UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45090; *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P.*, Case No. 17-op-45004; *The City of Cleveland, Ohio, et al. v. Purdue Pharma L.P.*, Case No. 18-op-45132	MDL No. 2804 Hon. Dan Aaron Polster

DISTRICTORS' MOTION FOR SPECIAL MASTER TO WITHDRAW PART I OF DISCOVERY RULING NO. 12

Distributors[1] respectfully move the Special Master to withdraw Part I of Discovery Ruling No. 12, the "short discourse on the concept of 'Suspicious Orders'" (the "Short Discourse"). *See* Doc. No. 1174 ("Ruling"). That portion of the Ruling is unnecessary to the ultimate discovery ruling and should be withdrawn because the legal issues addressed therein have not been briefed by the parties. What the legal requirements are for reporting suspicious orders (including what is—and what is not—required by 21 C.F.R. § 1301.74(b)), the proper interpretation and applicability of *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), the legal validity of DEA's 2006/2007 letters (as well as other DEA guidance over the years), and generally "how a distributor's Suspicious Order Monitoring System [should] work,"

[1] "Distributors," as used herein, includes AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Discount Drug Mart, Inc., HBC Service Company, H.D. Smith, LLC f/k/a/ H.D. Smith Wholesale Drug Co., McKesson Corporation, Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Service Center, Walgreen Co. and Walgreen Eastern Co.

Ruling at 5, are some of the most critical and hotly-disputed issues in these cases, as concern Distributors. None have been fully briefed; some have not even been touched on. In addition, the factual record on many of these issues still is being developed, through ongoing party discovery and discovery from DEA.

Distributors therefore submit that these are issues for the Court to first address at summary judgment on a full factual and legal record. We are not asking, and indeed, think it would be inappropriate, to try to resolve these issues now on the merits. At this stage, we ask only that the Special Master withdraw that portion of the Ruling and leave resolution of those disputes for another day.

A. The Short Discourse Is Unnecessary to the Ultimate Discovery Ruling.

As rewritten in Discovery Ruling No. 7 (Doc. No. 1051), Distributors' Interrogatory No. 23 requested that Plaintiffs "[i]dentify each Suspicious Order for Prescription Opioids that you ***contend*** was shipped to Your geographic area by any National Retail Pharmacy Defendant or Distributor Defendant during the Relevant Time Period." (Emphasis added). The interrogatory also asked Plaintiffs "to ***explain the criteria*** you used to identify these Suspicious Orders." Dkt. 1051. Interrogatory No. 23 thus is a contention interrogatory. Distributors seek to discover which orders ***Plaintiffs*** contend are suspicious and to learn the basis for that contention. In other words, the Interrogatory requires Plaintiffs to do two things—(1) identify the allegedly suspicious orders and, in so doing, (2) articulate their position about which orders the law requires Distributors to report. To accomplish those two things, Plaintiffs do not need to know either what position Distributors take or how the Court ultimately may decide the question of what the law requires.

The Short Discourse therefore was not necessary to a ruling on whether Plaintiffs had sufficiently responded to the Interrogatory, and were the Short Discourse withdrawn, nearly the

entirety of the Ruling could stand without modification. Only a few small changes would be necessary to Parts II and III of the Ruling,[2] none of which changes the substance of the Ruling or the Court's ability to enforce it.

Because it is unnecessary to the Ruling, the Special Master should withdraw the Short Discourse.

B. The Short Discourse Improperly Addresses Disputed Legal Issues Before Full Briefing and Discovery on Those Issues.

As discussed, the point of Interrogatory No. 23 was to learn what ***Plaintiffs*** contend about the facts and the law. While Distributors made a passing reference in their December 4 letter to their disagreement with Plaintiffs' interpretation of *Masters*, those are issues for another day—i.e., at summary judgment—and neither Distributors nor Plaintiffs fully briefed the proper interpretation or applicability of *Masters*. Distributors certainly did not brief, for example, what 21 C.F.R. § 1301.74(b) requires, whether that regulation contains a "Shipping Requirement," or whether the DEA's 2006/2007 letters, other guidance, or subsequent enforcement actions constitute valid rulemaking.

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[2] One change would be to modify the second sentence of the second paragraph on p. 8 (in Part II) to read: "That criterion is *what Plaintiffs contend is* the first criterion listed in *Masters Pharmaceutical* (see footnote five)—*or what I will refer to herein as* the 'Monthly Total Rule'" (modification in italics). The second would be to strike the second sentence of Footnote 9 (in Part III): "Moreover, as *Masters Pharmaceutical* makes clear, only thorough due diligence can clear a suspicious order, and the parties are sure to disagree whether a defendant's due diligence on various orders was sufficient." As will be more fully briefed at the appropriate time and stage of this case, Distributors dispute that the regulation requires this or that this was even the DEA's informal guidance prior to 2007. *See infra* Part B. The last would be to strike the last clause of the last sentence of Footnote 9: "even though the burden of *proving* proper identification and reporting of suspicious orders remains on defendants." Again, as will be more fully briefed in due course, none of Plaintiffs' claims require Distributors to prove this point, and this apparent burden-shifting is unnecessary to the discovery dispute at issue.

Nevertheless, the Ruling includes the Short Discourse, which makes numerous findings about the rules governing wholesale distributors. Distributors disagree with many of those findings, but mention only a few examples here for purposes of demonstrating why a full factual and legal record are necessary before a ruling on these issues.

First, the Short Discourse appears to hold that *Masters* is controlling authority and that it establishes "rules" for determining "suspicious" orders, including (1) the so-called "Monthly Total Rule," which provides that "an order is suspicious if 'that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months"; an (2) "Order Form Rule"; and (3) an "Order Timing Rule." Ruling at 2–3 & n.2.[3] These "rules" were only specific criteria of Masters' self-created reporting protocol. When the Acting DEA Administrator revoked Masters' controlled substance license—the decision on appeal in *Masters*—he found that Masters had not followed its own rules. Neither the Administrator nor the D.C. Circuit found it necessary to articulate "rules" for reporting, nor did they hold that Masters' own "rules" were applicable to any other wholesale distributor. The Administrator assumed that Masters' own self-determined rules were adequate, but then determined that Masters disregarded them.[4]

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[3] The Short Discourse also mentions several other possible "rules," including the "Consecutive Order Rule," the "Multi-Distributor Rule," the "Percentage Increase Rule," and the "Pharmacy Comparison Rule." Ruling at 3 n.2. It is not clear from where the Special Master has derived these rules.

[4] Although the Ruling recognizes later that Distributors are "not required to use the Monthly Total Rule," Ruling at 6, we nevertheless take issue with the statement that something even approximating a "rule" can be derived from *Masters*' discussion of Masters' unique SOM program.

Second, the Ruling states that "[w]hen a distributor first identifies an order as suspicious … it cannot ship the order without doing some investigation. If that investigation does not 'dispel all red flags indicative that a customer is engaged in diversion,' then the distributor … must not ship the order." Ruling at 5–6. The Short Discourse states that this is "how a distributor's Suspicious Order Monitoring System ***must*** work." *Id.* at 5 (emphasis added). But the very existence of a "Shipping Requirement"—nowhere set forth in the Code of Federal Regulations—is a contested legal issue, and Distributors have arguments on the issue that never have been presented to the Special Master or the Court.

Even apart from those arguments, *Masters* itself is clear that any supposed "Shipping Requirement" did not exist prior to 2007. *See Masters*, 861 F.3d at 221–22. Prior opinions confirm this view:

> According to the regulations, if a suspicious order is detected, the registrant's obligation is to "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." 21 C.F.R. § 1301.74(b). The government offered testimony that the ***DEA sought to expand drug wholesalers' obligations by a policy change in 2006 and 2007, although there was never a change to the regulations. One of the changes in interpretation by the DEA concerned the circumstances under which a distributor should suspend shipments to a customer if it identified an order as suspicious. That change in policy apparently prompted concern within the DEA compliance sectors that confusion would result, since the prior "report-only" policy had been in place for 35 years***….
>
> The evolution of the policy and the corresponding briefings, however, are not available because Wright, remarkably, deleted all his e-mails even after this lawsuit was commenced and Wright was called upon to respond to discovery.
>
> ***In all events,*** [***DEA Unit Chief***] ***Wright testified that the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA.***

United States v. $463,497.72 in U.S. Currency, 853 F. Supp. 2d 675, 682 (E.D. Mich. 2012) (emphases added).[5]

In addition, discovery on these issues, including from DEA, is ongoing. Any discourse on the Shipping Requirement—or other legal requirements—therefore is premature before the full factual record has been developed and before the parties have had an opportunity to present their full legal arguments on this issue.

Third, the Special Master concludes that "[t]he legal authorities … leave unclear exactly when an order is deemed suspicious, and thus when a distributor is required to inform the DEA that it received a suspicious order"—an observation with which Distributors agree. But the Special Master immediately followed that observation with a flowchart that purports to set forth "how a distributor's Suspicious Order Monitoring System must work, and diagrams the process a distributor must undertake when it receives a suspicious order." Ruling at 5. That flowchart—understandably, given the complete lack of briefing on these issues and the still-ongoing factual development—could not capture the myriad ways in which various distributors complied, over a lengthy period of time, with DEA's ever-changing guidance on how suspicious order monitoring systems could or should work. The flowchart and the accompanying text regarding "yellow lights" and "red lights" contain numerous presumptions and assumptions regarding how distributor SOMs work, including when and how an order is first identified as "suspicious."

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[5] Distributors also contend that any discussion of the "Shipping Requirement" in *Masters* was dicta—as the D.C. Circuit itself recognized. *Masters*, 861 F.3d at 222 ("[T]he Administrator's holding rests on Masters' violation of the Reporting Requirement, not the Shipping Requirement…. Consequently, even if the Administrator expansively read the Shipping Requirement, that reading had no effect on his ultimate decision, and so provides no basis for relief."). In addition, Distributors dispute the DEA's ability to add new requirements under 21 C.F.R. § 1301.74(b) through informal guidance letters without following the Administrative Procedures Act.

Because those presumptions and assumptions are, again understandably, uninformed by any legal briefing or factual presentation, the entire flowchart and related "red/yellow light" discussion is improper and premature.[6]

* * *

The issue, for now, is not who is right about *Masters* or the other legal requirements imposed on Distributors, but that such important legal disputes should not be decided as dicta in a discovery ruling when the parties have not briefed the issues, discovery on the issues is ongoing, and the issues were not ripe for consideration. Moreover, Distributors submit that the Special Master should not be weighing in at this stage regarding what a proper suspicious order monitoring system should or should not include, much less what it "must" include. Ruling at 5. The Special Master therefore should withdraw the Short Discourse.

[6] In addition, Distributors dispute that all wholesale distributors must have some algorithm-based suspicious order monitoring system. *See* Ruling at 6. The nature and extent of the "system to disclose to the registrant suspicious orders of controlled substances" required under 21 C.F.R. § 1301.74(b) is only one part of a fact-intensive inquiry of whether a distributor is in "substantial compliance" with the general security requirements set forth in 21 C.F.R. § 1301.71, and to make that determination, the Administrator considers the "overall security system and needs of the … registrant," 21 C.F.R. § 1301.71(b).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Ashley W. Hardin, hereby certify that the foregoing document and supporting papers were served via the Court's ECF system to all counsel of record.

/s/ Ashley W. Hardin
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