April 2, 2018

VIA ECF

Hon. Claire C. Cecchi, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Bldg. & U.S. Courthouse
Courtroom MLK 5B
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Re: Proton-Pump Inhibitor Products Liability Litigation, 2:17-md-2789 (CCC)(MF) (MDL 2789)
Proposed Bundled Complaints Case Management Order

Dear Judge Cecchi:

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On behalf of Defendants, we write in response to the letter of Plaintiffs' Steering Committee ("PSC"), dated March 27, 2018, and the PSC's proposed Case Management Order regarding bundled complaints (the "Proposed Bundling CMO"). As set forth below, the PSC's proposed order should be rejected because it would directly contradict recently entered Case Management Order No. 7 (the "Direct Filing CMO") and undercut Case Management Order No. 9 (the "PFS Enabling Order"). Not only are these unilateral rewrites unnecessary, they would substantially prejudice Defendants and undermine the parties' lengthy meet and confer processes that yielded the two agreed-upon orders. The Proposed Bundling CMO is also improper, as it is an attempt by Plaintiffs to achieve tolling, suspend their Rule 11 obligations, and avoid substantial filing fees, without the consent of Defendants. Similar bundling proposals have been rejected by multiple other MDL courts and this one should be no exception.

As an initial matter, the Proposed Bundling CMO is unnecessary. After many months of negotiations, the PSC and Defendants agreed to a Direct Filing CMO, which provided a mechanism for Plaintiffs' counsel to directly file individual short-form complaints while complying with their basic obligations of due diligence prior to naming a defendant in a complaint. Defendants agreed to the Direct Filing CMO only after the PSC agreed to remove bundling. Had the PSC refused to remove the bundling provision, the Defendants would not have agreed to the Direct Filing CMO. Section III.J of the Direct Filing CMO provides:

> **Single-Plaintiff Filings**. Actions filed directly in this Court pursuant to this Order ***shall not name more than a single plaintiff in the case***, provided, however, that any such case may include consortium and/or derivative plaintiff(s) and, in the event of a wrongful death action, the representative(s) and/or distributees of the estate. (Emphasis added.)

Plaintiffs aggressively sought the direct filing order in this action, and Defendants made a number of concessions toward the goal of coming up with a mutually agreeable complaint-filing mechanism. With the ink barely dry on the Direct Filing CMO, the PSC now improperly seeks tolling via the filing of bundled complaints. The PSC contends this new approach is required because "[o]ver the past year, Plaintiffs' counsel have come to better understand that the rampant use of PPIs over the past 30 years has resulted in thousands of potential claims and that obtaining medical and pharmacy records that span decades is an arduous and time-consuming task." Ltr. at 2. But this is not a new development in the last two months since the Direct Filing CMO was entered. Members of the PSC, a very experienced group, have known about the volume of potential claims and the history of PPI products long before this MDL was established. Almost 18 months ago, in October 2016 (in an initial petition seeking an MDL proceeding), a leading member of the PSC stated that he had "over 5,000 Proton-Pump Inhibitor ("PPI") possible cases under investigation with additional potential clients making contact and asking for information each passing day." *In re Proton-Pump Inhibitor Prods. Liab. Litig.* (MDL No. 2757), Doc. No. 1-1, Mem. of Law in Support of Plaintiffs' Mot. for Transfer Pursuant to 28 U.S.C. § 1407, filed Oct. 17, 2016, at 1. There have been numerous similar representations from Plaintiffs' counsel in this Court and others. Accordingly, despite assembling case inventories for well over a year, some Plaintiffs' counsel have not done the requisite work to determine whether their clients have potential PPI claims appropriate for this MDL and, if so, who the proper defendants are.

The PSC was absolutely aware of this litigation's potential size when it agreed to remove the bundling provision from the Direct Filing CMO.[1] The single

[1] In September 2017, the PSC's initial draft of the Direct Filing CMO included such a provision. On October 3, 2017, Defendants objected to the PSC's proposal. On October 16, 2017, the PSC agreed to remove that provision and the parties proceeded to negotiate on the premise that only individual plaintiff complaints would be filed. Although the parties disagreed regarding various terms of the Direct Filing CMO in their submissions to the Court (in November and December of last year), the PSC agreed to single-plaintiff filings and did not raise any issue about the potential difficulty in assessing claims as an impediment to direct filings. Without such a concession by the PSC, Defendants would not have agreed to the Direct Filing CMO that was ultimately entered in this case.

plaintiff filing provision was critical for Defendants to agree to the Direct Filing CMO. The PSC's sudden urgency to reverse this agreed-upon language is troubling, amounting to nothing more than an abrogation of applicable statutes of limitations as well as counsel's concomitant obligation to diligently and timely investigate claims. Moreover, the timing of Plaintiffs' bundling proposal – less than two months after the entry of the Direct Filing CMO – suggests that Plaintiffs never intended to proceed pursuant to the Direct Filing CMO that Defendants assumed was negotiated in good faith.

The Proposed Bundling CMO would also undermine the PFS Enabling Order, which allows plaintiffs 120 days (90 days plus a 30-day grace period) after filing their complaints to complete a PFS and produce records demonstrating use of Defendants' products. As Your Honor may recall, this 120-day period is, again, the result of a compromise following months of negotiations where Defendants sought a shorter period and Plaintiffs sought a longer one. The Proposed Bundling CMO would negate this heavily negotiated compromise by giving the Plaintiffs nine months (more than twice the agreed-upon time) to meet these basic obligations. The Defendants would not have stipulated to entry of the PFS Enabling Order if Plaintiffs were given nine months to merely collect their own medical and pharmacy records.[2]

The PSC asserts that the Proposed Bundling CMO is helpful to Defendants in that "it accelerates discovery that they have requested and saves them time and money in not having to Answer complaints . . ." Ltr. at 3. As an initial matter, Defendants have already agreed to answer the Short-Form Complaints with a Short-Form Answer, per the agreed-upon Direct Filing CMO. Moreover, the answering of the Complaint by Defendants triggers the production of a Plaintiff Fact Sheet and production of the requisite records under the PFS Enabling Order, which is a more robust production, and under a much shorter timetable, than what the Proposed Bundling CMO contemplates.

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[2] The Proposed Bundling CMO also undermines the PFS Enabling Order because, even after nine months, "evidence of PPI use may be satisfied by an Affidavit executed by Plaintiff." *See* ¶ I, n.1. But the reason plaintiffs purportedly need the extra time is to obtain medical and pharmacy records. If plaintiffs are afforded additional time to obtain those records and can only muster an affidavit, their claims should be dismissed. The parties previously agreed in the PFS Enabling Order that, even in a permitted single-plaintiff case, an affidavit will not suffice to advance the case to further discovery (and is deemed a "Stage 2" case). Thus, there is a mechanism already in place to address those cases in which the only "proof" of use is an affidavit.

In essence, the PSC is requesting a nine-month suspension of the requirements that plaintiffs have a good faith basis for asserting claims against the named defendants. The PSC states the time is needed so their claims are "adequately vetted," admitting that they have not done so when filing their bundled complaints. Permitting this Proposed Bundling CMO would give plaintiffs the otherwise-unauthorized right "to join parties, make claims, or present defenses without any factual basis or justification." *See* Fed. R. Civ. P. 11, 1993 Amendments, Advisory Cmte. Note.

Furthermore, the proposed bundling is prejudicial to Defendants. Under the proposal, there is no requirement for any bundled complaint to have a good faith basis to allege that the potentially hundreds of Plaintiffs in the complaint ingested the named Defendants' products. The PSC concedes that it does not yet have records for these potential Plaintiffs. This will exponentially increase the number of Plaintiffs asserting claims against various Defendants, requiring those Defendants to report, process and monitor such claims, regardless of whether the Plaintiffs are ultimately able to produce underlying records. Specifically, for FDA and global regulatory purposes, each alleged claim is an "adverse event" that triggers regulatory obligations that could overburden the Defendants' internal Patient Safety and Regulatory teams – or put differently, a complaint with 300 Plaintiffs triggers 300 separate internal reviews and 300 individual case reports that need to be filed with the FDA and regulators throughout the world with the potential for periodic follow-up reports thereafter.

Such prejudice to Defendants is not theoretical, but actual. Even without entry of the Proposed Bundling CMO, certain firms on the PSC have begun filing hundreds of short-form complaints which assert allegations against every manufacturer regarding every PPI. Some complaints on their face are implausible, such as alleging usage when certain of the named products were not even on the market. Such shotgun filings have exponentially increased the size of this MDL and have already turned it into a parking ground for non-meritorious cases. Entry of the Proposed Bundling CMO would exacerbate this problem.

If Plaintiffs' proposed CMO is entered, this MDL will rapidly mushroom in size with non-meritorious claims. This highlights Judge Land's precise concern when he observed:

> "MDL consolidation for products liability actions does have the unintended consequence of producing more new case filings of marginal merit in federal court, many of which would not have been filed otherwise. . .

> . At a minimum, transferee judges should be aware that they may need to consider approaches that weed out non-meritorious cases early, efficiently and justly. The undersigned has struggled with the best way to accomplish that. Hopefully, the robust use of Rule 11 will help."

In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig., No. 4:08-MD-2004 (CDL), 2016 WL 4705827, at *2 (M.D. Ga. Sept. 7, 2016).

It is no surprise, then, that the use of bundled complaints has been routinely rejected by MDL courts, including those in New Jersey. *See, e.g.*, *In re Invokana Prods. Liab. Litig.*, No. 3:16-md-02750 (D.N.J. May 5, 2017) ("From the date of this order, no multi-plaintiff complaint may be directly filed in the MDL"); *In re Johnson & Johnson Talcum Powder Prods. Marketing, Sales Practices and Prods. Liab. Litig.*, No. 3:16-md-2738 (D.N.J. Dec. 6, 2016) ("Multi-plaintiff complaints may not be filed in this MDL proceeding"); *In re Prempro Prods. Liab. Litig.*, Nos. 4:03-cv-1507 & 4:09-cv-00021 (E.D. Ark. Jan. 14, 2009) (expressing "disfavor" with "generic, omnidirectional complaints . . . Simply claiming that you took hormone therapy and suing every hormone therapy manufacturer . . . is not enough"). The PSC cites no authority for the Proposed Bundling CMO, which should be rejected here as prejudicial to Defendants and the Court.

Finally, as previously raised with the Court, Defendants' consent to any direct filing order is required due to the personal jurisdiction and venue infirmities – in addition to the circumvention of the ordinary MDL transfer procedures under 28 U.S.C. § 1407 – implicated by such orders. *See* Ltrs. dated Nov. 6, 2017 & Dec. 13, 2017*; see also In re Samsung Top-Load Washing Machine Marketing, Sales Practices and Prods. Liab. Litig.*, No. 5:17-ml-02792 (W.D. Okla. Jan. 12, 2018) ("Without consent of both parties, direct filing is at odds with the mandate of 28 USC § 1407 and *Lexecon* . . . prohibiting a transferee court from transferring new cases to itself"). Defendants do not consent to any direct filings other than by individual plaintiffs, pursuant to the negotiated terms of the Direct Filing CMO. The PSC's agreement to single plaintiff complaints was a prerequisite for Defendants to negotiate a direct filing order, and was acceded to by the PSC in October.

Therefore, the PSC's latest proposal directly contravenes the PSC's prior agreements, this Court's Direct Filing CMO and PFS Enabling Order, and the holdings of other MDL courts. In addition, the PSC lacks Defendants' consent to either toll the statute of limitations or directly file their out-of-state claims in this forum. Calling the proposal a "temporary" CMO remedies neither the inconsistency

with the agreed upon Direct Filing CMO issued only two months ago nor the fundamental flaws of such a process. Accordingly, the Court should reject the PSC's proposal without further consideration.[3]

Respectfully submitted,

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[3] However, if the Court seriously entertains the PSC's reversal of position on this very important and prejudicial issue, the Defendants would like to be heard and, if necessary, have an opportunity to further brief the issue.

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