UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE : ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	MDL NO. 1:15-md-2657-FDS This document relates to: All Actions

DEFENDANT GLAXOSMITHKLINE LLC'S RESPONSE IN OPPOSITION TO PLAINTIFFS' STEERING COMMITTEE'S MOTION FOR ENTRY OF MDL ORDER NO. 25 APPOINTING A SETTLEMENT MASTER

Appointment of a special master would not be a prudent use of the Court's and the parties' resources. GSK has maintained since the inception of this litigation that there is no reliable scientific support for Plaintiffs' claims that Zofran® caused their alleged injuries. Moreover, FDA's repeated affirmation of Zofran®'s label is fatal to Plaintiffs' claims. GSK is not interested in engaging in mandatory, time-consuming meetings with a settlement master. The Court should deny the PSC's request for the appointment of a settlement master and decline to order GSK to engage in any settlement discussions. If the Court decides to pursue this avenue, a settlement subcommittee of the PSC, instead of appointing a costly third-party settlement master, would suffice.

I. APPOINTING A SETTLEMENT MASTER WOULD BE INEFFICIENT AND LIKELY FUTILE.

In May, GSK moved for entry of an order scheduling a "Science Day" to "educate the Court on the medical and scientific issues central to general causation" as well as to schedule deadlines for completion of fact and expert discovery and motion practice. (Dkt. 719). Plaintiffs opposed, believing GSK's Science Day and proposed discovery schedule to be "inefficient" and "premature" considering their view of the state of discovery. (Dkt. 724). According to Plaintiffs,

it was "too early in the game" to be discussing science.[1] Plaintiffs instead thought it more prudent to delay a Science Day until after conducting expert depositions and to push *Daubert* motion practice further in the future. *See id.* Plaintiffs' position that they need more discovery before they can discuss science is seemingly irreconcilable with their request for immediate appointment of a settlement master.

Moreover, while this litigation has been pending, FDA has twice reconfirmed its position that there is insufficient scientific support for a Zofran® birth defect warning. First, in October 2015, FDA denied a Citizen Petition calling for the same sort of Zofran® birth defect warnings that MDL Plaintiffs maintain were required under state law.[2] Also in 2015, FDA declined to alter the Zofran® labeling to suggest that use of Zofran® in pregnancy can cause harm to a fetus. These clear FDA pronouncements call into serious question Plaintiffs' ability to overcome GSK's general causation and preemption defenses.

Ultimately, Plaintiffs have it backwards. What is "inefficient," "premature," and likely futile, is a settlement master. The appropriate next step is completion of Phase 2–4 fact discovery and swift resolution of general causation and preemption. As GSK noted in its recently submitted "Motion for Entry of An Order Concerning Phase 2–4 Fact Discovery and Phase 3 Expert Discovery, and Related Motion Practice," addressing general causation "serve[s] to either resolve or significantly narrow the cases and claims at issue in this litigation." (Dkt. 875 at *3). The same goes for preemption. Under GSK's proposed schedule, the parties can conclude fact and expert discovery in relatively short order and then return to case dispositive motion practice. And, in the unlikely event that some portion of the cases remain following motion practice, case-

[1] *See* June 20, 2017 Hr'g Tr. at 18: 7–8. (Statement of Tobi Millrood).

[2] *See* FDA's Response to Citizen Petition of James P. Reichmann, available at http://www.regulations.gov/contentStreamer?documentId=FDA-2013-P-0048-0009&attachmentNumber=2&disposition=attachment&contentType=pdf

specific discovery and motion practice would be necessary to properly evaluate any remaining claims. Only after these issues are resolved would initial settlement discussions make sense.

MDL best practices support GSK's view. First, settlement master appointments are disfavored unless there is agreement to the appointment by both sides. *See* Manual for Complex Litigation (Fourth) §11.52 (2016) ("It is generally preferable to appoint special masters with the parties' consent."). In addition, the timing of a settlement master appointment should "be consistent with the articulated objectives for the proceeding." Duke Law Center for Judicial Studies, *Standards and Best Practices for Large and Mass-Tort MDLs*, at 6 (2014). ("For example, to avoid diverting the parties' energies from identified priorities, the court may wish to defer appointing a settlement master until the court believes it is timely to begin addressing settlement options."). Here, of course, the Court prioritized general causation and preemption as key dispositive issues. *See* MDL Order No. 19 (prioritizing fact discovery related to general causation and preemption over general liability discovery). Resolving those issues will, in GSK's view, resolve the litigation, obviating the need for a settlement procedure.

The authority cited in the PSC's motion does not counsel a different result. Only one of the cases cited by the PSC in support of a settlement master—*In re Testosterone*—actually involved the appointment of a special master (as opposed to appointment of a settlement committee). In the *Testosterone* MDL, Judge Kennelly, appointed a special master in March 2017. *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 1:14-md-01748, CMO No. 40 Appointing a Settlement Master, Dkt. No. 1795 (N.D. Ill. Mar. 20, 2017). By that time, the MDL had been pending for over three years, *Daubert* motion briefing was complete, the parties had completed case specific discovery in twenty-four individual actions, and the first bellwether trial would begin in just two months. *See In re Testosterone*, Docket Sheet, 1:14-cv-01748. The

Zofran® MDL is far from this advanced stage of pre-trial proceedings. Indeed, none of those events have taken place in the Zofran® MDL. The authority in Plaintiffs' brief thus supports GSK's position that appointing a settlement master would be inappropriate now.

II. IF A FORMAL APPOINTMENT IS NEEDED, THE COURT SHOULD CREATE A PSC SETTLEMENT COMMITTEE INSTEAD OF APPOINTING A SETTLEMENT MASTER.

Although GSK believes that settlement negotiations would be futile, if the PSC is interested in pursuing settlement, the proper avenue for formalizing those efforts would be through the appointment of a settlement committee consisting of current PSC attorneys, rather than a paid, third-party settlement master. Two of the three MDLs cited by the PSC in their motion appointed settlement committees. In *Taxotere*, the MDL judge solicited applications from counsel involved in the litigation and selected five plaintiffs' attorneys to serve as committee members. *In re Taxotere (Docetaxel) Prod. Liab. Litig.*, 2:16-md-02740, PTO No. 6 – Order Appointing Settlement Committees, Dkt. No. 133 (E.D. La. Dec. 13, 2016). The court charged these members with "hold[ing] regular discussions … in an attempt to resolve [the] matter prior to remand of some or all of the member cases." *Id.* Similarly, the *Hip Resurfacing* MDL judge appointed a select number of plaintiffs' counsel "to engage in general settlement discussions with appropriate counsel designated by Defendant." *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 1:17-md-02775, CMO No. 4 Plaintiffs' Settlement Counsel, Dkt. No. 108 (D. Md. July 20, 2017).

Although GSK does not view any formalized settlement procedure as a worthwhile endeavor in the face of significant, dispositive legal and factual issues, a settlement committee made up of PSC attorneys would be superior to Plaintiffs' proposal for appointment of a settlement master. Unlike a settlement committee consisting of attorneys who have been part of

the Zofran® MDL for months or years, a settlement master would need to spend many hours acquiring a basic understanding of the litigation and the parties' respective positions. A settlement committee also allows for greater flexibility. Under Plaintiffs' proposal, the parties would have to meet with the settlement master at least once a month, despite the fact that the parties do not share a mutual interest in settlement. A settlement committee, on the other hand, could meet when it makes most sense considering developments in the litigation. A settlement committee also avoids problematic *ex parte* communication concerns that may arise under Plaintiffs' proposal, which allows for *ex parte* communications between the settlement master and the Court. *See* Fed. R. Civ. P. 53, Committee Notes on Rules – 2003 Amendment ("Ex parte communications between a master and the court present troubling questions.").

III. CONCLUSION

The Court should deny the PSC's request for entry of an order appointing a settlement master as futile. Settlement discussions are of no benefit until there is first resolution of GSK's general causation and federal preemption challenges. Plaintiffs' proposal would divert resources from resolving these case-dispositive issues. Plaintiffs' Motion should be denied.

Dated November 2, 2017

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

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