to physicians to induce them to prescribe any BIPI medicine" (*See e.g.* Doc. 77 Rog.

1). The plaintiffs ask BIPI to identify (a) witnesses related to any such lawsuit; (b) employees who provided input or were responsible for implementing changes to procedure, policies, or reviews related to any such lawsuit; (c) employees accused of engaging in off-label promotion or "kick-backs;" employees who gave testimony or sworn statements related to any such lawsuit. The plaintiffs also ask BIPI to describe the settlement details of any such lawsuit (Docs. 77, 75-2).

III. THE PARTIES' ARGUMENTS

With regard to relevancy, BIPI raises several arguments. First, BIPI contends that because Pradaxa is the only medication at issue in this MDL, evidence relating to other medications is irrelevant. Second, BIPI contends that this litigation has nothing to do with marketing. As support for this claim, BIPI notes that the plaintiffs' complaints do not specifically allege "off-label marketing" or "Kick-backs" in relation to Pradaxa. Instead, BIPI insists, the allegations in this MDL are solely limited to product liability claims premised on alleged personal injury; therefore, any evidence related to the Food and Drug Administration, the Department of Justice, or any other Federal agency regarding off-label marketing or "kick-backs" is irrelevant and not discoverable. Finally, BIPI argues that the disputed discovery is irrelevant because it seeks information about products and events that predate Pradaxa's approval, marketing and sales, and dates of alleged injury in this MDL.

BIPI also raises arguments with respect to the burden of production. BIPI contends that because the information being sought is irrelevant and far exceeds the scope of this MDL, obtaining the information will impose a great expense and an undue burden. Likewise, BIPI contends, a great deal of time and effort will be diverted to comply with the plaintiffs' discovery requests (if permitted) which will hinder BIPI in its efforts to comply with the Court's stated goal of an expeditious handling of this litigation.

The plaintiffs counter by arguing that rather than seeking information about other products, they are seeking information about BIPI's marketing related conduct. The plaintiffs note that a number of complaints allege that BIPI over-promoted the efficacy of Pradaxa and otherwise engaged in improper marketing of the product. The plaintiffs argue that their discovery requests seek information about any lawsuits involving similar promotional or marketing conduct, including the *qui tam* action which resulted in the CIA that governs BIPI's conduct relative to all of its drugs, including Pradaxa. The evidence potentially to be developed then, the plaintiffs contend, is relevant as Federal Rule of Evidence 404(b) conduct evidence to show BIPI's intent, plan or lack of mistake in engaging in certain sales practices that resulted in the over-promotion or otherwise improper marketing of Pradaxa.

The plaintiffs also contend that BIPI's alleged improper expansion of the approved indication for Pradaxa is at issue in this litigation. The plaintiffs allege that such expansion was pursued through the over-promotion of Pradaxa and

assure the Court that many, if not all, of the complaints assert claims pertaining to the over promotion or otherwise inappropriate marketing of Pradaxa.

Additionally, the plaintiffs contend that an appropriate consideration for discovery is to allow litigants the opportunity to gather sufficient evidence to permit appropriate cross examination through impeachment. The plaintiffs argue, in the event that a BIPI witness denies claims of over promotion or otherwise improper marketing by suggesting that BIPI would not engage in such conduct, the plaintiffs should have access to relevant conduct for the purpose of impeachment.

Finally, the plaintiffs contend that evidence of repeated improper conduct is relevant on the issue of punitive damages.

IV. RELEVANT LEGAL AUTHORITY

The federal discovery rules are liberal in order to assist in the preparation for trial and settlement of litigated disputes. *See Bond v. Utreras*, 585 F.3d 1061, 1075 (7th Cir. 2009). Pursuant to Federal Rule of Civil Procedure 26(b)(1), "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense ... Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1).

V. ANALYSIS

A. Preliminary Matter – Request to Unseal Document 81

In support of their response to BIPI's motion for a protective order, the plaintiffs' filed a document under seal ("Document 81") (Doc. 81). Document 81, was produced by BIPI and designated as confidential in accord with Case Management Order Number 2 (Doc. 5). At oral argument, the plaintiffs requested that the Court unseal Document 81 based on BIPI's request for an on-the-record oral argument related to the subject motion. The plaintiffs' request is **DENIED**. Case Management Order Number 2, provides a procedure for challenging a producing party's confidentiality designation (Doc. 81 ¶ 13). If the plaintiffs have a good faith belief that BIPI's confidentiality designation with regard to Document 81 is improper, they should initiate the procedure established in Case Management Order Number 2 for challenging confidentiality designations.

B. BIPI's Motion for a Protective Order

BIPI's request for a protective order to prevent it from responding to the plaintiffs' discovery requests is premised on the position that there is no issue in this litigation relative to how Pradaxa was marketed. Based on the complaints that have been reviewed by the Court and the arguments of the plaintiffs, this position is not well founded.[8] The plaintiffs have clearly asserted allegations

[8] Indeed, in July 2012 (prior to the creation of this MDL) the Court issued several orders resolving BIPI's motions to dismiss a number of cases that are now part of

related to the manner in which Pradaxa was marketed. Whether the plaintiffs' have specifically used the terms "off-label marketing" or "kick-backs" is not determinative. Accordingly, discovery into issues related to the marketing of Pradaxa, whether there was off-label promotion, over-promotion, misleading promotion, and the like is clearly relevant.

The *qui tam* lawsuit involves allegations that between 2000 and 2008, BIPI engaged in activity that amounted to off-label marketing and over-promotion of four BIPI products. The lawsuit also contains allegations that BIPI offered improper financial inducements to encourage doctors to write prescriptions for these four products. The conduct and events at issue in the *qui tam* lawsuit occurred in close temporal proximity and are similar to the allegedly improper marketing conduct at issue in this litigation. Certainly, the plaintiffs are entitled

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this MDL. Those orders include a detailed review of the claims asserted, many of which obviously involve claims about the manner in which Pradaxa was marketed. *See e.g. Boston v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 2012 WL 3021413, *2-*3 (S.D. Ill. July 24, 2012) (Herndon, C.J.) (noting the following allegations in the plaintiff's complaint: (1) "BIPI made affirmative misrepresentations regarding the efficacy, safety risk profile, and additional benefits of Pradaxa;" (2) inadequacies and affirmative misrepresentations were "included in the Pradaxa Marketing Campaign and in Pradaxa's labeling and prescribing information;" (3) the plaintiff and her physician relied on information disseminated by BIPI in its Pradaxa marketing campaign; (4) the Pradaxa marketing campaign included "detailing sessions" with physicians and "direct-to-consumer" advertising which overstated the effectiveness and benefits of Pradaxa; (5) the Pradaxa marketing campaign overstated the effectiveness and benefits of Pradaxa; (6) the Pradaxa marketing campaign improperly promoted Pradaxa as being more effective and convenient than its competitor's product; and (7) the Pradaxa marketing campaign failed to adequately disclose the risk and safety information relating to Pradaxa).

to inquire into allegations of improper marketing conduct similar to the improper marketing conduct alleged here.

The fact that the *qui tam* action involved drugs other than Pradaxa does not make the information irrelevant for purposes of discovery. It is entirely possible that the marketing policies and strategies at issue in the *qui tam* action extended to BIPI's marketing of Pradaxa. Thus, the plaintiffs' inquiry into those marketing practices and the individuals involved in those marketing practices appears to be reasonably calculated to lead to discovery of admissible evidence and is an appropriate subject of discovery. That is not to say that any evidence obtained regarding the *qui tam* lawsuit will necessarily be admissible. Admissibility, however, is not the question before the Court. The question before the Court is whether the discovery requests satisfy the relevancy requirements set forth by Rule 26. Considering the marketing allegations at issue in this litigation, and for the reasons discussed above, the Court finds that the discovery requests satisfy the relevancy requirements of Rule 26.

Likewise, other lawsuits or allegations that BIPI engaged in similar improper marketing conduct are an appropriate area of inquiry, subject to reasonable time constraints. The plaintiffs' discovery requests currently provide no timeframes for the requests about "any lawsuit." The Court finds that absent an appropriate timeframe these requests are overly broad. Accordingly, the Court will limit these requests to any lawsuits filed during the year 1990 or later. The

Court finds that lawsuits filed prior to 1990 are too remote in time to be relevant.[9] Should evidence emerge indicating that the improper marketing conduct alleged in the *qui tam* action was common practice prior to 1990, the Court will consider expanding the relevant period of time.

In addition to the above, the prior conduct is appropriate for the purpose of Federal Rule of Evidence 404(b). Rule 404(b) potentially allows evidence of other acts of a defendant to be admitted at trial to prove motive, intent, plan, common scheme, and the like.[10] Once again, the manner in which Pradaxa was marketed is an issue in this litigation. Accordingly, prior conduct related to off-label marketing or over-promotion is potentially admissible under Rule 404(b) for the stated issues of intent and plan. Because the information sought is relevant and potentially admissible under Rule 404(b), discovery of evidence of other acts by BIPI is permissible under Rule 26.

With regard to the CIA, BIPI contends that it is not relevant because it was entered into in October 2012, approximately two years after Pradaxa was

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[9] The Court notes that BIPI has indicated that it is not presently aware of any litigation similar to the *qui tam* action discussed in this case.

[10] Rule 404(b) provides, in pertinent part:

> Crimes, Wrongs, or Other Acts.
>
> (1) Prohibited Uses. Evidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character. (2) Permitted Uses; Notice in a Criminal Case. This evidence may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.

approved by the FDA. However, the CIA is a continuation of BIPI's voluntary Compliance Program, effective 2001 and modified in 2010 (the year Pradaxa was approved). Clearly, there is a great deal of relevant inquiry regarding BIPI's marketing conduct as it relates to the Compliance Program, which was in effect before, during and after Pradaxa's approval in October 2010. As to the CIA itself, the Court notes that in this vast litigation cases are being filed on an ongoing basis. It is likely that later filed cases will involve conduct occurring after the CIA's enactment in 2012. Accordingly, although the CIA may not be relevant to conduct occurring prior to its enactment in 2012, it is certainly relevant to those cases involving conduct occurring after its enactment in 2012.

As to the parties' punitive damages arguments, the Court finds that the issue need not be resolved at this time. For the reasons discussed above, the Court finds that the information the plaintiffs are seeking is relevant and discoverable. Whether the information sought is or is not admissible on the question of punitive damages is a question for another day.

With regard to the burden on BIPI, from a cost benefit analysis, the Court finds that this evidence is extremely probative. The identity of witnesses and documentation sought is not that extensive in relative terms. The *qui tam* lawsuit did not end all that long ago. Thus, the information pertaining to that lawsuit will surely still be readily obtainable. With regard to other similar lawsuits or allegations, as noted above, the Court has limited such requests to lawsuits filed in 1990 or later. With the Court's temporal limitation, to the extent that any such

lawsuits exist (and BIPI has indicated that they are not aware of any such lawsuits), the information should be readily obtainable.

Finally, the Court does not view the matter as a detriment to its objective of efficient, effective and expedited litigation.

VI. CONCLUSION

For the reasons discussed herein, BIPI's motion for a protective order is **DENIED**. Further, the plaintiffs' request, made during oral argument, to unseal Document 81 is **DENIED.**

IT IS SO ORDERED.

David R. Herndon

Digitally signed by David R. Herndon
Date: 2013.01.18 13:19:59 -06'00'

Chief Judge
United States District Court

Date: January 18, 2013