

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION)	CASE NO. 1:17-MD-2804
OPIATE LITIGATION)	
)	SPECIAL MASTER COHEN
THIS DOCUMENT RELATES TO:)	
“Track One Cases”)	
)	<u>RULING ON MOTION TO</u>
)	<u>WITHDRAW PORTION OF</u>
)	<u>DISCOVERY RULING NO. 12</u>
)	

After the undersigned filed Discovery Ruling no. 12 (“DR-12”) (docket no. 1174), the distributor defendants filed a motion asking “the Special Master to withdraw Part I” of that Ruling. Motion at 1 (docket no. 1188). Distributors assert that Part I “of the Ruling is unnecessary to the ultimate discovery ruling and should be withdrawn because the legal issues addressed therein have not been briefed by the parties.” *Id.*

For the reasons stated below, the motion is **DENIED**. But the Special Master adds some points of clarification.

DR-12 addressed the distributor defendants’ contention that the answer plaintiffs gave to an interrogatory, which asked plaintiffs to “Identify each Suspicious Order for Prescription Opioids that you contend was shipped to Your geographic area,” was deficient. In order to understand and explain the obligation this interrogatory imposed on plaintiffs, the Special Master put forth in Part I of DR-12 a “short discourse on the concept of ‘Suspicious Orders.’” DR-12 at 1-2. This discourse

examined federal regulations and case law discussing what makes an opioid order “suspicious,” *see id.* at 2 (citing 21 C.F.R. §1301.74 and *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017)), and also discussed various “rules” a distributor might use as part of an “algorithm” to identify suspicious orders, *see id.* at 3 n.2 (discussing the “Monthly Total Rule,” the “Order Form Rule,” the “Order Timing Rule,” and others).

Defendants insist this discourse on the concept of suspicious orders “was not necessary to a ruling on whether Plaintiffs had sufficiently responded to the Interrogatory.” Motion at 2.

The Special Master disagrees. Researching and writing the discourse allowed the undersigned (and allows the reader) to understand: (1) *some* of the legal authority that defines a suspicious order, and (2) *some* of the different ways a distributor might identify an order as suspicious. Moreover, the flowchart shown on page 5 of DR-12 helped demonstrate why “[t]he legal authorities reviewed above leave unclear exactly when an order is deemed suspicious.” DR-12 at 4. Without this discourse, the Special Master could not intelligently address the ultimate question the distributors had raised: did the complicated approach that plaintiffs used to respond to the interrogatory actually avoid answering it, as distributors contended? Or did plaintiffs’ three methods for identifying orders as suspicious fail to conform with applicable law?

The Special Master concluded in DR-12 that the distributors’ lament – that is, that “Plaintiffs’ [interrogatory] response leaves them unsure regarding exactly which orders they will be called upon to defend at trial” – had some merit. *Id.* at 14. Therefore, the Special Master directed plaintiffs’ to amend their interrogatory response. *Id.* Still, distributors now complain that “the Short Discourse appears to hold that *Masters* is controlling authority and that it establishes ‘rules’ for determining ‘suspicious’ orders.” Motion at 4; *see id.* at 5 (citing earlier case law for the proposition

that, even if *Masters* is **currently** controlling, distributors' obligations surrounding suspicious orders have changed over time). Distributors also assail the flowchart because it does "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." *Id.* at 6.

The Special Master answers distributors' complaint as follows. First, the discourse actually states there are many ways for a distributor to reckon whether an opioid order is suspicious. *See* DR-12 at 3 n.2 ("There are many . . . algorithms a distributor could use to identify opioid orders as suspicious."); *id.* at 6 ("the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious."). Distributors' concern that DR-12 holds strictly that they must follow given, established rules to identify suspicious orders is undue.

Second, the discourse was not meant to be authoritative or conclusive on how all suspicious order monitoring systems ("SOMS") must work. As distributors note, resolution of whether their SOMS met applicable legal requirements over time is a question "for another day." Motion at 3. DR-12 simply analyzed some of the legal authority the Court will apply when that day comes. The analysis in DR-12 was in the context of resolving a discovery dispute, not the distributors' liability.

And third, the flowchart is obviously simplified, presented to explain why there is some **lack of clarity** on whether and when an order meets the definition of "suspicious" – which explains, in turn, why there was legitimately some lack of clarity in plaintiffs' interrogatory response. Just as distributors will surely muster additional legal authority in their summary judgment motions on the topics of what makes an order suspicious and when and whether it must be reported, they will surely

also offer complete descriptions – perhaps with detailed flowcharts – illustrating how their SOMS actually functioned over time. That the distributors will later supply additional legal and factual input does not make Part 1 of DR-12 so infirm that it must be withdrawn.

In sum, distributors are correct that Discovery Ruling no. 12 was exactly that – a discovery ruling – and not a definitive pronouncement on their legal obligations. But neither was Part I “unnecessary” or, in the Special Master’s view in hindsight, in any way incorrect. Accordingly, the motion to withdraw is denied.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: December 16, 2018