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 (N.D. Ohio)*** ***The County of Cuyahoga v. Purdue Pharma L.P., et al., Case No. 17-OP-45004 (N.D. Ohio); and*** ***City of Cleveland v. AmerisourceBergen Drug Corp., et al., Case No. 18-OP-45132 (N.D. Ohio).***	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

SECOND AMENDED RESPONSES AND OBJECTIONS OF DEFENDANTS CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., AND WATSON LABORATORIES, INC. TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and the Court's Case Management Order One (Dkt. No. 232), Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. ("Teva") and Defendants Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Watson Laboratories, Inc. ("the Teva-Acquired Actavis Entities") (collectively, the "Teva Defendants"),[1] by and through their undersigned counsel, hereby provide the following Responses and Objections ("Responses") to Plaintiffs' First Set of Interrogatories ("Interrogatories") and state as follows:

[1] The Interrogatories served by Plaintiffs on the Teva-Acquired Actavis Entities improperly grouped them with entities not affiliated with the Teva Defendants. These Responses are made on behalf of the Teva Defendants.

PRELIMINARY STATEMENT

1. The Responses are made solely for the purposes of the three cases designated in "Track One" of Case Management Order One ("CMO 1") and are not to be used in connection with any other action except as expressly provided in the Protective Order entered on May 15, 2018, as Case Management Order No. 2 (Dkt. 441).

2. The Responses are based on diligent investigation conducted by the Teva Defendants and their counsel to date, documents and information available to the Teva Defendants at this time, and reflect the Teva Defendants' knowledge, information, and belief as of the date of the Responses. The Responses are true and correct to the Teva Defendants' best knowledge as of this date.

3. The Teva Defendants may engage in further investigation, discovery, and analysis, which may lead to changes in the Teva Defendants' Responses herein. Such investigation and discovery are continuing, and the Responses are given without prejudice to the Teva Defendants' right to produce evidence of any subsequently-discovered facts, documents, or interpretations thereof, or to supplement, modify, change, or amend the Responses, and to correct for errors, mistakes, or omissions. Reference in the Responses to a preceding or subsequent response incorporates both the information and the objections set forth in the referred-to response.

4. The Teva Defendants will make reasonable efforts to respond to every Interrogatory, to the extent the Interrogatory has not been objected to, as the Teva Defendants understand and interpret the Interrogatory. In the event that Plaintiffs subsequently assert an interpretation of an Interrogatory that differs from that of the Teva Defendants, the Teva Defendants reserve the right to amend and/or supplement their Response, but undertake no obligation to do so.

5. In responding to the Interrogatories, the Teva Defendants do not waive, and hereby expressly reserve: (a) their right to assert any objections as to the competency, relevancy, materiality, privilege, or admissibility as evidence, for any purpose, of any information produced in response to the Interrogatories; (b) their right to object on any ground to the use of the information produced in response to the Interrogatories at any hearing, trial, or other point during the litigation; and (c) their right to object on any ground at any time to a demand for further responses to the Interrogatories.

6. No incidental or implied admissions are intended in these Responses. That the Teva Defendants have responded to all or any part of an Interrogatory should not be taken as, and indeed does not constitute, an admission that the Teva Defendants accept or admit the existence of any fact set forth or assumed by the Interrogatory or that the Teva Defendants' Responses constitute admissible or relevant evidence. That the Teva Defendants have responded to all or any part of an Interrogatory also is not intended to be, and indeed does not constitute, a waiver by the Teva Defendants of all or any part of its objection(s) to the Interrogatory.

7. The following Objections to Definitions and Instructions apply to each and every one of the Interrogatories, and should be considered part of the Teva Defendants' response to each and every one of the Interrogatories. Any specific objections provided below are made in addition to the Objections to Definitions and Instructions, and failure to reiterate an Objection to Definitions and Instructions below does not constitute a waiver or limitation of that or any other objection.

OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS

The Teva Defendants hereby assert the following Objections to Definitions and Instructions, which are hereby incorporated into each of the specific responses and objections to the Interrogatories set forth below.

1. The Teva Defendants object to Plaintiffs' definition of "You" and "Your" as vague and/or ambiguous, overly broad, unduly burdensome, and not proportional to the needs of the case, and thus outside the scope of permissible discovery because it purports to encompass, without limitation, "officers, directors, employees, partners, representatives, agents, corporate parent, subsidiaries, affiliates, divisions, predecessors, or successors-in-interest, and other persons or entities acting on [their] behalf or controlled by" the Teva Defendants. The Teva Defendants will only produce documents in the possession, custody, or control of Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., or Watson Laboratories, Inc.

2. The Teva Defendants interpret the terms "You" and "Your" as used in these Interrogatories to refer only to Defendants Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Watson Laboratories, Inc. Defendants expressly exclude Defendant Teva Pharmaceutical Industries, Ltd., which is an Israeli entity not subject to personal jurisdiction in this action,[2] and/or any of its other respective subsidiaries or affiliates from the terms "You" and "Your" and no response herein should be interpreted to include such other entities.

3. The Teva Defendants object to Plaintiffs' definition of "You" and "Your" as overly broad, unduly burdensome, and not proportional to the needs of the case, and thus outside the scope of permissible discovery, because it purports to encompass, without limitation, "Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc." The Teva-

[2] Teva Pharmaceutical Industries, Ltd. is a foreign company. It is not subject to personal jurisdiction in this litigation and has a motion dismiss on those grounds pending before the Court. Teva Pharmaceutical Industries, Ltd. is not a proper party and has expressly reserved all defenses and objections to personal jurisdiction and service. Accordingly, Teva Pharmaceutical Industries, Ltd.is not required to and therefore does not join in the Teva Defendants' responses and objections to these Interrogatories.

Acquired Actavis Entities, which did not become affiliated with any Teva entity until 2016, only sell generic opioid drugs and do not sell, market, or otherwise distribute any branded opioid product. For the Track 1 discovery cases, none of the complaints contain any specific allegations concerning promotion by the Teva-Acquired Actavis Entities concerning their generic opioids, nor do they allege any wrongful conduct by those Entities that could serve as a basis for any claim against them. Therefore, any non-privileged information that is responsive to these Interrogatories, if any exists, is not relevant to this litigation, and would be unduly burdensome to collect and would not be proportionate to any legitimate need by Plaintiffs. Nevertheless, the Teva Defendants will provide substantive responses in response to these Interrogatories as set forth in the individual Responses below.

4. The Teva Defendants object to Plaintiffs' definition of "Opioid" to the extent that it means opioids "used to control pain, including, but not limited to, the drugs referenced in Plaintiffs' Complaint in the above-referenced matter" as vague, ambiguous, and overbroad. The Teva Defendants will provide information relating to their Schedule II opioid products, including ACTIQ® (fentanyl citrate) oral transmucosal lozenge CII and FENTORA® (fentanyl buccal tablet) CII. ACTIQ®, and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on

around-the-clock opioids while taking ACTIQ® or FENTORA®. The generic opioid products sold by the Teva Defendants are each FDA-approved generic versions of branded opioid products that were also approved by the FDA, and the indication for each generic opioid product speaks for itself. The Teva Defendants will provide information about the generic opioid products that they sold during the relevant period.

5. Any information provided by the Teva Defendants in response to requests for information about "Opioids" does not mean that these products were promoted for or "used to control pain" or any other use beyond that which has expressly been approved by the FDA, nor does it suggest that the Teva Defendants ever promoted, marketed, or sold any opioids in the jurisdictions at issue. The Teva Defendants also object to any implication or presupposition that they can or do control or know how any opioid product is "used" once prescribed.

6. The Teva Defendants object to the definition of "Communication" as calling for the search and collection of sources like "MySpace," "Twitter," and "shared applications from cell phones" that would be unduly burdensome, overbroad, not reasonably calculated to lead to the discovery of admissible evidence, and not proportional to the needs of the case.

7. The Teva Defendants object to the definition of "Document" as overly broad and unduly burdensome to the extent it purports to impose upon the Teva Defendants any obligation inconsistent with the Federal Rules of Civil Procedure.

8. The Teva Defendants object to the use of the phrase "above-captioned matter" to the extent it purports to reference cases other than the three cases included in Track One of the Court's CMO 1.

9. The Teva Defendants object to the definition of "Defendants" to the extent it purports to name Defendants who are not named in the three cases included in Track One of the Court's CMO 1.

10. The Teva Defendants object to the definition of "Plaintiffs" to the extent it purports to name Plaintiffs who are not named in the three cases included in Track One of the Court's CMO 1.

11. The Teva Defendants object to the definition of "Person" to the extent it purports to impose obligations to produce information outside of the Teva Defendants' knowledge, possession, custody, and control.

12. The Teva Defendants object to the definition of "Marketing" as overly broad, unduly burdensome, vague, ambiguous, not relevant to any party's claim or defense, and not proportional to the needs of the case to the extent it encompasses "providing information about Opioids or Opioid Products" as well as to the extent it characterizes "continuing medical education" and "scientific medical" articles or publications as "Marketing." The Teva Defendants will interpret "Marketing" to refer to the action or business of promoting and selling Opioids as alleged against the Teva Defendants in the Complaint.

13. The Teva Defendants object to the definition of "Branded Marketing" to the extent it incorporates the defined term "Marketing," for the reasons stated above with respect to that defined term.

14. The Teva Defendants object to the definition of "Unbranded Marketing" to the extent it incorporates the defined term "Marketing," for the reasons stated above with respect to that defined term.

15. The Teva Defendants object to the definition of "Adverse Event" on the grounds that the phrase "undesirable experience" is vague and ambiguous and to the extent the definition is inconsistent with applicable regulatory terms and definitions.

16. The Teva Defendants object to the definition of "Scientific Research" as overly broad, unduly burdensome, vague, ambiguous, not relevant to any party's claim or defense, and not proportional to the needs of the case. Plaintiffs' definition, which encompasses, among other things, "comparisons," "reviews," and "analyses" conducted by undefined and unspecified "doctors, researchers, or other investigators" does not supply any meaningful criteria by which to identify the information sought.

17. The Teva Defendants object to the definition of "Suspicious Order" to the extent it purports to be "defined by DEA." DEA has not defined the term "suspicious order" and Plaintiffs do not identify one. The Teva Defendants further object to the definition of "Suspicious Order" due to its incorporation of the defined terms "Opioid" and "Opioid Products."

18. The Teva Defendants object to the definition of "DEA Quotas" to the extent that it purports to require the Teva Defendants to produce information outside its knowledge, possession, custody, or control.

19. The Teva Defendants object to the definition of "Identify" when used with respect to persons, on the grounds that it seeks irrelevant information, is overly broad and unduly burdensome, and purports to require the Teva Defendants to produce information outside the possession, custody, or control of the Teva Defendants. In particular, the Teva Defendants object to the definition of "Identify" to the extent it purports to require the Teva Defendants to provide any person's present or last known address and present or last known place of employment.

20. The Teva Defendants object to the "Instructions" of the Interrogatories as covering the time period "January 1, 1998 through the date of Your response" as overly broad and unduly burdensome because it requires them to produce documents that are outside the relevant statute(s) of limitations, are not relevant to the claims in the Complaints, and are not proportional to the needs of the case. Nevertheless, the Teva Defendants will provide information in response to these Interrogatories as set forth in the individual Responses below and in accordance with the Court's Discovery Ruling 2 (Dkt. No. 693).

21. The Teva Defendants further object to the "Instructions" of the Interrogatories as not proportional to the needs of the case to the extent that the Interrogatories seek information from the Teva Defendants that was previously obtained, is in the possession of the Plaintiffs, and/or has been deemed produced pursuant to CMO 1.

INTERROGATORIES

INTERROGATORY NO. 1:

Identify all individuals with knowledge concerning the subject matter of the allegations in the Complaint in the above referenced matter, including each individual likely to have discoverable information, and, for each, state the subjects on which they have knowledge or information.

AMENDED RESPONSE TO INTERROGATORY NO. 1:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 1 on the ground that it seeks information that is not relevant to the issues raised by the parties' claims or defenses, is overly broad, and is unduly burdensome or expensive because it encompasses "all individuals with knowledge concerning the subject matter of the allegations in the Complaint" no matter how tangential the relation to the claims and/or defenses. The Teva Defendants further object to Interrogatory No. 1 as not reasonably limited as to time or scope. The Teva Defendants further object that the phrase "the subject matter of the allegations" is vague and ambiguous.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that, based upon their reasonable investigation to date, they have identified the individuals listed in Appendix A.

INTERROGATORY NO. 2:

Identify all Scientific Research, studies, tests, trials or analysis that you relied on to test the safety or efficacy of each of your Opioid Products or that you relied on as a basis for any Marketing concerning the safety or efficacy of each of your Opioid Products. For each such Scientific Research, study, clinical trial or analysis identify:

a. The duration for which the patient population was given opioids;

b. The dose of opioids given to the patient population.

AMENDED RESPONSE TO INTERROGATORY NO. 2:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 2 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 2 as not reasonably limited as to time or scope. Subject to and without waiver of the foregoing objections, the Teva Defendants answer as follows:

The Teva Defendants refer Plaintiffs to TEVA_MDL_A_08235305, which the Teva Defendants produced in this litigation and which contains the responsive studies on ACTIQ® and FENTORA®. The Teva Defendants further answer that each study contains the requested dosage and duration information and speaks for itself.

The Teva Defendants' generic opioid products were approved by the FDA through Abbreviated New Drug Applications ("ANDAs"), which neither require nor permit submission of studies regarding the safety and efficacy of the proposed generic product. Instead, ANDAs rely on the FDA's previous determination that the branded version of the product (referred to as the "referenced list drug" or "RLD"), based on pertinent safety and efficacy studies, is safe and effective. ANDA applicants must follow one of two approval pathways established by the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 355(j), 355(b)(2). The first, which "may not be submitted if studies are necessary to establish the safety and effectiveness of the proposed product," requires "information to show that the proposed generic product 1) is the same as the RLD with respect to active ingredient(s), conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) and 2) is bioequivalent to the RLD." *See Determining Whether to Submit an ANDA or a 505(b)(2) Application*[,] *Guidance for Industry*, at 2-3, 10 (October 2017) (Draft Guidance) (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579751.pdf) (discussing ANDAs filed under 21 U.S.C. § 355(j)). The second, which is for a proposed generic that "differs from the RLD in its dosage form, route of administration, strength, or active ingredient" is only available if the "FDA determines . . . that studies are not necessary to establish the safety and efficacy of the proposed drug product." *Id.* at 3 (discussing "petitioned ANDAs" under 21 U.S.C. § 355(b)(2)). Thus, the FDA did not require scientific research, studies, tests, trials or analysis on the safety and efficacy of the Teva Defendants' generic opioid products beyond that which was reviewed in the course of each RLD's FDA approval. The Teva Defendants have not identified any such study and did not promote generic opioid products, and marketed only pricing and availability of generic opioids.

INTERROGATORY NO. 3:

Identify any controlled studies of which You are aware where the safety and efficacy of the use of opioids beyond 16 weeks was tested and Opioids were found to be safe and efficacious.

AMENDED RESPONSE TO INTERROGATORY NO. 3:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 3 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." The Teva Defendants further object to Interrogatory No. 3 as irrelevant and not proportional to the claims against them, as no allegations have been made that the Teva Defendants made any representations regarding the safety and efficacy of the use of opioids beyond 16 weeks. ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 3 on the ground that the term "aware" is vague, ambiguous, and overly broad to the extent it purports to encompass studies that the Teva Defendants did not control or sponsor. The Teva Defendants further object to Interrogatory No. 3 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 3 to the extent it calls for documents that are outside of their possession, custody, or control and/or purports to require the Teva Defendants to identify studies that they did not sponsor or control. The Teva Defendants further object to Interrogatory No. 3 to the extent it seeks documents that are publicly available and/or equally available to Plaintiffs as to the Teva Defendants.

Subject to and without waiver of the foregoing objections, the Teva Defendants incorporate their response to Interrogatory No. 2, which includes the information sought in Interrogatory No. 3.

INTERROGATORY NO. 4:

Identify any and all controlled studies that found that opioids improve patients' pain and function on a long-term basis (longer than 90 days).

AMENDED RESPONSE TO INTERROGATORY NO. 4:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 4 on the ground that it is vague, ambiguous, and overly broad in that it refers to all "opioids." The Teva Defendants further object to Interrogatory No. 4 as irrelevant and not proportional to the claims against them, as no allegations have been made that the Teva Defendants made any representations regarding opioids improving patients' pain and function on a long-term basis. ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 4 on the ground that it a duplicative of information requested in Interrogatory No. 3. The Teva Defendants further object to Interrogatory No. 4 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 4 to the extent it calls for documents that are outside of their possession, custody, or control and/or purports to require the Teva Defendants to identify studies that they did not sponsor or control. The Teva Defendants further object to Interrogatory No. 4 to the extent it seeks documents that are publicly available and/or equally available to Plaintiffs as to the Teva Defendants.

Subject to and without waiver of the foregoing objections, the Teva Defendants incorporate their response to Interrogatory No. 2, which includes the information sought in Interrogatory No. 4.

INTERROGATORY NO. 5:

Identify all physicians, professional associations and/or organizations that You, or any third party on Your behalf, compensated in any way for speaking, publishing endorsing or promoting Opioids and/or your Opioid Products from 1998 to present, the identify of those receiving compensation and detail the amount of compensation to each.

AMENDED RESPONSE TO INTERROGATORY NO. 5:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 5 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 5 as vague, ambiguous, and overly broad to the extent it seeks information from "third part[ies]" that are outside the Teva Defendants control. The Teva Defendants further object to Interrogatory No. 5 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 5 to the extent it seeks documents that are publicly available and/or equally available to Plaintiffs as to the Teva Defendants.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that transfers or payments of items of value to prescribers is publicly available information pursuant to The Physician Payments Sunshine Act (PPSA) – also known as Section 6002 of the Affordable Care Act (ACA) of 2010 – and can be found at openpaymentsdata.cms.gov. Answering further, the Teva Defendants produced a compilation of available data regarding payments relating to ACTIQ® and FENTORA® in excess of $1,000 by Teva to healthcare professionals on a nationwide basis from 2009 to 2017 at TEVA_MDL_A_00764244. The Teva Defendants further

state that the Teva-Acquired Actavis Entities did not compensate any physicians, professional associations and/or organizations for the services described in Interrogatory No. 5.

INTERROGATORY NO. 6:

Identify each and every time You, a Person You employed or a Person or entity who received compensation from You cited the publication J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) as support for a claim that Opioids or Your Opioid Products were safe or rarely addictive including the date of each citation.

AMENDED RESPONSE TO INTERROGATORY NO. 6:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 6 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 6 as not reasonably limited as to time or scope. The Teva Defendants further object to Interrogatory No. 6 to the extent it calls for documents that are outside of their possession, custody, or control. The Teva Defendants further object to Interrogatory No. 6 on the ground that, to the extent it exists, the information is published by third parties, maintained by those third parties, equally accessible to the Plaintiffs from the third parties, and more appropriately sought from those third parties than from the Teva Defendants.

Subject to and without waiver of the foregoing objections, the Teva Defendants have not identified any instances or documents in which the publication above was cited as or used as described in Interrogatory No. 6.

INTERROGATORY NO. 7:

Identify any Persons employed by You, or who received compensation or anything of value from You, including any former employees, who reviewed or analyzed data regarding the prescribing, use, sale, Marketing or distribution of Opioids or Opioid Products or who reviewed, analyzed data regarding the possible abuse, illicit use or Suspicious Order of Opioids or Opioid Products.

AMENDED RESPONSE TO INTERROGATORY NO. 7:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 7 on the ground that it is vague, ambiguous, and overly broad because it requires the identification of any employee, agent, or contractor who has ever reviewed any data regarding the marketing, sale, or distribution of opioids. The Teva Defendants further object to Interrogatory No. 7 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that following employees have reviewed and analyzed data as part of the Teva Defendants' Suspicious Order Monitoring programs:

- Nancy Baran;
- Matthew Benkert;
- Randy Bradway;
- Michael Clarke;
- Sarah Everingham;
- Dennis Ferrell;

- Rachelle Galant;
- Tracey Hernandez;
- Kevin Kreutzer;
- Colleen McGinn;
- Tom Napoli;
- Joseph Tomkiewicz; and
- Mary Woods.

The Teva Defendants further state that numerous additional employees in various departments, including Sales and Marketing, Sales Operations, DEA Compliance, and their equivalents at the various Teva Defendants over time, reviewed information relating to sales, prescriptions, and distribution of the Teva Defendants' opioid products for various business purposes.

INTERROGATORY NO. 8:

Identify any data systems or sources of data that you have used from 1998 to present to study, review or analyze prescribing, sales, distribution, use, consumer or medical community perceptions, insurance coverage, diversion, misuse, or abuse (including overdoses, hospitalizations or other injuries or fatalities) of Opioids or Your Opioid Products, including data regarding prescriber histories and trends.

AMENDED RESPONSE TO INTERROGATORY NO. 8:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 8 on the ground that it is vague, ambiguous, and overly broad in that it purports to encompass "all data systems or sources of data." The Teva Defendants further object to Interrogatory No. 8 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for

the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that, based upon their reasonable investigation to date, prescribing and sales data is housed with the Sales Operations Department, distribution and suspicious order monitoring data is housed with the DEA Compliance Department, and consumer and medical community perceptions data is housed with the Market Research Department. The Teva Defendants further state they have received data like that described in Interrogatory No. 8 from the following sources:

- IQVIA (f/k/a IMS);
- Symphony (f/k/a Wolters Kluwer);
- RADARS System;
- The TIRF REMS Industry Group;
- FDA's MedWatch System;
- McKesson;
- AmerisourceBergen; and
- ValueCentric.

The Teva Defendants further state that they received certain information regarding the sales of their opioid products from various distributors with which they did business in the form of chargeback data that was submitted to the Teva Defendants at the option of the distributors.

The Teva Defendants further state that they used the following systems to analyze data like that described in Interrogatory No. 8:

- ARGUS, a database in which the Teva-Acquired Actavis Entities housed adverse event data;

- ArisG, a database in which Teva housed adverse event data;
- SAP – Enterprise Resource Platform; and
- ValueTrak, a data processing platform hosted by ValueCentric, LLC.

INTERROGATORY NO. 9:

Identify all industry associations or organizations relating to the production, marketing, sale or distribution of pharmaceuticals that You are or were a member of from 1998 to present.

AMENDED RESPONSE TO INTERROGATORY NO. 9:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 9 on the ground that it is vague, ambiguous, and overly broad in that it requires the Teva Defendants to identify "all industry associations or organizations." The Teva Defendants further object to Interrogatory No. 9 on the ground that it is not reasonably limited as to time, scope, or subject matter of the litigation, which relates to opioids; calls for information that is not relevant to any claim in this case; and is not proportionate to any purported need by Plaintiffs. The Teva Defendants further object to Interrogatory No. 9 to the extent it seeks documents that are publicly available and/or equally available to Plaintiffs as to the Teva Defendants.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that, based upon their reasonable investigation to date, Teva holds and/or held memberships with the following industry associations and organizations:

- Alliance to Prevent Abuse of Medicines;
- Association for Accessible Medicines f/k/a Generic Pharmaceutical Association;
- Healthcare Distribution Alliance f/k/a Healthcare Distribution Management Association;
- National Association of Chain Drug Stores;

- Pain Care Forum; and
- Pharmaceutical Research and Manufacturers of America.

The Teva Defendants further state that, based on their reasonable investigation to date, the Teva-Acquired Actavis entities held memberships with the following industry associations and organizations:

- American Society of Health-System Pharmacists;
- Association for Accessible Medicines f/k/a Generic Pharmaceutical Association;
- Healthcare Distribution Alliance f/k/a Healthcare Distribution Management Association;
- National Wholesale Druggists Association; and
- Pharmaceutical Care Management Association.

INTERROGATORY NO. 10:

Identify any Scientific Research, studies, tests, clinical trials or analysis regarding the safety and efficacy of Your Opioid Products that You decided not to publish and the reasons for that decision.

AMENDED RESPONSE TO INTERROGATORY NO. 10:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 10 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 10 on the ground that it is overly broad, unduly burdensome, and not proportional to the needs of this case. The Teva

Defendants further object to Interrogatory No. 10 on the ground that it is overly broad, unduly burdensome, vague, and ambiguous in that it references "decided not to publish," which is subject to many interpretations.

Subject to and without waiver of the foregoing objections, the Teva Defendants incorporate their response to Interrogatory No. 2, which includes the information sought in Interrogatory No. 10.

INTERROGATORY NO. 11:

Did You instruct your employees or sales agents to market any Opioids or any Opioid Product as virtually non-addictive and what was the basis for that instruction?

AMENDED RESPONSE TO INTERROGATORY NO. 11:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 11 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 11 on the ground that it is overly broad, unduly burdensome, vague, and ambiguous in that it references "virtually non-addictive," which is an undefined phrase.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that their employees were instructed that, to the extent they had any discussions with prescribers at all, those discussions were required to be consistent with the information provided in the FDA-approved Full Prescribing Information ("FPI") and Risk Evaluation and Mitigation Strategy ("REMS") for ACTIQ® and/or FENTORA®, which includes information about the risk of

addiction. The Teva Defendants further state that they did not promote any generic opioid products, marketed only pricing and availability of generic opioids, and are not aware that the instruction described in Interrogatory No. 11 was given to any person involved in such activities.

Answering further, the Teva Defendants have not actively promoted ACTIQ at all since 2006; have had extensive compliance policies and procedures in place to prevent off-label discussions with respect to its opioid products during the relevant period; were subject to a Corporate Integrity Agreement, which imposed very significant controls and obligations with respect to the appropriate promotional activities from 2008 through 2013; and since April 2012, have participated in a stringent REMS program for its Transmucosal Immediate Release Fentanyl ("TIRF") products which includes ACTIQ® and FENTORA®. The TIRF REMS program requires, among other things, enrollment by the prescribing physician and patient as condition of prescribing and receiving TIRF products, with re-enrollment required every two years. As part of the enrollment process, the physician and patient must sign agreements in which, among other acknowledgments and disclosures, both the physician and patient acknowledge that they have reviewed and discussed the FPI and Medication Guide, which includes the FDA-approved risk disclosures regarding addiction and other risks associated with these prescription medicines.

INTERROGATORY NO. 12:

Did You instruct your employees and sales agents that there was no upper limit on dosing for Opioids or any Opioid Product? Describe how that instruction was tested in terms of safety and efficacy and have You subsequently ever placed restrictions on Your recommended dosing limits and why?

RESPONSE TO INTERROGATORY NO. 12:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 12 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are

"used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 12 on the ground that it is overly broad, unduly burdensome, vague, and ambiguous in that it references "no upper limit on dosing," which is an undefined phrase.

Subject to and without waiver of the foregoing objections, the Teva Defendants incorporate their response to Interrogatory No. 11 and specifically state that the instruction provided to employees included dosing in accordance with the prescribing information and REMS.

INTERROGATORY NO. 13:

Have you ever placed limits on the amount of Opioid Products you supplied to distributors, retailers or end users because of reports of addiction, abuse, potential diversion, overprescribing, Adverse Events or potential Suspicious Orders. If so, specifically what limits and when did they occur?

AMENDED RESPONSE TO INTERROGATORY NO. 13:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 13 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 13 on the ground that it is overly broad, unduly burdensome, vague, and ambiguous in that it references "distributors," "retailers," and "end users," which are undefined terms.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that they have not placed prospective or general limits on opioid products based on reports of addiction, abuse, potential diversion, overprescribing, Adverse Events, or potential Suspicious Orders, but that the Teva Defendants have at all times maintained sophisticated and compliant suspicious order monitoring programs to identify orders of interest and determine whether they constitute suspicious orders in compliance with the Controlled Substances Act. The Teva Defendants have, through the regular operation of those suspicious order monitoring programs, and for a variety of reasons, withheld or delayed shipments of opioid products.

INTERROGATORY NO. 14:

From 2010 to present please identify the revenue received from Your Opioid Products sold outside the United States.

RESPONSE TO INTERROGATORY NO. 14:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 14 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. The Teva Defendants further object to Interrogatory No. 14 on the ground that it is not relevant, overly broad, unduly burdensome, and not proportional to the needs of this case because it is not limited in scope to conduct in the United States when the allegations in the Complaints are limited to conduct in the United States.

INTERROGATORY NO. 15:

After the CDC declared an opioid epidemic in 2011 and introduced guidelines to help reduce Opioid prescribing did you reduce the amount of Opioid Products You supplied to the

market? If so detail specifically what steps did you take to reduce prescribing or supply of Your Opioid Products and when?

AMENDED RESPONSE TO INTERROGATORY NO. 15:

The Teva Defendants incorporate their Preliminary Statement and Objections to Definitions and Instructions. The Teva Defendants object to Interrogatory No. 15 on the ground that it is vague, ambiguous, and overly broad because the definition of "Opioid" is opioids that are "used to control pain." ACTIQ® and FENTORA® are each FDA-approved opioid agonists indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Subject to and without waiver of the foregoing objections, the Teva Defendants state that prescriptions of ACTIQ® and FENTORA® have declined since 2011 and represent an extremely small percentage of opioids prescribed in an outpatient setting. In 2016, for example, there were fewer than 15,000 prescriptions of those two products, combined, in the entire United States. Answering further, the Teva Defendants state that the CDC has never declared that either of these two FDA-approved medications for the treatment of breakthrough cancer pain caused or contributed in any way to an opioid epidemic, nor did the CDC ever state or suggest that prescriptions or supply of these critically-needed medications should be reduced. Indeed, the second sentence of the CDC guideline makes clear that "it is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care." *See Guideline for Prescribing Opioids for Chronic Pain*, *available at* https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.

The Teva Defendants further state that at all times the total number of opioid products that the Teva Defendants supplied to the market has been regulated by the DEA Office of Diversion

Control through the use of quotas that limit amount of controlled substances available to pharmaceutical manufacturers, including the Teva Defendants.

Dated: March 4, 2019

Respectfully submitted,

/s/ *Steven A. Reed*

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Attorneys for Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Watson Laboratories, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 4th day of March 2019, the foregoing has been served via email only to the following liaison counsel:

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/s/ *Wendy West Feinstein*
Wendy West Feinstein

APPENDIX A

Name	Title	Subject Matter
Brandy Anderson	Teva Pharmaceuticals Regulatory Affairs Associate, Neurology, Pain & Migraine	TIRF REMS & Medical Affairs
Valli Baldassano	Former Cephalon Executive Vice President & Chief Compliance Officer	Compliance
Christine Baeder	Teva Pharmaceuticals Chief Operations Officer, US Generics	Teva Generics
Jeannette Barrett	Former Actavis Senior Medical Director	Actavis medical affairs
Nancy Baran	Former Actavis Executive Director, Customer Relations Operations	Actavis compliance and sales operations
Bryan Bart	Teva Pharmaceuticals Senior Director, Product Operations	Product information for generic opioid products; supply and distribution for generic opioid products
Deborah Bearer	Teva Pharmaceuticals Director, Health Systems Marketing	Marketing and managed care issues
Stacey Beckhardt	Former Cephalon Associate Director, Alliance Development	Medical education grants
Doug Boothe	Former Actavis Chief Executive Officer	Actavis general operations
Joseph Caminiti	Former Cephalon Inc., Vice President, Sales and Marketing Operations and Effectiveness	Sales, marketing, and managed care issues
Napoleon Clark	Teva Pharmaceuticals Vice President, Marketing	Product information for generic opioid products; supply and distribution for generic opioid products
Michael Clarke	Former Actavis Vice President, Ethics and Compliance	Actavis Compliance
Cynthia Condodina	Teva Pharmaceuticals Director, Commercial Training & Development	Sales training
Matthew Day	Former Teva Pharmaceuticals Director, Marketing, CNS & Pain Care Franchises	Marketing issues
Chuck DeWildt	Former Teva Pharmaceuticals Vice President, Regional Payers	Sales training
Joyce DelGaudio	Teva Pharmaceuticals Senior Director, Regulatory Affairs Pre Approval, Generic	Regulatory affairs

Name	Title	Subject Matter
Francine Del Ricci	Teva Pharmaceuticals Vice President, Project & Alliance Management	Project and alliance management
Simon Diaz	Teva Pharmaceuticals Director, Regulatory Affairs	Regulatory affairs
Chris Doerr	Teva Pharmaceuticals Vice President, Trade Relations & Distribution Strategy	Sales to distributors/trade customers
Michael Dorsey	Teva Pharmaceuticals Director, National Accounts	Generic opioid products
Rachelle Gallant	Former Actavis Senior Product Manager	Generic opioid products
Tricia Glover	Teva Pharmaceuticals Vice President, US Chief Compliance Office	Compliance
Kishore Gopu	Teva Pharmaceuticals Director of REMS	Risk management and REMS programs
John Hassler	Teva Pharmaceuticals Senior Vice President and General Manager, CNS	Topics in Plaintiffs' 30(b)(6) notice to the Teva Defendants
Rod Hughes	Former Cephalon Vice President, Scientific Communications	Medical education grants
Denisa Hurtukova	Teva Pharmaceuticals Vice President, Head of North America Medical Affairs	Medical Affairs
Dolly Judge	Teva Pharmaceuticals Vice President, U.S. Government Affairs	Government affairs and lobbying
Jerry Kester	Teva Pharmaceuticals Director of Trade Strategy and Former Associate Director, REM Operations	Risk management and REMs Programs
James G. King	Teva Pharmaceuticals Director, US Medical Information	TIRF REMS & Medical Affairs
Ernest Kopecky	Teva Pharmaceuticals Vice President, Clinical Development; Head, Global Pain Medicine	Medical Affairs
Richard Kosich	Former Cephalon Senior Safety Associate, Pharmacovigilance	Pharmacovigilance
Gary Kozloski	Former Allergan Vice President, Global Pharmacovigilance	Pharmacovigilance
Susan Larijani	Teva Pharmaceuticals Senior Director, Medical Information	Medical information requests
Nathalie Leitch	Teva Senior Vice President	Generic opioid products

Name	Title	Subject Matter
Penny Levine	Former Teva Pharmaceuticals Director, Regulatory Affairs	Regulatory Affairs, risk management, and REMS programs
Karen Lowney	Former Teva Pharmaceuticals Senior Director, Global Compliance	Compliance
Carol Marchione	Former Teva Pharmaceuticals Senior Director and Group Leader for Oncology Regulatory Affairs	Regulatory affairs and submissions to FDA
Greg Martin	Teva Pharmaceuticals Director, Scientific Information	Sales and promotional practices
Sheila Mathias	Teva Pharmaceuticals Director, Regulatory Affairs	Risk management planning and drug development process
Jinping McCormick	Former Actavis Director of Product Marketing	Generic opioid products
Colleen McGinn	Teva Pharmaceuticals Senior Director, DEA Compliance	DEA compliance
Scott Megaffin	Former Cephalon Vice President, Pain Franchise	Sales and marketing
Chris Meyer	Teva Pharmaceuticals Senior Director, Sales Analytics and Incentive Compensation	Sales and promotional practices
Wendy Miller	Former Teva Pharmaceuticals Director, Marketing Insights & Analytics	Marketing issues
Tamala Mallett Moore	Former Cephalon Director Risk Management, Regulatory Affairs	Regulatory affairs
Michael Morreale	Teva Pharmaceuticals Sales Manager, Ohio Valley	Sales and promotional practices
Matthias Mueller	Teva Pharmaceuticals Head Global Therapeutic Areas and Scientific Communications, Global Medical Affairs	Medical Affairs
David Myers	Teva Pharmaceuticals Senior Manager, Product Marketing	Marketing issues
Arvind Narayana	Former Teva Pharmaceuticals Senior Global Medical Director	Research and development
Tom Napoli	Former Actavis Associate Director, Controlled Substance Compliance	DEA compliance
Terri Nataline	Former Actavis Vice President, Regulatory and Medical Affairs	Regulatory Affairs and Medical Affairs related to generic opioid products
Alexander Nikas	Teva Pharmaceuticals Senior Director, Executive Counsel	Marketing issues

Name	Title	Subject Matter
Jennifer Pansch	Director, Regulatory Affairs, Pain Therapeutic Area	Medical Affairs
Mike Perfetto	Former Actavis Vice President	Sales of generic opioid products
Andrew Pyfer	Former Cephalon National Sales Director, Pain Care Division	Sales and promotional practices
Jim Reilly	Former Teva Pharmaceuticals Vice President, Sales	Sales and promotional practices
Michael Richardson	Former Cephalon Senior Director of Product Planning for Pain Franchise	Marketing issues
Brian Shanahan	Teva Pharmaceuticals Associate General Counsel	Corporate structure
Eric Siegel	Former Cephalon Vice President, Deputy General Counsel and Chief Compliance Officer	Medical education grants
Randy Spokane	Former Teva Pharmaceuticals National Sales Director, Pain Care	Sales and promotional practices
Dieter Schultewolter	Teva Pharmaceuticals Senior Director, Head of Global Medical TA CNS	Medical Affairs
Terrence Terifay	Former Cephalon Product Director, FENTORA®	Marketing issues
Sarita Thapar	Former Actavis Director, Pharmacovigilance	Pharmacovigilance related to generic opioid products
Jerri Ann Thatcher	Former Cephalon Senior Director, Pain Franchise Marketing	Marketing issues
Joseph Tomkiewicz	Teva Pharmaceuticals Manager, DEA Compliance	DEA compliance
Scott Tomsky	Teva Pharmaceuticals Vice President, Generics Regulatory Affairs, North America	Generics regulatory affairs
Jamie Warner	Teva Pharmaceuticals Vice President, Global Labeling and Brand Management	Product labeling
Amanda Wilhelm	Teva Pharmaceuticals Associate Director, NeuroPsych and Pain Medical Science Liaison Team	Research and development
Paula Williams	Teva Pharmaceuticals Director, Medical Education	Medical education programs and marketing issues
Sheryl Williams	Former Cephalon Vice President, Corporate & Public Affairs	Medical education grants
Dan Winkelman	Former Cephalon Product Manager and Research Manager for ACTIQ® and FENTORA®	Marketing issues

Name	Title	Subject Matter
Mary Woods	Allergan Executive Director, Customer Relations	Actavis suspicious order monitoring

VERIFICATION

I, John Hassler, state that I am the Senior Vice President and General Manager of TEVA CNS and am employed by Teva Sales and Marketing Inc., a subsidiary of Teva Pharmaceuticals USA, Inc. I have reviewed the foregoing Second Amended Responses and Objections of Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc. to Plaintiffs' First Set of Interrogatories and I verify that, to the best of my knowledge, information and/or belief, the facts set forth in the Responses are true and correct. Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Actavis LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc. reserve the right to make any changes should it appear that any omissions or errors have been made.

Overland Park, KS
Location

Dated: March 1, 2019

John Hassler