UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION, OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 17-md-2804
This document relates to:	)	Hon. Dan Aaron Polster
All Cases	)	

ALLERGAN FINANCE, LLC'S FIRST AMENDED OBJECTIONS AND RESPONSES TO PLAINTIFFS' FOURTH SET OF INTERROGATORIES

Pursuant to Federal Rules of Civil Procedure 26 and 33 as well as the Case Management Order (Dkt. No. 232) in *In re: National Prescription Opiate Litigation*, Defendant Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) hereby responds and objects to Plaintiffs' Fourth Set of Interrogatories.

Affirmation That Discovery Responses Herein Are Submitted On Behalf of All Current Allergan Entities And Include Information Collected About Prior Affiliates No Longer Owned by Allergan

These responses are made on behalf of Allergan Finance, LLC and Allergan plc (collectively "Allergan").[1] Allergan confirms that its previous and ongoing discovery investigation and production of documents -- regarding Kadian®, Norco®, and generic opioids manufactured and/or sold by the Actavis Generics Entities sold to Teva (and where appropriate, "opioids generally" or unbranded marketing) -- has included all responsive documents and information reasonably accessible to all of its current affiliates, including Allergan plc generated by the Parties' negotiated search terms and custodians.

[1] In an order entered November 9, the Court lifted the stay on service of foreign entities, noting at a telephonic hearing that foreign parents including Allergan plc were deemed to be parties in the case. Allergan plc objects to the lack of due process and to the Court's refusal to allow briefing contesting personal jurisdiction on behalf of a foreign entity not subject to jurisdiction in this Court.

GENERAL OBJECTIONS

1. Allergan asserts the following General Objections to the Interrogatories. General Objections are incorporated by reference in the specific responses set forth above and are neither waived nor limited by the specific responses.

2. Allergan objects to the Interrogatories to the extent that they seek information that is protected by the attorney-client privilege, the work product doctrine, the joint defense privilege, the common interest privilege or any other applicable doctrine or privilege. Inadvertent disclosure of any such information shall not be deemed a waiver of any privilege or immunity.

3. Allergan objects to the Interrogatories to the extent that they seek to impose any requirements or obligations on Allergan in addition to or different from those imposed by the Federal Rules of Civil Procedure, any order that this Court has or will enter, any stipulation or agreement of the Parties, or any other applicable source or governing law.

4. Allergan objects to the Interrogatories to the extent that they seek premature expert testimony or disclosures. Allergan expressly reserves the right to supplement these responses as necessary.

5. Allergan objects to the Interrogatories to the extent that the Interrogatories, or any word or term used therein, are vague, ambiguous, subject to different interpretations, lacking in definition, and/or require subjective knowledge by any party other than Allergan. Allergan will answer to the extent possible based on the most objectively reasonable interpretation of the Interrogatories.

6. Allergan objects to the Interrogatories to the extent that they seek to limit the documents or information that Allergan may rely upon at trial in this litigation. Allergan's fact investigation, discovery, and trial preparation in connection with the case are continuing, and

Allergan's responses are limited to information obtained and reviewed to date. As a result, Allergan's responses are given without prejudice to Allergan's right to amend, modify or supplement its responses after considering information obtained or reviewed through further discovery or investigation, and Allergan reserves the right to provide and rely on additional information in response to these Interrogatories.

7. Allergan objects to the Interrogatories to the extent they assume facts not in evidence.

8. By answering, responding or objecting to any request or part thereof, Allergan does not admit the existence of any information described or assumed or any allegations set forth or assumed by such request or that such answer or response or objection constitutes admissible evidence. The fact that Allergan has answered or responded to any request or any part thereof is not intended and shall not be construed as a waiver of all or any part of any objection to any request.

9. Allergan's responses are made solely for the purpose of this action.

10. Allergan reserves all evidentiary objections. Each response is subject to all objections as to competence, relevance, privilege, materiality, propriety and admissibility.

11. Allergan objects to the extent that these Interrogatories purport to call for information and responses regarding any other opioids aside from Kadian®. Allergan specifically objects to the extent that these Interrogatories purport to call for information and responses regarding opioids manufactured or sold by the generics business sold to Teva in August 2016. Requests for information about those opioids should be issued to those businesses, which are now under Teva's control.

12. Allergan objects to the extent that these Requests purport to call for information solely relating to geographical areas that are irrelevant and that are not proportional to the needs of this litigation.

OBJECTIONS TO THE DEFINITIONS

1. Allergan objects to the term "You" or "Your" to the extent it includes companies that are now owned by Teva and are represented by separate counsel. These responses are made on behalf of Allergan Finance, LLC and Allergan plc.

2. Allergan objects to the term "Formula" because it assumes facts not in evidence. Orders detected by formulas or algorithms were not automatically deemed to be Suspicious Orders. Rather, the formulas and algorithms would detect potential orders of interest, which were then thoroughly and holistically investigated considering factors such as: purchase and shipping history; information from internal departments (*i.e.*, updated forecasts, special orders, short-date, new contracts, new product launches, etc.); market conditions; available data such as 852, 867, or chargeback data; customer contact and call logs; partnership calls; site visits; and more. The holistic investigation, not the formula, is what led to the determination that an order was or was not actually suspicious. The holistic investigation requires an evaluation based on the totality of the circumstances and is not subject to any mechanical formula or algorithm. Accordingly, Allergan will define "Formula" as the criteria or calculation established by Allergan to detect orders of interest.

3. Allergan objects to the term "Suspicious Order" to the extent it is inconsistent with 21 C.F.R. § 1301.74(b), which states that "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Suspicious Orders do not necessarily include "orders of interest." Orders of interest were orders which met the criteria

set out in Allergan's Formulas, but these orders of interest were thoroughly and holistically investigated considering factors such as: purchase and shipping history; information from internal departments (*i.e.*, updated forecasts, special orders, short-date, new contracts, new product launches, etc.); market conditions; available data such as 852, 867, or chargeback data; customer contact and call logs; partnership calls; site visits; and more. The holistic investigation, not the formula, is what led to the determination that an order was or was not actually suspicious. Accordingly, Allergan will define "Suspicious Order" as orders which were deemed suspicious after the investigation.

SPECIFIC OBJECTIONS AND RESPONSES

INTERROGATORY NO. 35: For each year from 1996 to the present: (a) identify with specificity the Formula(s) actually used to detect Suspicious Orders; (b) apply the Formula to Your own Historical Transactional Data; (c) provide a list of each Order which is detected under the Formula; (d) identify any of the Suspicious Orders that actually were reported to the DEA; and (e) state whether the Order was shipped or Blocked. The Formula(s) should be described with sufficient specificity as to allow the Plaintiffs to independently apply each Formula to the Historical Transactional Data.

FEB. 25, 2019 RESPONSE TO INTERROGATORY NO. 35: Allergan objects that the information sought in this Interrogatory seeks expert opinions that are more appropriately addressed during expert discovery. Allergan also objects that Plaintiffs ask Allergan to run a "Formula" over Historical Transactional Data that is no longer in Allergan's possession, as the databases that contain this information were provided to Teva in connection with the sale of the Actavis Generics Entities. Allergan further objects to the extent this Interrogatory seeks documents and information in a manner that is not kept in the ordinary course of business.

Subject to and without waiving its objections, with respect to Interrogatory 35(a), based on Allergan's investigation to-date, the following responses describe the Formulas, algorithms, or system logic used to detect potential orders of interest in Allergan's order management systems. As explained above, these orders of interest were then investigated to evaluate whether the orders of interests were Suspicious Orders.

WATSON PHARMACEUTICALS, INC.

Prior to 2004: ALLERGAN_MDL_01844864 indicates that, as of at least September 2001, "the system will compile a past history of control substances by each customer to establish a 12-month average" and that the order might be flagged "due to more frequent or larger quantities than the customer's normal ordering pattern." Watson used a system called ManFact at this time. The orders identified would then be investigated to determine whether they were Suspicious Orders.

From 2004 to 2012: Watson began using the SAP system in 2004 and developed a new formula that ran across orders contained within this system and applied to all controlled substances. The SOMS logic developed for the SAP system is described in ALLERGAN_MDL_02081605, which is hereby incorporated into this response. The program "compare[d] customer orders for controlled substance items with four (4) historical purchasing benchmarks by customer and by the respective customer's class and type." *Id.*

Benchmarks

The four benchmarks included:

Customer Class & type:

1) Average/Month - Average monthly purchase of a controlled substance item by customer's customer class and type during the prior twelve (12) month period; only those months containing purchases are included in the average.
2) Average/Purchase - average item quantity per order purchased by customer's customer class and type during the prior twelve (12) months; total controlled

substance item quantity purchased during the prior twelve (12) months divided by the number of times purchased by all customers within the customer class and type.

Customer:

3) Customer (ship-to)/Month - average monthly purchase of a controlled substance item by customer during the prior twelve (12) month period; only those months containing purchases are included in the average.

4) Customer (ship-to)/Purchase - average item quantity per order purchased by customer during the prior twelve (12) months; total controlled substance item quantity purchased during the prior twelve (12) months divided by the number of times purchased.

ALLERGAN_MDL_02081605 at -1606.

Multiplier

As described in ALLERGAN_MDL_03952864, ALLERGAN_MDL_03738529, ALLERGAN_MDL_03886124, and Acquired_Actavis_01675888, the multipliers used for each class of trade changed over time. The multiplier, also known as the tolerance factor, "is a single entry that applies to all benchmarks for a specific class of trade. This represents a multiple (for example, 1.5) which is applied to each benchmark for comparison against the sale." ALLERGAN_MDL_02081605 at -1606. Some of the classes of trade and their respective multipliers are explained below:

- In 2004, the multipliers were as follows: Chain (3), Distributor (1.5), Mailorder (1.5), Manufacturer (1.5), Wholesaler (1.5).
- In 2007, the multipliers were as follows: Chain (6), Distributor (3), Mailorder (3), Manufacturer (1.5 and 3); Wholesaler (3).
- In the first half of 2010, the multipliers were as follows: Chain (1.5); Distributor (1.25); Mailorder (1.25); Manufacturer (1.25); and Wholesaler (1.25).
- In June of 2010, the multipliers were as follows: Chain (3); Distributor (1.25); Mailorder (1.25); Manufacturer (1.25); Wholesaler (2).

- As of February 1, 2012, the multipliers were as follows: Chain (3); Distributor (1.25); Mailorder (1.25); Manufacturer (1.25); Wholesaler (3).
- In February 2013, every class of trade was set to 1.25.

Order Flagged if Greater Than Benchmark Times Multiplier

ALLERGAN_MDL_01852265 depicts the four reasons why orders might be blocked in the SOMS system: (1) if the total current quantity > Sales History monthly average, the order would hit SOMS block 12: Suspect (SH avg/mth); (2) if the total current quantity > sales history average order, the order would hit SOMS block 13: Suspect (SH avg/order); (3) if the total current quantity > class of trade monthly average, the order would hit SOMS block 10: Suspect (COT avg/mth); (4) If the total current quantity > class of trade average order, the order would hit SOMS block 11: Suspect (COT avg/order).

The Formula described above was in existence until Watson Pharmaceuticals, Inc. acquired Actavis Inc. The orders identified by this Formula would then be investigated to determine whether they were Suspicious Orders.

ACTAVIS INC.

Prior to 2012: Since at least 2000 until their system enhancement in 2012, the Actavis suspicious order monitoring system added up "[a]ll of the quantities ordered and a count of the number of lines" by "customer / part combination," using the previous month's invoices for regular sales transactions. ALLERGAN_MDL_02128514. The system stored the last 6 months of data. "The totals of each for the past 6 months (rolling) are added up and an average is computed by dividing the 6 month qty ord / 6 month line count. This is your 'customer item average.'" *Id.* New sales orders would appear on a report called the DEA Suspicious Order Report "if the qty ordered

is more than 1.25 * the customer average (ie., more than 25% over average)." *Id.* These orders would then be investigated to determine whether they were indeed Suspicious Orders.

In addition to the above Formula that applied to all controlled substances sold by Actavis Inc. (including oxycodone), Actavis Inc. also developed an additional procedure to identify orders of interest for oxycodone in 2011. Actavis Inc. would "run a monthly tracking report at a minimum of once per month in the Actavis order reporting system, for Oxycodone IR Tablets" and "compare the month-to-date orders for each customer, down to the customer DC level, against the rolling six month order history." ALLERGAN_MDL_00490306. Actavis Inc. would then "[i]dentify any individual customer locations that have ordered 50% or greater than their established six month order average." *Id.* The orders identified by this Formula would then be investigated to determine whether they were Suspicious Orders.

Enhanced System Developed in 2012: Actavis Inc. retained BuzzeoPDMA LLC (also known as Cegedim Compliance Solutions) to "develop a customized suspicious order monitor (SOM) statistical model using consulting team so that it can be implemented into Actavis' existing order management system." ALLERGAN_MDL_03402123.

Actavis Inc. began running the new algorithm in the production environment (parallel mode) in March 2012, and the system went live in October 2012. Actavis Inc. continued to use this algorithm until it was acquired by Watson Pharmaceuticals, Inc.

The statistical model is described in ALLERGAN_MDL_03401708:

> The SOM model that has been developed and recommended by CCS is thus designed to evaluate orders and determine whether they are more likely to fit the DEA's definition of a "suspicious order" or less likely to fit the DEA's definition of a "suspicious order." In order to do this, a "score" is given for each product line item in an order. The "score" is based on a number of attributes (or order qualities) which are independent variables that represent characteristics of the item in the order. The attributes are based on markers or data calculated from a twelve month

historical database. The model also includes identifiers – binary variables that must be either yes (assigned a value of 1) or no (assigned a value of 0).

For each order, an analysis is performed to determine whether or not the order contains a number of factors (attributes) that would be associated with a suspicious order. Each of these factors (attributes) is assigned a numerical value. For some factors, the factor is deemed to be more important, significant, or indicative of a potentially "suspicious order" and those factors are assigned a higher value. These higher value factors are referred to as having weighted values. The weighted values are expressed in mathematical terms referred to as co-efficients. The various numerical values associated with each factor for each product line item are totaled and the totals represent the "scores." If an order has a number of factors (attributes) that have a high numerical value (thus increasing the overall score), the order likely would meet the DEA's definition of what is considered potentially suspicious and the CCS model would indicate the order should be "pended" to allow further investigation to determine whether the order is in fact a "suspicious order" for reporting purposes.

The CCS model looks at and utilizes attributes and identifiers (and their assigned numerical values) that could be considered suspicious, and seeks to apply statistical techniques to establish "norms" and "deviations" so that the overall "suspiciousness" of the order can be evaluated. The CCS approach considers both the types of order qualities (attributes) that can make an order "suspicious" and also establishes parameters related to "normal" ordering patterns so that orders that "deviate from a normal pattern" can be readily identified. At its core, the system uses a heavily modified multiple logistic regression model that returns a score or "index" – quite simply, a number between zero and one – that is used to gauge the likelihood that an item is either ordered in error or is fraudulent (the model does not distinguish between the two). Items with low scores are allowed to proceed for processing, and items with large scores are pended for review. The model has been designed so that any order with a score of 0.15 or higher should be identified as potentially suspicious, pended, and investigated further.

As previously indicated, the model uses a number of variables and indicators ("attributes") that are used to calculate the SOM score. These attributes are calculated for every item in an order according to a twelve month history in the Actavis database. The attributes are primarily functions of the history fields (markers) that were previously supplied and are repeated in the section below. An important feature of the SOM model is that it is based on the monthly totals (i.e., sums) of the controlled substances as measured in milligram (mg) amounts of active ingredient. That is, the model does not distinguish between different brands, formulas, or package sizes. When an order is placed that contains a Controlled Substance, the total Version 1.0 – September 2011 - 3 - milligram amount must be calculated for each item, and then these values are added to the existing milligram amounts that have already been ordered for the month; then, these cumulative quantities are evaluated for "suspicion" based on the monthly totals of the particular

controlled substance for the previous twelve months in the Actavis database via the SOM model.

ALLERGAN_MDL_03401708.

The Buzzeo / Cegedim Formula, including the Suspicious Order Validation Logic, binary indicators, continuous variables, coefficients, constant values, evaluation formulas, reason codes, and reason code calculations are all described in ALLERGAN_MDL_00675261, ALLERGAN_MDL_03755775 and ALLERGAN_MDL_03757053. The orders identified by this Formula would then be investigated to determine whether they were Suspicious Orders.

ACTAVIS, INC.

After Watson Pharmaceuticals, Inc. acquired Actavis Inc. and became Actavis, Inc., the company utilized the Watson Pharmaceuticals, Inc. SOM system described above. This was effective as of approximately February 2013. This continued until the Actavis Generics Entities were sold to Teva in 2016. After that point, Allergan no longer was a DEA registrant for the manufacture or distribution of Schedule II controlled substances and thus had no further suspicious order monitoring obligations under the Controlled Substances Act.

* * *

With respect to Interrogatories 35(b) - (e), Allergan objects that these requests are overbroad and unduly burdensome as Allergan has already provided an extensive set of documents, information, and testimony regarding these topics to Plaintiffs. Further, these requests ask Allergan to create work product that is not kept in the ordinary course of business and seeks work product that is more appropriate for expert discovery.

Subject to and without waiving these objections, Allergan directs Plaintiffs to Tom Napoli's deposition at 260:3-261:19; 338:22-341:5; and 339:18-340:14.

MAY 31, 2019 RESPONSE TO INTERROGATORY NO. 35: Allergan Finance, LLC incorporates all objections and statements set forth in its February 25, 2019 Objections and Responses to Plaintiffs' Fourth Set of Interrogatories. With respect to Interrogatories 35(d)-(e), Allergan supplements its Interrogatory response with the following information about Suspicious Orders that were reported to the DEA. Because Allergan is unaware of any written record of all Suspicious Orders reported to the DEA, Allergan cannot confirm that the list below contains all Suspicious Orders that were ever reported to the DEA by Allergan (or any of its prior subsidiaries), or whether additional orders were reported verbally, electronically, or in writing. Allergan reserves the right to supplement this list with information about additional Suspicious Order reports to the extent that information becomes available.

1. TopRx, Inc.

Investigation reports detailing the suspicious order investigations and subsequent actions related to TopRX, Inc. can be found at ALLERGAN_MDL_02187198, ALLERGAN_MDL_02187201, and ALLERGAN_MDL_02467197. These documents discuss nine orders that were cancelled by TOP RX, and they indicate that the Watson DEA Affairs team "determined TOP RX's orders to be suspicious and in accordance with federal regulation, must report these suspicious orders to the DEA." ALLERGAN_MDL_02187198. Additionally, the DEA Affairs team "canceled pending orders" and Watson "agreed to discontinue all sales of controlled substances to TopRX." ALLERGAN_MDL_02467197. The investigation summaries also contain Watson investigative findings about Dr. Christopher J. Fisher, MD and Buena Vista Pharmacy. ALLERGAN_MDL_02187198. Tom Napoli testified that he personally remembers reporting TopRX to the DEA and "providing all this information [from the investigation summary]

to the DEA" -- specifically, to Tim Lenzi in the Chicago Field Office. *See* Napoli Dep. 260:3-261:19; 340:15-21.

2. Capital Wholesale Drug Co.

Investigation reports detailing the suspicious order investigations and subsequent actions related to Capital Wholesale Drug Co. can be found at ALLERGAN_MDL_02187195 and ALLERGAN_MDL_03765743. These documents indicate that the order at issue was an October 24, 2012 order for 48 units of Hydrocodone/APAP 10/650 mg (NDC 00591050301; Order # 580581). ALLERGAN_MDL_02187195. DEA Affairs "determined Capital's order to be suspicious and in accordance with federal regulation, must report suspicious orders to the DEA." *Id.* Further, DEA Affairs recommended "discontinuing sales of controlled substances to Capital." *Id.* Tom Napoli testified that he personally remembers reporting Capital Wholesale Drug Co. to the DEA-- specifically, Tim Lenzi in the Chicago Field Office. *See* Napoli Dep. 339:3-14; 340:22-341:5.

3. R & S Northeast / Dixon Shane Drug Company

Investigation reports detailing the suspicious order investigations and subsequent actions related to R & S Northeast, LLC (ship-to party Dixon-Shane Drug Company) can be found at ALLERGAN_MDL_02176521, ALLERGAN_MDL_02176522, ALLERGAN_MDL_03356576, and ALLERGAN_MDL_03912159. The order at issue was a July 20, 2010 order for thirty-six 100-count bottles of Hydrocodone/Apap 10/325 mg and twenty-four 100-count bottles of Hydrocodone/APAP 5/325 mg. ALLERGAN_MDL_02176521; ALLERGAN_MDL_03356576; ALLERGAN_MDL_03912159. When Watson requested justification for the order, R & S Northeast stated that "a new customer came on board -- Palm Beach Pain & Rejuvenation." ALLERGAN_MDL_02176521. Upon researching Palm Beach Pain

& Rejuvenation, the DEA Affairs team at Watson "concluded that the order was suspicious and agreed to cancel R & S Northeast's July 20th Hydrocodone order." *Id.* The order was reported to the DEA, as indicated within subsequent meeting minutes stating that Watson reported a suspicious order from Dixon Shane to the Chicago Field Office. ALLERGAN_MDL_02176488 at -6490.

4. Quality King Healthcare, Inc.

Documents reflecting some of the correspondence related to the investigation of Quality King Healthcare, Inc. include Acquired_Actavis_01675041 and ALLERGAN_MDL_03407212. Tom Napoli testified that after the acquisition of Actavis Inc., he personally remembers preemptively reporting Quality King to Richard Springer of the Long Island DEA office, before taking them on Quality King as a customer. *See* Napoli deposition 339:18-340:14. There were no particular orders at issue.

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Respectfully submitted,

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