UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17-MD-2804**
	)	
	)	**SPECIAL MASTER COHEN**
THIS DOCUMENT RELATES TO: "*Track One Cases*"	)	
	)	
	)	
	)	**DISCOVERY RULING NO. 12 REGARDING SUSPICIOUS ORDER INTERROGATORY**
	)	
	)	

In Discovery Ruling no. 7 ("DR7"), the Special Master ordered plaintiffs to answer the following rewritten interrogatory:

> Identify 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. * * * Furthermore, explain the criteria you used to identify these Suspicious Orders.

DR7 at 6 (docket no. 1051). Each plaintiff responded with 12 pages of objections and explanations, together with an extremely detailed and prolix chart.[1] Nonetheless, defendants assert plaintiffs' responses are deficient and ask the Special Master to order plaintiffs to amend their responses. To rule on defendants' request, the Special Master first presents the following short discourse on the

[1] *See, e.g.*, City of Cleveland's Amended Responses and Objections to the National Retail Pharmacy Defendants' First Set of Interrogatories and Distributor Defendants' Fourth Set of Interrogatories (12 pages of objections and explanation) and Exhibit A thereto (581 pages of complicated tables and charts) (collectively, "Cleveland Response").

concept of "Suspicious Orders."

I. Suspicious Orders, Due Diligence, and the Reporting Requirement.

Distributors of opioids are required to "'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA (the Reporting Requirement)." *Masters Pharmaceutical*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Thus, an order for opioids received by a distributor from a retail pharmacy may qualify as "suspicious" for any of a number of different reasons. *See, e.g.* footnote 2 below (describing various reasons). The simplest example is that a given order for an opioid may be suspicious if it was of "unusual size" – say, an order that pushed a pharmacy's monthly total number of opioid doses to exceed the monthly totals the same pharmacy had ordered in the prior six months. The Special Master refers below to this algorithm as the "Monthly Total Rule." (*Masters Pharmaceutical* described the "Monthly Total Rule" as follows: 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."

Id. at 213.)[2]

As noted, once it has identified a suspicious order, a distributor is required to report it to the Drug Enforcement Agency ("DEA"). *See* 21 C.F.R. §1301.74(b) ("The [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [distributor]."). Furthermore, having received a suspicious order, the distributor "must make one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Id.* at 212–13. Of course, a distributor's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor

---

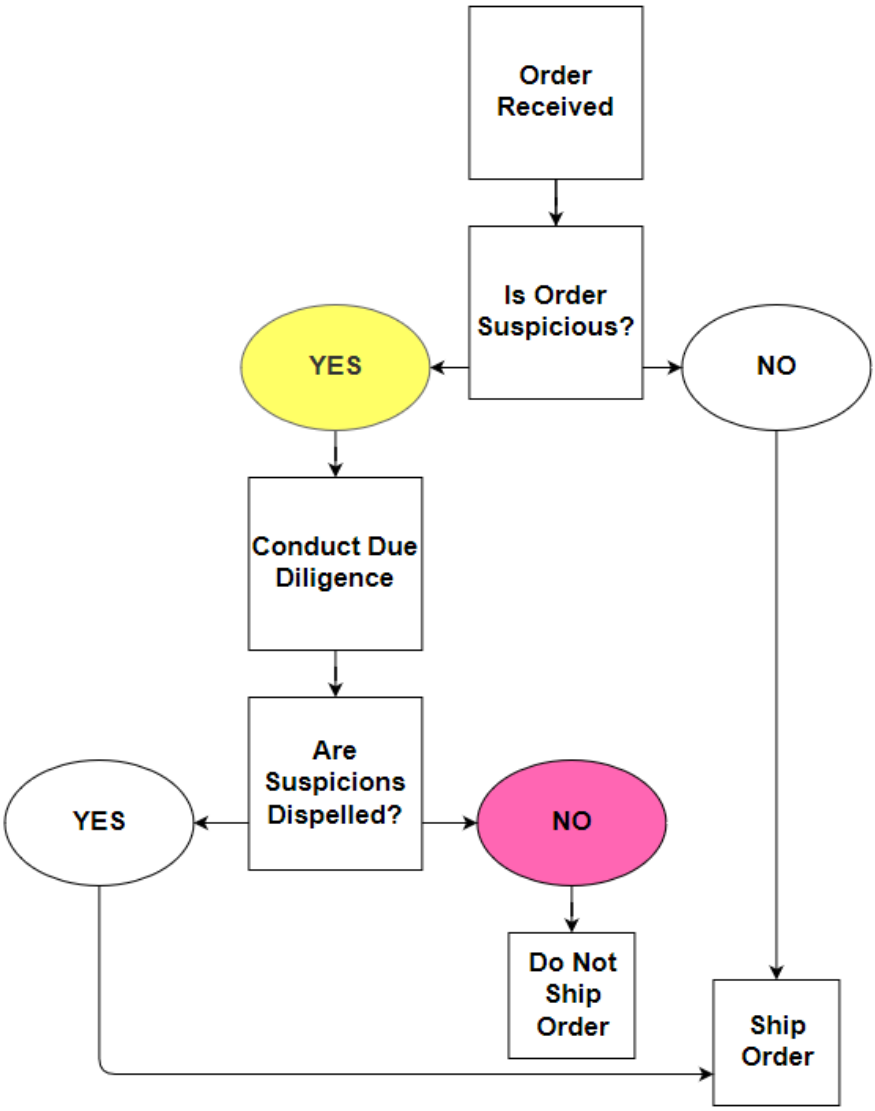
[2] Of course, an order may be suspicious for other reasons, even if it doesn't fit the Monthly Total Rule, such as that the pharmacy-customer "submitted more order forms in a 30-day period than it had in any of the prior six calendar months [the 'Order Form Rule'], or if the timing of the order did not comport with the customer's general ordering pattern over those six months [the 'Order Timing Rule']." *Id.* There are many other algorithms a distributor could use to identify opioid orders as suspicious, including: (1) the order for the opioid was placed within 30 days of an earlier suspicious order for the same opioid (the "Consecutive Order Rule"); (2) the order for the opioid was placed within 30 days of an order for the same opioid from a different distributor (the "Multi-Distributor Rule"); (3) the percentage increase in the amount of opioid ordered exceeded a certain threshold (the "Percentage Increase Rule"); or (4) the amount of opioid ordered exceeded by some threshold the amounts ordered by other similar or nearby pharmacies ("the Pharmacy Comparison Rule").

See also Masters Pharmaceuticals, Inc., Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) ("a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy that engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious."); *id.* at *55478 (noting that "suspicion" is a low bar: it "is simply a far lower standard of proof than whether it is 'likely' that the circumstance exists," and "the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.")

'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed." *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) (hereinafter, "*Decision and Order*"). Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence." *Masters Pharmaceuticals*, 861 F.3d at 212.[3]

Before returning to the question at hand – that is, did plaintiffs in this case adequately answer the defendants' interrogatory seeking identification of suspicious orders – the Special Master adds one last observation. The legal authorities reviewed above 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. The following flowchart illustrates the issue.

[3] The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.



This flowchart shows how a distributor's Suspicious Order Monitoring System must work, and diagrams the process a distributor must undertake when it receives a suspicious order. Notably, there is a "yellow light" (caution) and a "red light" (stop) in the process. When a distributor first identifies an order as suspicious, this is a "yellow light" – 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 gets a "red light" and must not ship the order. *Masters Pharmaceutical*, 861 F.3d at 222. Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), 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. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.

With regard to the Reporting Requirement, it is not entirely clear whether a distributor's obligation to inform the DEA attaches: (1) when the "yellow light" flashes – that is, when the distributor first identifies an order as suspicious; or (2) only after the "red light" flashes – which would mean a distributor does not have to inform the DEA it received a suspicious order if investigation shows the order was legitimate, after all. Indeed, the authorities cited above provide support for each approach, as shown by the following quotations.

"Red Light"

- "[I]f, ***even after investigating the order***, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed. *Decision and Order*, 80 Fed. Reg. at *55478.

- "DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, ***unless the suspicion is dispelled***, the obligation to report. *Masters Pharmaceuticals*, 861 F.3d at 215 (citing *Decision and Order*, 80 Fed. Reg. at *55,479; and 21 C.F.R. §1301.74(b)).

"Yellow Light"

- "***Once a distributor has reported a suspicious order***, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping

Requirement)." *Masters Pharmaceutical*, 861 F.3d at 212–13.[4]

In other words, it is unclear whether an order is "suspicious" (and so must be reported to the DEA) as soon as a distributor's SOMS flags it as suspicious, or only after due diligence fails to dispel any suspicion. Obviously, this definitional issue affects the plaintiffs' response to the rewritten interrogatory.

In any event, it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless investigation shows them to be legitimate. And distributors are required to report suspicious orders to the DEA. With this background, the Special Master now turns to the adequacy of plaintiffs' discovery responses.

II. The Rewritten Interrogatory.

To repeat, in DR7 the Special Master directed plaintiffs to "Identify each Suspicious Order for Prescription Opioids that you contend was shipped to Your geographic area," and also to "explain the criteria you used to identify these Suspicious Orders." Plaintiffs complained that the distributor defendants "have failed to answer this very-same discovery request," but plaintiffs went ahead and responded with a chart listing many thousands of orders, as well as an explanation of how the chart was derived.

Plaintiffs' written explanation states the suspicious orders identified in the chart met one or more of six criteria:

---

[4] If this sentence said "identified" instead of "reported," then these authorities would be unanimous that reporting of a suspicious order must occur at the "red light" stage, not at the 'yellow light." In their response, plaintiffs generally identified orders as suspicious based on their status at the "yellow light" stage – that is, the chart lists an order as "suspicious" even if any assumed due diligence later "cleared" it.

> [each order listed in the chart] (a) met [one of] the criteria ratified in *Masters Pharm., Inc. v. Drug Enf't Administration*, 861 F.3d 206, 216–17 (D.C. Cir. 2017); (b) was shipped within thirty days of an order of the same national drug code ("NDC") that was deemed suspicious and reported to DEA; (c) included the same drug family ordered by the same customer in the same month from multiple distributors; (d) was in top 10% for percentage increases for the same drug family or for total orders for the month or year; (e) was shipped after the prescriber's license was revoked where the shipment was sent directly to that prescriber; and/or (f) was of excessive size for the drug family for a customer whose prescribing significantly exceeded other similar pharmacies in the jurisdictions.

Cleveland Response at 11.[5]

In fact, however, the plaintiffs principally employed only one of these six criteria to identify the suspicious orders listed in their chart. That criterion is the first criterion listed in *Masters Pharmaceutical* (see footnote five) – in other words, the "Monthly Total Rule."[6] Essentially, this Rule compares a given opioid order to all orders placed in the prior six months. Using available data, plaintiffs used this criterion to identify suspicious orders placed each month for the period of January of 1996 through May of 2018, broken out by defendant and by drug. *See, e.g.*, Cleveland

---

[5] Plaintiffs explain that the "criteria ratified in *Masters Pharmaceutical*" are described as follows:

> an order [is suspicious] if: (a) 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; (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; or (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months.

Masters Pharmaceutical, 861 F.3d at 216. These criteria are in the alternative. Ultimately, plaintiffs used *Masters* criterion (a) above, alone, to identify suspicious orders.

[6] Plaintiffs used the Monthly Total Rule to identify hundreds of thousands of suspicious orders listed in the first 559 pages of their 580-page chart, and then used other criteria to identify several hundred other suspicious orders listed in the last 21 pages of their chart. Because plaintiffs overwhelmingly relied upon the Monthly Total Rule, the Special Master examines only that aspect of their response.

Response Exh. A at PDF page nos. 11-21 (using the criterion to list thousands of suspicious orders of hydrocodone shipped by Cardinal); *id.* at 141-152 (using the criterion to list thousands of suspicious orders of oxycodone shipped by Walgreen).

Moreover, plaintiffs employed this single criterion using three different "Methods," with each Method using a different assumption about the distributors' efforts at due diligence. *See* Cleveland Response at 11 n.3. A description of the three different Methods follows. The hypothetical table below will help explain how each Method works.[7]

JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP
110	120	130	140	150	160	170	165	100
		Suspicious under Method 1?				yes	no	no
		Suspicious under Method 2?				yes	yes	no
		Suspicious under Method 3?				yes	yes	yes

Method One was the least complicated: plaintiffs simply compared a given order to all orders in the immediately preceding six months. This method ignored the question of whether any prior order had itself been suspicious. Thus, for example, an opioid order placed by ABC Pharmacy to Cardinal Distribution on July 15, 2010, was compared to all opioid orders placed by ABC Pharmacy to Cardinal Distribution between January 1 and June 30, 2010 – even if some of those prior orders had been suspicious. If the order in question pushed ABC Pharmacy's monthly total number of opioid doses to exceed all of the monthly totals it had ordered in the immediately preceding six months, then the order was listed as suspicious in plaintiffs' chart.

The simplified table above illustrates Method One as follows. ABC Pharmacy placed an opioid order in July for 170 pills. This amount exceeded the highest monthly total for the previous

[7] This simple table assumes ABC Pharmacy placed a single order each month for a single type of opioid pill. Of course, the actual ordering data analyzed by plaintiffs involved hundreds of pharmacies placing thousands of orders each month for a large variety of opioids.

six months (January through June – the highest total was June at 160), so the algorithm identifies the July order as suspicious. When the same pharmacy places an opioid order for 165 pills in August, the algorithm shows it is lower than at least one of the six prior months (July at 170), so the August order is not identified as suspicious. And a September order for 100 pills is also lower than at least one of the six prior months, so it is also not identified as suspicious.

Because Method One ignores the question of whether any prior order was identified as suspicious, it essentially assumes each such order is later "cleared" through due diligence. In other words, if a distributor believed a pharmacy had placed a suspicious order in July, it would presumably not ship a similar order received from the same pharmacy in August, unless it had first investigated the prior July order and determined it was legitimate. Thus, the algorithm used in Method One gives the distributor-defendants the greatest benefit of the doubt regarding their due diligence efforts.[8] Using Method One on defendants' actual data, plaintiffs identified 52,554 suspicious orders between January of 1996 through May of 2018, or 5.4% of all orders analyzed.

Method Two was similar to Method One, except it compared a given order to all orders in the immediately preceding six months *that were not themselves suspicious*. The simplified table above illustrates Method Two as follows. As with Method One, ABC Pharmacy's opioid order in July for 170 pills exceeded the highest monthly total for the previous six months (January through June – the highest total was June at 160), so the algorithm identifies the July order as suspicious. When the pharmacy places an opioid order for 165 pills in August, the algorithm compares 165 with all orders in the six prior months *that were not suspicious* – which includes May through June, but

[8] As noted in footnote four, under Method One the plaintiffs' chart lists an order as suspicious even if any assumed due diligence later "cleared" it.

not July (which was suspicious). Because 165 exceeds the highest monthly total for non-suspicious orders placed in the previous six months (which is 160, in June), the August order is identified as suspicious. The September order for 100 pills, however, is lower than at least one of the non-suspicious orders placed in the six prior months, so it is not identified as suspicious.

In contrast to Method One, Method Two assumes the distributor-defendants did no due diligence on suspicious orders. That is, the Method Two algorithm assumes no suspicious order was ever "cleared" through subsequent investigation as legitimate, so the comparison of a given order to prior orders does not give the distributor-defendants any benefit of the doubt regarding their due diligence efforts. Using Method Two on defendants' actual data, plaintiffs identified 364,291 suspicious orders between January of 1996 through May of 2018, or 35.9% of all orders analyzed.

Finally, Method Three was similar to Method Two, except the algorithm included the rule that once a pharmacy places a suspicious order, *all* subsequent orders are also suspicious – that is, the pharmacy was permanently "blackballed."

Note that Method Two assumed a pharmacy could place a non-suspicious order even after it had earlier placed a suspicious order; so long as the later order was for an amount lower than all non-suspicious orders in the prior six months, the later order was deemed legitimate. Thus, under Method Two, the September order for 100 pills was not suspicious, even though the two preceding orders in July and August were suspicious.

The algorithm plaintiffs used in Method Three was less forgiving, as it did not allow for rehabilitation. Having placed one suspicious order, the algorithm designated all subsequent orders from that same pharmacy for the same opioid as also suspicious, even if those subsequent orders were for lower amounts than the orders placed in all six prior months. Essentially, Method Three

assumed the distributor-defendants did no due diligence on suspicious orders, and therefore every pharmacy that placed a suspicious order remained suspicious permanently. This algorithm gave the distributor-defendants the least benefit of the doubt. Using Method Three on defendants' actual data, plaintiffs identified 875,055 suspicious orders between January of 1996 through May of 2018, or 86.2% of all orders analyzed.

III. Analysis and Conclusion.

Defendants complain that plaintiffs' response is so convoluted it is ultimately not helpful at all. Despite plaintiffs' attempt at answering the rewritten interrogatory using variations on a theme, defendants object they are ultimately left without a roadmap of what plaintiffs actually claim. Defendants write:

> the Defendants still do not know which orders they are defending. Without knowing which orders Plaintiffs contend are at issue, the Defendants cannot use the fact discovery period in the way it is intended: to develop facts and defenses relating to the alleged misconduct. Plaintiffs . . . say that either very few or virtually every order was suspicious. That is not a meaningful response.

Letter from J. Keyes to Special Master at 1 (Dec. 4, 2018).

In rejoinder, plaintiffs explain they answered the rewritten interrogatory using three variations on the Monthly Total Rule because they have not received from defendants complete (or, in some cases, any) information regarding the defendants' own due diligence efforts or their SOMS. Therefore, each Method uses a different assumption regarding the defendants' due diligence: the Method One algorithm gives defendants the greatest benefit of the doubt (every distributor conducted due diligence on ***every*** suspicious order, and all orders identified as suspicious were later proved legitimate); the Method Three algorithm gives defendants the least benefit of the doubt (each

distributor conducted due diligence on ***no*** suspicious order, so once a pharmacy placed a suspicious order, all of its subsequent orders must also be designated as suspicious); and the Method Two algorithm employs a compromise approach.

Having reviewed carefully the response plaintiffs gave and also the problems defendants have with this response, it appears to the Special Master that plaintiffs have done the best they can with the information they have, but also that defendants raise a legitimate complaint. Without comprehensive information from each distributor-defendant on (1) their due diligence policies generally and (2) their due diligence efforts for each suspicious order specifically, plaintiffs cannot identify for the defendants all of the orders that are suspicious.[9] But plaintiffs do explain for defendants their general approach: put simply, plaintiffs contend that, at a minimum, any order that does not meet the Monthly Total Rule is suspicious, and it remains suspicious if the defendant did not "clear" it using a robust investigation. This response gives defendants a fair idea of the "facts

[9] This problem is compounded by the issue that, as explained above, it is still unclear whether an order is and remains suspicious once it is identified as such by a defendant's SOMS, or instead an order is no longer suspicious if it is "cleared" as legitimate by subsequent due diligence. 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.

Also, federal law begins by placing the obligation to identify suspicious orders and to conduct due diligence on defendants. So it is ***defendants*** who should be able to produce: (1) a chart of every suspicious order they identified, and whether due diligence subsequently "cleared" the suspicious order; and (2) the algorithms, policies, methods, and rules used to determine initially whether an order was suspicious (the SOMS), as well as the actual efforts undertaken to assess whether a suspicious order was legitimate. It is somewhat unfair for defendants to ask plaintiffs to produce what defendants have, to some extent, not yet produced themselves; but defendants are entitled to understand the factual underpinnings for plaintiffs' claims. Thus, the Special Master's rewritten interrogatory recognizes plaintiffs' burden of *production* regarding identification of suspicious orders in discovery, even though the burden of *proving* proper identification and reporting of suspicious orders remains on defendants.

and defenses" they need to develop to defend their conduct.[10]

On the other hand, defendants' criticism has some merit. Plaintiffs' response leaves them unsure regarding exactly which orders they will be called upon to defend at trial. Accordingly, the Special Master rules as follows.

Plaintiffs do not need to alter or amend their existing responses to the rewritten interrogatory. However, plaintiffs must ***also*** respond to the following additional interrogatory, which will provide defendants with a more precise understanding of the nature and type of opioid orders that plaintiffs contend are suspicious:

> For each National Retail Pharmacy Defendant and Distributor Defendant, identify 10 Suspicious Orders for Prescription Opioids that you contend were shipped to Your geographic area during the Relevant Time Period. For each order, identify the date the order was shipped, the manufacturer, name, and amount of the medication that was shipped, the name of the defendant that shipped the order, and the name and location of the person or entity that placed the order. Furthermore, explain in detail all criteria you used to identify these Suspicious Orders, including whether and why you contend (i) any due diligence actually conducted was insufficient, and (ii) the order was so suspicious that there was no amount of due diligence that could have removed every basis to suspect the customer was engaged in diversion.

Plaintiffs must answer this additional interrogatory on or before December 31, 2018.

---

[10] In addition, the rewritten contention interrogatory asks for information that will certainly be the subject of expert testimony. Accordingly, it remains true that "plaintiffs' answer to this contention interrogatory does not limit their experts from using different criteria to identify suspicious orders, and therefore from concluding that there exist suspicious orders in addition to those identified by plaintiffs in their response." DR7 at 6; *see* text order (Nov. 26, 2018) (overruling defendants' objection to this provision).

Finally, because the parties' communications on this issue indicate they have already formed potential objections, the Special Master rules that parties must file any objection to this *Discovery Ruling* on or before December 12, 2018. A successful objection must demonstrate abuse of discretion. *See* Fed. R. Civ. P. 53(f)(5); *Order of Appointment* (docket no. 69) at 5.

RESPECTFULLY SUBMITTED,

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

Dated: December 9, 2018